As filed with the Securities and Exchange Commission on October 29, 2024.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Amendment No. 1
to
FORM 20-F

(Mark One)

☒ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended _____

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ **to** _____

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report: _____ **Commission file number** _____

Telix Pharmaceuticals Limited

(Exact name of registrant as specified in its charter and translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

55 Flemington Road
North Melbourne, Victoria 3051, Australia
(Address of principal executive offices)

Christian Behrenbruch
55 Flemington Road
North Melbourne, Victoria 3051, Australia
Tel: +61 3 9093 3855
(Name, telephone, e-mail and/or facsimile number and address of company contact person)

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55 Flemington Road
North Melbourne, Victoria 3051, Australia
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Craig Hilts
Jason Kropp
Wilmer Cutler Pickering Hale & Dorr LLP
60 State St.
Boston, MA 02109
(617) 526-6000

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American depositary shares, each representing one ordinary share, no par value	**TLX**	**The Nasdaq Global Select Market**
Ordinary shares, no par value*		

* Listed not for trading, but only in connection with the registration of the American Depositary Shares, pursuant to the requirements of the Securities & Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None.**
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None.**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: N/A.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☐

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☐

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ABOUT THIS REGISTRATION STATEMENT

We are incorporated under the laws of Australia. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Unless otherwise indicated, all amounts presented in this registration statement are presented in U.S. dollars, or US$. Our reporting and functional currency is the Australian dollar, or A$. Solely for the convenience of the reader, this registration statement contains translations of certain Australian dollar amounts into U.S. dollars at specified rates. No representation is made that Australian dollar amounts referred to in this registration statement could have been or could be converted into U.S. dollars at such rates or any other rates. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding. Throughout this registration statement, all references to "ADSs" mean American depositary shares, each of which represents one of our ordinary shares, no par value, and all references to "ADRs" mean the American depositary receipts that evidence the ADSs.

Our reporting and functional currency is the Australian dollar, and our financial statements included elsewhere in this registration statement are presented in Australian dollars. The consolidated financial statements and related notes included elsewhere in this registration statement have been prepared in accordance with International Financial Reporting Standards, or IFRS Accounting Standards, as issued by the International Accounting Standards Board, or IASB, which differ in certain significant respects from generally accepted accounting principles in the United States, or U.S. GAAP.

Unless otherwise stated or the context indicates otherwise, all references herein to "Telix," "Telix Pharmaceuticals," the "Company," "our company," "we," "us," "our" and similar references refer to Telix Pharmaceuticals Limited and its consolidated subsidiaries, taken as a whole.

INDUSTRY AND MARKET DATA

This registration statement contains estimates and information concerning our industry and our business, including estimated market size and projected growth rates of the markets for our product candidates. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This information involves a number of assumptions and is based on limited available information. Although we are responsible for all of the disclosure contained in this registration statement and we believe the third-party market position, market opportunity and market size data included in this registration statement are reliable, we have not independently verified the accuracy or completeness of this third-party data. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 3. Key Information — D. Risk Factors." These and other factors could cause results to differ materially from those expressed in these publications and reports.

TRADEMARKS AND SERVICE MARKS

"Telix Pharmaceuticals," the Telix logo and other trademarks or service marks of Telix appearing in this registration statement are the property of Telix or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this registration statement are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this registration statement are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This registration statement contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this registration statement, including statements regarding our future results of operations, financial condition, business strategy, prospective products, product approvals, research and development costs, future revenue and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties, other factors and assumptions, including the risks described in "Item 3. Key Information — D. Risk Factors" and elsewhere in this registration statement, regarding, among other things:

- the ongoing commercialization of Illuccix and our preparation for the commercialization of our products and product candidates, if or when they are approved;
- the timing and review of submissions for regulatory approval of our product candidates, including review of our accepted submission for TLX007-CDx, our planned resubmission for TLX250-CDx and our submission for TLX101-CDx, and our ability to obtain and maintain such regulatory approvals;
- the initiation, timing, progress and results of our ongoing and planned clinical trials, including the timing of dosing of patients, enrollment and completion of these trials, including multi-national trials, and the anticipated results from these trials;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of Illuccix and any future products;
- our ability to obtain an adequate supply at reasonable costs of raw materials we may incorporate into our products and product candidates;
- our ability to address the fulfillment and logistical challenges posed by the time-limited stabilization of our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy, including the timing and costs of expanding our manufacturing capabilities;
- the rate and degree of market acceptance and clinical utility of our products and product candidates;
- the pricing and reimbursement of our products and product candidates, if and after they have been approved;
- estimates of our expenses, future revenues and capital requirements;
- our financial performance;
- developments relating to our competitors and industry;
- the success of our collaborations and partnerships with third parties;
- our ability to maintain, expand, protect and enforce our regulatory exclusivity and intellectual property, or IP, portfolio;
- our expectations regarding our ability to obtain and maintain regulatory exclusivity and intellectual property protection for our products and product candidates;
- our ability to consummate the acquisition of RLS (USA) Inc., or RLS, that we announced in September 2024;
- our ability to successfully integrate the businesses that we have acquired or may acquire in the future;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- legal and regulatory developments in the United States, Australia and other jurisdictions;

- our ability to remain compliant with the respective listing rules and standards of the Australian Securities Exchange, or ASX, and the Nasdaq Global Select Market, or Nasdaq;
- our ability to attract and retain key scientific or management personnel;
- the success of competing therapies that are or may become available;
- our expectations regarding the period during which we qualify as an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;
- the volatility of currency exchange rates;
- the impact of and changes in governmental regulations or the enforcement thereof, tax laws and rates, accounting guidance and similar matters in regions in which we operate or will operate in the future; and
- other risks and uncertainties, including those listed under "Item 3. Key Information — D. Risk Factors."

These risks are not exhaustive. Other sections of this registration statement may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this registration statement primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We undertake no obligation to update any forward-looking statements made in this registration statement to reflect events or circumstances after the date of this registration statement or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this registration statement. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this registration statement and the documents that we reference and have filed as exhibits to the registration statement with the understanding that our actual future results, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

EXPLANATORY NOTE

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals. Our mission is to be the global leader in radiopharmaceuticals by combining therapeutic and diagnostic modalities for the benefit of patients, an innovative precision medicine concept generally referred to as "theranostics". We have an extensive pipeline of theranostic radiopharmaceutical product candidates with a focus in urologic oncology (prostate and kidney), neuro-oncology (glioma), musculoskeletal oncology (sarcoma) and bone marrow conditioning. Our theranostic approach is intended to use imaging and therapy together to "see and treat" cancer and rare diseases, to both better inform treatment decisions and deliver personalized therapy for patients.

Our company was incorporated under the laws of Australia in January 2017. In November 2017, we completed an initial public offering of our ordinary shares and the listing of our ordinary shares on the ASX. Our corporate headquarters and registered offices are located at 55 Flemington Road, North Melbourne, Victoria, 3051, Australia. Our reception telephone number is +61 3 9093 3855. Our agent for service of process in the United States is Telix Pharmaceuticals (US) Inc., located at 11700 Exit 5 Pkwy, Suite 200, Fishers, Indiana 46037. Our website address is www.telixpharma.com. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not part of this registration statement on Form 20-F or incorporated by reference herein.

A substantial portion of our workforce is based in the United States with our United States office in Indianapolis, Indiana and research, development and manufacturing facilities in Angleton, Texas, Sacramento, California and Vancouver, Canada. We have facilities in Australia (Melbourne, Sydney and Brisbane), Belgium (Brussels and Liège), Switzerland (Geneva) and Japan (Kyoto). The primary listing of our ordinary shares is the ASX and this registration statement relates to a secondary listing of our ordinary shares, in the form of ADSs, on Nasdaq.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS.

A. Directors and Senior Management

The following discussion sets forth information regarding our directors and executive officers as of the date of this registration statement on Form 20-F. The following table lists the names of our directors and executive officers. The business address for our directors and executive officers is c/o 55 Flemington Road, North Melbourne, Victoria 3051, Australia.

Name	Age	Position
Non-Executive Directors		
H Kevin McCann	83	Independent Non-Executive Director and Chairman
Mark Nelson	65	Independent Non-Executive Director
Tiffany Olson	65	Independent Non-Executive Director
Jann Skinner	67	Independent Non-Executive Director
Executive Officers		
Christian Behrenbruch	49	Managing Director and Group CEO
Darren Patti	52	Group Chief Operating Officer
Darren Smith	59	Group Chief Financial Officer
David Cade	56	Group Chief Medical Officer

The responsibilities of our board of directors are described in our Board Charter and Constitution, each of which are filed as exhibits to this registration statement on Form 20-F. Our executive officers are responsible for making and executing decisions that build value in accordance with board-approved delegated authorities.

The following is the biographical information of our directors and executive officers:

H. Kevin McCann has served as a Non-Executive Director and Chairman of our board of directors since September 2017. Previously, Mr. McCann served as Chairman of Macquarie Group and Macquarie Bank Limited from December 1996 to March 2016, Chairman of Origin Energy Limited from January 2000 to October 2013, Chairman of the Sydney Harbour Federation Trust from June 2001 to June 2010 and from June 2015 to June 2018, Director of Bluescope Steel Ltd from May 2002 to April 2013, Director of E&P Financial Group Ltd from February 2020 to November 2021 and Chairman of China Matters from November 2018 to December 2023. He was also a Director of the United States Studies Centre at the University of Sydney from June 2010 to June 2020 and was a Trustee of the Sydney Opera House from January 2018 to December 2023. He has served as a Member of Champions of Change Founding Group since April 2010, Chairman of Sydney Harbour Foundation Management since August 2015, Director of Australian Haydn Ensemble since December 2020, Chair and Board Advisor of Blueprint Institute since June 2022 and Director of Billard Leece Partnership Pty Limited since October 2024. Mr. McCann practiced as a commercial lawyer as a partner of Allens Arthur Robinson (now Allens) from 1970 to 2004 and was Chairman of Partners from 1995 to 2004. Mr. McCann received a Bachelor of Arts and a Bachelor of Law (Honors) from Sydney University and a Master of Law from Harvard University and was awarded an honorary Doctor of Laws from the University of Sydney. He is a Life Fellow of the Australian Institute of Company Directors. We believe that Mr. McCann's extensive Board experience with some of Australia's most recognized companies qualifies him to serve on our board of directors.

Christian Behrenbruch is one of our Co-Founders, has served as Group Chief Executive Officer since January 2017 and joined our board of directors as Managing Director in January 2017. He has previously served as Chief Executive Officer at Mirada Solutions from July 2001 to December 2002, President at CTI Molecular Imaging (now Siemens Healthcare) from August 2003 to September 2006, Chief Executive Officer at Fibron Technologies, Inc. from June 2008 to December 2011 and Chief Executive Officer at ImaginAb, Inc from October 2007 to February 2015. He served as a Director at Siemens Molecular Imaging Ltd from May 2005 to September 2006, Momentum Biosciences LLC from July 2007 to June 2009, Radius Health Ltd (now Adaptix Ltd) from May 2009 to February 2011, Factor Therapeutics Limited from October 2015 to May 2021 and Amplia Therapeutics Limited from May 2016 to February 2020, and he was the Chairman of Cell Therapies Pty Ltd (a partnership with the Peter MacCallum Cancer Centre) from October 2012 to July 2014. Dr. Behrenbruch holds a Doctor of Philosophy (PhD) in biomedical engineering from the University of Oxford, an executive Master of Business Administration (MBA) jointly awarded from New York University, HEC Paris and the London School

of Economics (TRIUM Program) and a Juris Doctor from the University of Melbourne. Dr. Behrenbruch is a Fellow of Engineers Australia in the management and biomedical colleges and a Graduate of the Australian Institute of Company Directors. We believe Dr. Behrenbruch's expertise and over 20 years of experience in healthcare entrepreneurship and executive leadership qualify him to serve on our board of directors.

Mark Nelson has served as a Non-Executive Director since September 2017. Dr. Nelson has served as Chairman of the Caledonia Investments Group since January 2012, and as a Director of The Caledonia Foundation since August 2002. He previously served as Chief Executive Officer and Co-Chief Investment Officer of the Caledonia Investments Group from February 1992 to January 2012. He has also served as Director of Kaldor Public Art Projects since October 2005, Governor of the Florey Neurosciences Institute since October 2007, Director of the Mindgardens Neuroscience Network since February 2018 and Chairman of Art Exhibitions Australia since 2019. Dr. Nelson received his B.Sc. from the University of Melbourne, his M.Phil from the University of Cambridge and his Ph.D. from the University of Melbourne. We believe Dr. Nelson's qualifications and experience in capital, equity and investment markets, including in the life sciences industry, qualify him to serve on our board of directors.

Tiffany Olson has served as Non-Executive Director since March 2022. She previously served as President and CEO of Roche Diagnostics Corporation from June 2005 to May 2008, Vice President, Diagnostics, at Eli Lilly and Company from November 2009 to July 2011, President of NaviMed from August 2011 to July 2013 and President of Cardinal Health Nuclear & Precision Health Solutions from July 2013 to October 2021. Ms. Olson has served as a Director of Castle Biosciences, Inc. since April 2021, Advisory Board Member of Langham Logistics since August 2021, Director of Education and Research Foundation, Nuclear Medicine & Molecular Imaging since April 2022, Partner of Trusted Health Advisors since August 2023 and Director of MiMedx Group, Inc. since March 2024. She was previously a Director at Asuragen, Inc. from August 2016 to March 2021 and BioTelemetry, Inc. from February 2019 to February 2021. Ms. Olson received her Master of Business Administration (MBA) at the University of St. Thomas in Minnesota and her Bachelor of Science in Business (BSB) at the University of Minnesota. We believe Ms. Olson's experience in commercialization and corporate strategy in oncology, including in the radiopharmaceutical sector, qualify her to serve on our board of directors.

Jann Skinner has served as a Non-Executive Director since June 2018. Ms. Skinner was a partner at PricewaterhouseCoopers from 1987 to 2004. She has served as Director of Create Foundation Limited since June 2004. She also served as Non-Executive Director of QBE Insurance Group Limited from October 2014 to May 2024 and Director of HSBC Bank Australia Limited from April 2017 to April 2023. Ms. Skinner is a Fellow of both Chartered Accountants Australia & New Zealand and the Australian Institute of Company Directors. She received her Bachelor of Commerce (BCom) from the University of New South Wales. We believe Ms. Skinner's expertise in audit and accounting and prior board experience qualify her to serve on our board of directors.

Darren Patti was appointed as our Group Chief Operating Officer in March 2024. Prior to transitioning to this role, he was the Chief Operating Officer and General Manager of our Americas operations from March 2021 to March 2024. Previously, he served as Vice President of Operations at Sofie Biosciences Inc. from November 2019 to March 2021, and, preceding this role, he served in numerous other leadership capacities over his 15 year tenure at Sofie, including managing high capacity PET manufacturing facilities and directing regional operations over multiple PET manufacturing locations. Prior to joining Sofie, he worked in brachytherapy manufacturing with a small startup which was eventually acquired by CR Bard. He has over 20 years of experience in radiopharmaceutical and device manufacturing with expertise in network management and operations, including new radiopharmaceutical manufacturing, implementation and compliance. Dr. Patti holds a Doctor of Pharmacy (Pharm.D.) from the University of Illinois at Chicago and a Bachelor of Arts from Southern Illinois University at Carbondale. He is also an Authorized Nuclear Pharmacist and is a licensed pharmacist in multiple states within the United States.

Darren Smith has served as our Group Chief Financial Officer since August 2022. Previously, he was Global Chief Financial Officer and Company Secretary at Sirtex Medical Ltd from June 2008 to March 2019. Mr. Smith has over 20 years of experience in executive finance and general management experience across a broad range of industries, including life-sciences, for publicly listed, private, international, and Australian government organizations. Mr. Smith holds a Master of Business Administration (MBA) from the University of New South Wales in Australia and a Bachelor of Business (Accounting) from Western Sydney University. He has been a Fellow Certified Practicing Accountant for 20 years.

David Cade has served as our Group Chief Medical Officer since January 2024. Prior to transitioning to this role, he was the Chief Executive Officer of our Asia Pacific operations from May 2021 to December 2023 and our Chief Business Officer and Head of Investor Relations from October 2019 to April 2021. Previously, he served as Chief Medical Officer at Sirtex Medical Limited from January 2007 to September 2017 and Chief Medical Officer at Cochlear Limited from October 2017 to September 2019. He received a Bachelor of Medicine and Bachelor of Surgery (MBBS) from Monash Medical School and a Master of Business Administration (MBA) from Melbourne Business School and ESADE Business and Law School Barcelona. He is also a Graduate of the Australian Institute of Company Directors.

B. Advisers

Our U.S. legal counsel is Wilmer Cutler Pickering Hale and Dorr LLP, located at 60 State Street, Boston, Massachusetts 02109. Our Australian legal counsel is Herbert Smith Freehills, located at 80 Collins Street, Melbourne, Victoria 3000, Australia.

C. Auditors

PricewaterhouseCoopers has been our auditor since 2017. The address for PricewaterhouseCoopers is 2 Riverside Quay, Southbank, Victoria 3006, Australia.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

The table below sets forth our cash and cash equivalents and our total capitalization as of June 30, 2024, on:

- an actual basis; and
- an as adjusted basis to give effect to the issuance of an aggregate principal amount of A$650.0 million of 2.375% unsecured convertible notes due 2029, or the Convertible Bonds, which closed on July 30, 2024, after deducting expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and the related notes included elsewhere in this registration statement, the information set forth in "Item 5. Operating and Financial Review and Prospects" and other financial information contained elsewhere in this registration statement.

	As of June 30, 2024	
	Actual	As Adjusted(1)
	A$	
	(in thousands, except share data) (unaudited)	
Cash and cash equivalents	118,837	753,837
Borrowings, non-current portion (Convertible Bonds)	—	539,400
Borrowings, non-current portion (other)	9,952	9,952
Total non-current debt	9,952	549,352
Equity: 334,231,398 ordinary shares, no par value, outstanding	587,408	587,408
Share capital reserve	(68,343)	27,257
Foreign currency translation reserve	7,103	7,103
Share-based payments reserve	112,823	112,823
Financial assets at fair value through other comprehensive income reserve	(1,513)	(1,513)
Accumulated losses	(233,504)	(233,504)
Total equity	403,974	499,574
Total capitalization	413,926	1,048,926

(1) Proceeds raised from the issuance of Convertible Bonds are allocated between equity and financial liabilities in accordance with IFRS Accounting Standards.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this registration statement, including our consolidated financial statements and related notes included elsewhere in this registration statement, before making an investment decision. If any of the following risks actually occur, it could harm our business, prospects, results of operations and financial condition. In such event, the trading price of our ordinary shares and the ADSs could decline, and you might lose all or part of your investment.

Risk Factors Summary

Our business and our ability to implement our business strategy are subject to numerous risks. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this "Risk Factors" section. You should read these risks before you invest in us. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include the following:

- We have a history of significant net losses, our operating expenses may increase in the future, and we may not be able to maintain profitability in future periods.
- We may need to raise capital to achieve our business objectives if we are unable to fund our operations with our cash flows from the sale of our products. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and/or commercialization efforts.
- We may not consummate the acquisition of RLS at all, or the acquisition may not occur within the expected time frame, which may negatively affect the benefits we expect to obtain from the transaction and increase transaction costs.
- We may not be able to effectively integrate the businesses that we have acquired and/or may acquire in the future.
- Our business is substantially dependent on the commercial success of Illuccix and our product candidates. If we are unable to successfully commercialize Illuccix as currently approved or to successfully commercialize our product candidates, our business, financial condition and results of operations will be materially harmed.
- Clinical development is a lengthy and expensive process, with uncertain timelines and outcomes. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.
- If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.
- The results of previous clinical trials may not be predictive of future trial results, and preliminary, interim or top-line data may be subject to change or qualification based on the complete analyses of data and, therefore, may not be predictive of the final results of a trial.
- Due to their radioactive nature, Illuccix and our product candidates have time-limited stability, and as a result, we may encounter difficulties with fulfillment and logistics.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- The commercial success of Illuccix and our product candidates, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community.
- We may be unable to generate and/or obtain a sufficient supply of radioisotopes to support clinical development or manufacturing at commercial scale.

- Even if we are able to effectively commercialize Illuccix or any product candidates for which we obtain approval, the products may not receive coverage or may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, all of which would harm our business.
- We depend on collaborations with third parties for certain aspects of the development, marketing and/or commercialization of Illuccix and our product candidates. If those collaborations are not successful, or if we are not able to maintain our existing collaborations or establish additional collaborations, we may have to alter our development and commercialization plans and may not be able to capitalize on the market potential of Illuccix or our product candidates.
- If we are unable to obtain and/or maintain commercially valuable regulatory exclusivity and patent claims or to protect our patents, trademarks, know-how and trade secrets, our ability to successfully commercialize our products and product candidates would be adversely impacted.
- There has been no prior market for the ADSs and an active and liquid market for our securities may fail to develop, which could harm the market price of the ADSs.
- As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs.

Risks Related to Our Financial Position and Capital Requirements

We have a history of significant net losses, our operating expenses may increase in the future, and we may not be able to maintain profitability in future periods.

Until 2023, we incurred significant operating losses. Our operating profit was A$15.8 million for the year ended December 31, 2023 and A$42.0 million for the six months ended June 30, 2024. Our net operating cash inflow was A$23.9 million for the year ended December 31, 2023 and A$39.1 million for the six months ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of A$233.5 million. Although we launched Illuccix in April 2022 and have recognized profits in recent periods, we cannot be certain that we will sustain profitability or positive cash flows from operations in future periods.

We have invested most of our resources in developing our technology and product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We continue to incur significant research and development, or R&D, and other expenses related to ongoing operations and may incur losses in the future. Investment in biotechnology product development, as well as medical device development, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will be unable to demonstrate effectiveness or an acceptable safety profile, gain regulatory approval, gain competitive pricing or reimbursement and become commercially viable. To date, our only product to receive marketing authorization in any jurisdiction is Illuccix, which has been approved by the FDA, the Australian Therapeutic Goods Administration, or the TGA, and by Health Canada. We are currently pursuing marketing authorizations for Illuccix, either directly or in collaboration with regional commercial partners, in the United Kingdom and in 19 European countries, as well as countries in Asia and Latin America, which will require substantial additional resources and time before we receive regulatory clearance or approval and begin generating revenue in such jurisdictions.

We have historically financed our operations principally through product sales, private and institutional placements of our ordinary shares, proceeds from our initial public offering of ordinary shares on the ASX, proceeds from our issuance of the Convertible Bonds, loan agreements with financial institutions and cash generated from our business development activities. Substantially all of our operating losses in previous periods have resulted from costs incurred in connection with our research and development programs, the pursuit of regulatory approvals within and outside of the United States, and the commercialization of Illuccix. We expect to continue to incur significant expenses as we continue to commercialize Illuccix in the United States, Australia,

New Zealand, and Canada and other jurisdictions following regulatory approval and engage in activities to prepare for the potential approval and commercialization of our other product candidates. The profits or losses we incur may fluctuate significantly from quarter to quarter and year to year.

While we began to generate revenue from the sales of Illuccix in April 2022, there can be no assurance as to the amount or timing of future product or license and other revenues, and we may not be able to maintain profitability in future periods. Our ability to remain profitable depends significantly on our success in many areas, including:

- effectively commercializing Illuccix or any future products either on our own or with a collaborator, including by maintaining a full commercial organization required to market, sell and distribute our products, and achieving an adequate level of market acceptance;
- the impact of current or future competing products on product sales of Illuccix or any of our future products;
- obtaining sufficient pricing, coverage and reimbursement, under U.S. federal healthcare programs, such as Medicare and Medicaid, and from private payors, for Illuccix and any of our other approved products from private and government payors and the impact of any pricing changes;
- initiating and successfully completing clinical trials required to file for, obtain and maintain regulatory approval for our product candidates;
- obtaining and maintaining regulatory approvals, and the timing of such approvals;
- manufacturing at commercial scale;
- establishing and managing any collaborations for the development, marketing and/or commercialization of our products and product candidates, including the level of success of any such collaborators' efforts and the timing and amount of any milestone or royalty payments we may receive; and
- obtaining, maintaining and protecting our intellectual property rights.

We anticipate that our operating expenses will continue to be significant and increase as we continue to:

- commercialize Illuccix in the United States, Australia, New Zealand, Canada and other jurisdictions following regulatory approval, including maintaining our commercial infrastructure;
- obtain and/or maintain regulatory approval for Illuccix and our product candidates, including completing any required post-marketing requirements to the satisfaction of the FDA or other regulatory agencies;
- expand our research and development programs, identify additional product candidates and initiate and conduct clinical trials, including clinical trials required by the FDA or other regulatory agencies in addition to those that have been or are currently expected to be conducted;
- maintain, expand and protect our intellectual property portfolio;
- manufacture Illuccix and our product candidates;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future radiopharmaceutical commercialization efforts;
- operate as a publicly listed company in the United States and Australia; and
- acquire or in-license other products, product candidates or technologies.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of our revenue and expenses or if we will be able to maintain profitability. We cannot be certain that our revenue from sales of Illuccix alone, in the currently approved indications, will be sufficient for us to remain profitable in future periods. We may not generate revenues that are significant or large enough to sustain or increase profitability on an annual basis. Our failure to remain profitable would decrease the value of our company and could impair our ability to raise

capital, maintain our research and development and commercialization efforts, expand our business and/or continue our operations. This could result in a material adverse effect on the value of our company and could cause our shareholders and ADS holders to lose all or part of their investment.

We may need to raise additional capital to achieve our business objectives if we are unable to fund our operations with our cash flows from the sale of our products. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and/or commercialization efforts.

Discovering, developing and commercializing products involve time-consuming, expensive and uncertain processes that take years to complete. We have used substantial funds to develop Illuccix and expect our operating expenses to continue to increase as we continue to commercialize Illuccix or any future approved products, conduct further research and development of our product candidates, seek approval and prepare for commercialization of TLX250-CDx, TLX007-CDx and TLX101-CDx and continue to conduct clinical trials for our other product candidates. Furthermore, we will continue to incur additional costs associated with operating as a public company, hiring additional personnel and expanding our geographical reach. Although currently Illuccix is commercially available in four jurisdictions, we cannot be certain that our revenue from product sales of Illuccix will be sufficient for us to remain profitable on an annual basis. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives.

As of June 30, 2024, we had A$118.8 million in cash and cash equivalents. Additionally, in July 2024, we issued and sold Convertible Bonds in aggregate principal amount of A$650.0 million and received net proceeds of A$635.0 million. The amount and timing of our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, timing and costs of our current and planned development efforts and regulatory review of our product candidates;
- the amount and timing of revenues from sales of Illuccix or any product candidate for which we receive regulatory approval;
- the cost of, and our ability to expand and maintain, the commercial infrastructure required to support the commercialization of Illuccix and any other product for which we receive regulatory approval, including medical affairs, manufacturing, marketing and distribution functions;
- our ability to establish and maintain collaboration, partnership, licensing, marketing, distribution or other arrangements on favorable terms and the level and timing of success of these arrangements;
- the extent to which we acquire or in-license other products, product candidates and technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

In addition, the terms of any financing may adversely affect the holdings or the rights of our shareholders and ADS holders. If we raise funds by issuing equity securities, dilution to our existing shareholders and ADS holders will result, and this may also have an impact on the market price of our ordinary shares and ADSs. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing shareholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. Our ability to satisfy and meet any future debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. Any future fundraising efforts could divert our management's attention away from their day-to-day activities. Further, adequate additional financing may not be available to us on acceptable terms, or at all. In addition, raising funds in the current economic environment may present additional challenges. For example, any sustained disruption in the capital markets from adverse macroeconomic conditions, such as the disruption and uncertainty caused by rising inflation, increasing interest rates and slower economic growth or recession, could negatively impact our ability to raise capital and we cannot

predict the extent or duration of such macro-economic disruptions. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to delay, reduce or eliminate our research and development programs or any current or future commercialization efforts for one or more of our products or product candidates, any of which could have a material adverse effect on our business, operating results and prospects.

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause the trading price of our ordinary shares and the ADSs to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our profit or loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the current or future development of our programs;
- timing and status of enrollment for our clinical trials;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- timing of any milestone payments or other payment obligations to be paid by us pursuant to existing supply agreements, licenses or collaborations;
- timing of any milestone payments or other payments to be received by us pursuant to our license agreement;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any product candidate we may develop receives regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidate;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting Illuccix or any other of our product candidates or those of our competitors; and
- changes in general market and economic conditions, including as a result of the ongoing war between Russia and Ukraine and the ongoing war between Israel and Hamas.

If our operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares and ADSs could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our ordinary shares and ADSs to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our Loan Agreements with BNP Paribas and IMBC Group contain various covenants and other provisions, which, if violated, could result in the acceleration of payments due under such agreement, as well as affect the buildout of our Brussels South manufacturing facility.

In March 2022, one of our subsidiaries, Telix Pharmaceuticals (Belgium) SPRL (now Telix Pharmaceuticals (Belgium) SRL), entered into Loan Agreements, or the Loan Agreements, with BNP Paribas and IMBC Group. The borrowings under these Loan Agreements were used to fund in part the construction of our Brussels South

manufacturing facility. Pursuant to the Loan Agreements, Telix Pharmaceuticals (Belgium) SRL is required to comply with various covenants relating to the conduct of its business. The Loan Agreements also include customary events of default upon the occurrence of enumerated events, including non-payment of required repayments, failure to perform certain covenants and the occurrence of insolvency proceedings, specified judgments, specified cross-defaults or specified revocations. Upon the occurrence of an event of default and in the event of a change of control, BNP Paribas and IMBC Group may accelerate payments due under the Loan Agreements or terminate the Loan Agreements. In the event that we are unable to make required payments or the Loan Agreements are otherwise terminated, we would face significant challenges in continuing the construction of our Brussels South manufacturing facility, which would have a detrimental impact on the development timeline of our product candidates and other plans.

Future issuances of equity or convertible debt securities may cause dilution to our shareholders and ADS holders, restrict our operations or require us to relinquish rights to our product candidates.

We expect to finance our cash needs through a combination of revenues from product sales, equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders and ADS holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of ordinary shareholders and ADS holders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through further collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our research and product development or current or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our indebtedness could limit cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under our indebtedness.

On July 30, 2024, we issued A$650 million principal amount of Convertible Bonds. Additionally, as of June 30, 2024, we had A$11.9 million of other indebtedness. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which would reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing shareholders as a result of issuing ordinary shares upon conversion of the Convertible Bonds; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to pay the principal of or interest on the Convertible Bonds or to make cash payments in connection with any conversion of the Convertible Bonds depends on our future performance, which is subject, in part, to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Convertible Bonds or other future indebtedness and make necessary capital expenditures.

If we are unable to redeem the Convertible Bonds for cash when required, or repay the Convertible Bonds when due at maturity, we may need to seek alternative financing arrangements, which could impose restrictions on our operations and business.

On July 30, 2024, we completed our issuance of the Convertible Bonds to institutional and professional investors outside of the United States. The Convertible Bonds mature on July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms.

Subject to the satisfaction of conditions in the trust deed, we have the right at our option to redeem all of the bonds on or after August 13, 2027 if (i) the closing price of our ordinary shares on the ASX exceeds 130% of the then-applicable conversion price for at least 20 trading days, whether consecutive or not, during any consecutive 30 trading day period or (ii) conversion rights have been exercised in respect of 85% or more in principal amount of the Convertible Bonds.

We may be required to redeem the Convertible Bonds prior to the maturity date in certain circumstances. Upon the occurrence of an event constituting a change of control or the delisting of our ordinary shares on the ASX, each bondholder will have the right under the trust deed governing the Convertible Bonds to require us to redeem all or some of such bondholder's Convertible Bonds at their principal amount, together with accrued but unpaid interest. We are also required under the trust deed to redeem the Convertible Bonds on July 30, 2027 at the option of each holder at their principal amount, together with accrued but unpaid interest.

We may not be able to redeem all or any of such Convertible Bonds or pay all or any amounts due upon conversions thereof if we do not have sufficient funds to do so. Non-payment of any principal or interest payable with respect to the Convertible Bonds would constitute an event of default under the trust deed governing the Convertible Bonds. Upon the occurrence of an event of default, the full principal amount, together with accrued but unpaid interest, of the Convertible Bonds then outstanding will become due and payable. A default under the trust deed could also lead to a default under agreements governing any of our indebtedness outstanding at the time. If we are unable to redeem the Convertible Bonds at maturity or upon the occurrence of certain events specified by the trust deed governing the Convertible Bonds, we may need to seek alternative financing arrangements, which could impose restrictions on our operations and business. We cannot assure you that such alternative financing will be available to us on acceptable terms, if at all.

Servicing the Convertible Bonds will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on the Convertible Bonds.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Convertible Bonds depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient cash flow from operations in the future to service the Convertible Bonds. If we are unable to generate sufficient cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional share capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek to refinance such indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We have engaged and plan to engage in various acquisitions and strategic partnerships in the future. If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders and ADS holders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We have engaged and plan to continue to engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our shareholders and ADS holders;

- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

We may not consummate the acquisition of RLS at all, or the acquisition may not occur within the expected time frame, which may negatively affect the benefits we expect to obtain from the transaction and increase transaction costs.

We entered into an agreement to acquire RLS in September 2024. We cannot provide any assurances that the acquisition of RLS will be completed in the manner or on the time frame currently anticipated, or at all. Completion of the acquisition is subject to the satisfaction or waiver of a number of conditions as set forth in the stock purchase agreement that are beyond our control, including regulatory approvals, RLS shareholder approval, license transfers and third-party consents, and such conditions may prevent, delay or otherwise materially adversely affect its completion. Any delay in completing the acquisition may adversely affect the benefits that we expect to achieve from the acquisition. If the acquisition is completed but not within the expected time frame, such delay could result in additional transaction costs, loss of revenue or other effects associated with uncertainty about the acquisition.

We may not realize the anticipated benefits from the acquisition of RLS, and the acquisition could adversely impact our business and our operating results.

We may not be able to achieve the full potential strategic and financial benefits that we expect to achieve from the planned acquisition of RLS, or such benefits may be delayed or not occur at all, including if we are unable to complete the acquisition, including, among others, as a result of unanticipated costs and loss of customers by RLS. If we fail to achieve some or all of the benefits expected to result from the acquisition, or if such benefits are delayed, our business could be harmed.

RLS may have liabilities that are not known to us and the indemnities in the purchase agreement may not offer adequate protection.

As part of the acquisition, we have agreed to assume certain liabilities of RLS. In addition, there may be liabilities that we failed or were unable to discover in the course of performing due diligence investigations. Also, we may not have correctly assessed the significance of certain liabilities and assets identified in the course of our due diligence. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business, financial condition and results of operations. As we integrate RLS into our operations, we may learn additional information about the entity, such as unknown or contingent liabilities and issues relating to compliance with applicable laws, that could potentially have an adverse effect on our business, financial condition and results of operations.

We may not be able to effectively integrate the businesses that we have acquired and/or may acquire in the future.

Our ability to realize the anticipated benefits of acquisitions we have completed and/or may complete in the future, including the completed acquisitions of QSAM, ARTMS and IsoTherapeutics and the planned acquisition of RLS, will depend on our ability to integrate those businesses with our own. The combination of multiple independent businesses is a complex, costly and time-consuming process and there can be no assurance that we will be able to successfully integrate businesses into our business, or if such integration is successfully accomplished, that such integration will not be costlier or take longer than presently contemplated. If we cannot successfully integrate and manage the businesses within a reasonable time, such difficulties or delays could result in the loss of key employees from the acquired businesses, the disruption of the acquired businesses,

inefficiencies, or inconsistencies in standards, controls, information technology systems, procedures and policies, and we may not be able to realize the potential and anticipated benefits of such acquisitions, which could have a material adverse effect on our business, financial position, and results of operations. We face numerous risks relating to the integrated of acquired businesses, including:

- the inability to integrate effectively the operations, products, technologies and personnel of the acquired companies (some of which are in diverse geographic regions) and achieve expected synergies;
- the potential disruption of existing business and diversion of management's attention from day-to-day operations;
- the inability to maintain uniform standards, controls, procedures and policies;
- the need or obligation to divest portions of the acquired companies to satisfy regulatory requirements;
- the potential failure to identify material problems and liabilities during due diligence review of acquisition targets;
- the potential failure to obtain sufficient indemnification rights to fully offset possible liabilities associated with acquired businesses; and
- the challenges associated with operating in new product segments and/or geographic regions.

The failure to maintain our licenses and realize their benefits may harm our business.

We have acquired and in-licensed certain of our technologies from third parties. We may in the future acquire, in-license or invest in additional technology that we believe would be beneficial to our business. We are subject to a number of risks associated with our acquisition, in-license or investment in technology, including the following:

- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new R&D programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

Risks Related to Commercialization and Product Development

Our business is substantially dependent on the commercial success of Illuccix and our product candidates. If we are unable to successfully commercialize Illuccix as currently approved or to successfully obtain regulatory approvals to commercialize our other product candidates, our business, financial condition and results of operations will be materially harmed.

Our business and our ability to generate product revenue from the sales of diagnostic imaging agents and therapies that treat cancer and other diseases depend on continued commercialization of Illuccix, our prostate cancer imaging agent, on a global basis. Illuccix is currently approved and marketed in the United States, Australia, New Zealand and Canada for positron emission tomography, or PET, of prostate-specific membrane antigen, or PSMA, positive lesions in men with prostate cancer: (i) with suspected metastasis who are candidates for initial definitive therapy, (ii) with suspected recurrence based on elevated serum prostate-specific antigen, or PSA, level and (iii) currently in the United States only, for selection of patients with metastatic prostate cancer, for whom lutetium ^{177}Lu vipivotide tetraxetan PSMA-directed therapy is indicated. Illuccix is also commercially sold and available in New Zealand pursuant to a regulator exemption. We are also developing Illuccix for

additional indications, including to monitor patient response to radioligand therapy and progression in nonmetastatic castration-resistant prostate cancer and metastatic castration-resistant prostate cancer, or mCRPC. We may also seek to further develop and seek approval for the use of Illuccix for selection of patients with metastatic prostate cancer for whom lutetium ^{177}Lu vipivotide tetraxetan PSMA-directed therapy is indicated in countries where such therapy is not yet approved for use but is expected to be in the future. We are currently pursuing marketing authorizations for Illuccix, either directly or in collaboration with regional commercial partners, in the United Kingdom and in 19 European countries, as well as countries in Asia and Latin America. We believe that obtaining these regulatory approvals and successfully developing Illuccix for additional potential indications will be important to reach the full potential utilization of Illuccix, and failure to do so could have a material adverse effect on our business.

Our long-term prospects also depend on our ability to obtain regulatory approval for additional imaging and therapeutic product candidates. Regulatory approvals are subject to changing standards from time to time and the timing to obtain the required regulatory approvals is subject to many factors, some of which may be outside our control. For example, regulatory agencies may face resource constraints, causing delays in the review process, and there is no guarantee that the regulators are bound by any product development or regulatory advice offered earlier in the review process. In May 2024, we completed our submission of a biologics license application, or BLA, to the FDA for TLX250-CDx for the characterization of renal masses as clear cell renal cell carcinoma, or ccRCC. In July 2024, the FDA declined to review the BLA and issued a Refuse to File, or RTF, determination. An RTF determination is a response from the FDA following its preliminary review, communicating the FDA's determination that the application does not include all pertinent information and data. The denial of acceptance for filing was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment. While we believe that TLX250-CDx has met all sterility requirements of product release and that we will be able to complete the required remedial actions within 90 days and resubmit the BLA, even if we satisfy the requirements of the RTF determination, there can be no assurance that FDA will accept the BLA for review or that we will obtain regulatory approval from the FDA.

We have also submitted a new drug application, or NDA, to the FDA for TLX007-CDx for the imaging of prostate cancer, which was accepted by the FDA in July 2024 and assigned a Prescription Drug User Fee Action, or PDUFA, goal date of March 24, 2025. In August 2024, we submitted an NDA for TLX101-CDx for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025.

Any delay in resubmitting the BLA for TLX250-CDx, or adverse action by the FDA with respect to the BLA or NDAs, could delay our planned commercial development timelines or could prevent us from commercializing these product candidates. If the FDA determines that our submissions and the data supporting the submissions are not sufficient to support approval in these indications, we may be required to conduct an additional clinical trial or trials, which would increase our costs and delay the program. Any such delay or other adverse impact could have a material adverse effect on our business.

We have not submitted any applications for regulatory approval or obtained regulatory approval for any of our therapeutic product candidates. Our most advanced therapeutic candidate, TLX591 (^{177}Lu-rosopatamab tetraxetan), is a lutetium-labelled radio antibody-drug conjugate, or rADC, which we are evaluating in a Phase 3 clinical trial in patients with advanced prostate cancer. We dosed the first patient in this clinical trial in November 2023 in Australia. We received authorization to conduct the trial in the United States in April 2024 and have opened clinical trial sites in the United States. We cannot be certain that TLX591, or any of our clinical trials of our other therapeutic product candidates, will generate safety and efficacy data sufficient for regulatory approval in any jurisdiction.

The commercial success of Illuccix and our product candidates is dependent on many factors, some of which are beyond our control, including clinical development, the regulatory submission and approval process, market access or reimbursement frameworks, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts. If we are unable to continue to commercialize Illuccix or to develop, receive regulatory approval for and successfully commercialize Illuccix for other indications and for our other imaging and therapeutic product candidates, or experience delays as a result of any of these factors or otherwise, our business and results of operations could be substantially harmed.

Clinical development is a lengthy and expensive process, with uncertain timelines and outcomes. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Our long-term success depends in large part on our ability to continue to successfully develop additional product candidates in imaging and therapeutic indications. Clinical testing is expensive, time consuming, difficult to design and implement, and is inherently uncertain as to outcome. Clinical failure can occur at any stage of the clinical development process and, therefore, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later stage clinical trials. Furthermore, the failure of any product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our company or our products and/or cause the FDA or other regulatory authorities to require additional testing before any of our product candidates are approved.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval of our product candidates, including, but not limited to, the following:

- delays or failure to reach agreement with regulatory authorities on a trial design or the receipt of feedback requiring us to modify the design of our clinical trials, perform additional or unanticipated clinical trials to obtain approval or alter our regulatory strategy;
- clinical trials of our product candidates may produce negative or inconclusive results or other patient safety concerns, including undesirable side effects or other unexpected characteristics, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials, suspend ongoing clinical trials or abandon product development programs, including as a result of a finding that the participants are being exposed to unacceptable health risks;
- enrollment in our clinical trials may be slower than we anticipate or we may not be able to enroll the number of patients that we expect, including as a result of competition with other ongoing clinical trials for the same indications as our product candidates or because the patient population may be limited for orphan indications;
- regulators may revise the requirements for approving our product candidates, even after providing a positive opinion on or otherwise reviewing and providing comments on a clinical trial protocol, or such requirements may not be as we anticipate;
- delays or failure in obtaining the necessary authorization from regulatory authorities or institutional review boards to permit us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or the suspension or termination of a clinical trial once commenced;
- delays or failure to reach agreement on acceptable terms with prospective clinical trial sites or contract research organizations, or CROs;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including manufacturers or CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might be found to be non-compliant with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;

- regulators or institutional review boards/ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- any partners or collaborators that help us conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us; and
- negative impacts resulting from infectious disease epidemics or pandemics, including impacts to healthcare systems and our trial sites' ability to conduct trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate or are unable to successfully complete clinical trials of our product candidates or other testing, on a timely basis or at all, and/or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining, or not obtain at all, regulatory approval for the indication or product candidate;
- obtain regulatory approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining regulatory approval.

Further, we do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products, allow our competitors to bring products to market before we do or impair our ability to successfully commercialize our products, which would harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other applicable foreign regulator. In addition, some of our competitors may have planned or ongoing clinical trials or expanded access programs for approved and/or investigational products that would treat the same patients as our therapeutic product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in our competitors' clinical trials or expanded access programs. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;

- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- invasive procedures required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the ability of our companion diagnostics to identify patients;
- the size of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Serious adverse or unacceptable side effects related to Illuccix or our product candidates may delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial value of approved indications or result in significant negative financial consequences following any regulatory approval.

If Illuccix or any of our product candidates are associated with undesirable side effects or have characteristics that are unexpected in clinical trials or following approval and/or commercialization, we may need to abandon or limit their development or limit marketing to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Adverse events in our clinical trials to date have been generally predictable and typically manageable, with frequency and severity for adverse events applicable to imaging less than for therapy product candidates. The most common adverse events for Illuccix in clinical trials were nausea, diarrhea, and dizziness. The most common adverse events arising in the Phase 3 ZIRCON clinical trial of 300 patients dosed with TLX250-CDx were mild and non-serious, including nausea, procedural pain and headache. The most common severe adverse events were post-procedural hemorrhage (six events), urinary retention (three events), hypertension (three events), pyelonephritis (two events), anemia (two events), and syncope (two events). For TLX101-CDx there have been two events reported to date in an ongoing clinical trial, which are injection site reaction and nausea, both mild and non-serious.

With respect to our therapeutic product candidates, our most clinically advanced therapeutic product candidate, TLX591, has been evaluated in 242 patients across eight Phase 1 and 2 trials, including the Phase 1 ProstACT SELECT trial for which we disclosed interim data in October 2023 for 28 evaluable patients out of 30 in cohorts 1 and 2 who each received two doses. In this interim data, 21% of patients experienced grade 3 thrombocytopenia (6/28), 32% experienced grade 3 neutropenia (9/28), 21% experienced grade 4 thrombocytopenia (6/28) and 4% experienced grade 4 neutropenia (1/28). Four patients received intervention in the form of platelets, growth factors or both. Early-stage trial results should be interpreted with caution and efficacy outcomes should be evaluated for statistical and clinical significance in a larger Phase 3 randomized controlled trial.

The occurrence of adverse events in either our clinical trials or following regulatory approval could result in a more restrictive label for any product candidates approved for marketing or could result in the delay or denial of

approval to market any product candidates by the FDA or comparable foreign regulatory authorities, which could prevent us from generating sufficient revenue from product sales or maintaining profitability. Treatment-related adverse effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, result in potential product liability claims or cause patients and/or healthcare providers to elect alternative courses of treatment. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Inadequate training or education of healthcare professionals to recognize or manage the potential side effects of Illuccix or our product candidates, if approved, could result in increased treatment-related side effects and cause patients to discontinue treatment. Any of these occurrences may harm our business, financial condition and prospects significantly.

Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated by us or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Adverse events in the results of trials conducted by our competitors could also cause the FDA or comparable foreign regulatory authorities to raise concerns regarding our trials and product candidates, and/or impose additional safety and tolerance procedures on us, which may be costly. Many compounds that initially showed promise in early-stage trials for treating cancer or other diseases have later been found to cause side effects that prevented further development of the compound. If such an event occurs after any of our product candidates are approved and/or commercialized, a number of potentially significant negative consequences may result, including:

- regulatory authorities may withdraw the approval of such product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or impose distribution or use restrictions;
- patients and/or healthcare providers may elect to utilize other treatment options that have or are perceived to have more tolerable side effects;
- regulatory authorities may require one or more post-marketing studies;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- the product could become less competitive; and
- our reputation may suffer.

Further, we and our clinical trial investigators currently determine if serious adverse or unacceptable side effects are product-related in accordance with scientific practice and current knowledge. The FDA or foreign regulatory authorities may disagree with our or our clinical trial investigators’ interpretation of data from clinical trials and the conclusion by us or our clinical trial investigators that a serious adverse effect or unacceptable side effect was not product-related. The FDA or foreign regulatory authorities may require more information related to the safety profile of Illuccix or our product candidates, including additional preclinical or clinical data to support approval, which may cause us to incur additional expenses, delay or prevent the approval of one of our product candidates, and/or delay or cause us to change our commercialization plans, or we may decide to abandon the development of the product candidate altogether.

Any of these events could prevent the affected product candidate, if approved, from achieving or maintaining market acceptance, or could substantially increase costs and expenses of development or commercialization, which could delay or prevent us from generating sufficient revenue from the sale of Illuccix or any other approved product and harm our business and results of operations.

The results of previous clinical trials may not be predictive of future trial results, and preliminary, interim or top-line data may be subject to change or qualification based on the complete analyses of data and, therefore, may not be predictive of the final results of a trial.

Clinical failure can occur at any stage of the clinical development process and, therefore, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later stage clinical trials. For example, preliminary, interim or top-line data may be based on unaudited data provided by our clinical trial investigators. Finalization and cleaning of this data may change the conclusions drawn from this unaudited data provided by our clinical trial investigators indicating less promising results than we currently anticipate. Further, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety data sufficient to obtain regulatory approval to market our product candidates, if approved. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks.

We may publicly disclose preliminary, interim or top-line data from our clinical trials. Disclosures are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as further patient data become available and following a more comprehensive review of the data related to the particular study or trial. For any study that we report preliminary, interim or top-line data, we make assumptions, estimations, calculations and conclusions as part of our analyses of data. We may not have received or had the opportunity to fully and carefully evaluate all data, or our conclusions may differ from those of the FDA or other regulatory authorities. Consequently, the preliminary, interim or top-line data results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or based on differing views from regulatory agencies. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, these early data points should be viewed with caution until the final data are available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Furthermore, we may report interim analyses of only certain endpoints rather than all endpoints. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business.

If the preliminary, interim or top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Our approach to the discovery and development of therapeutic product candidates represents a novel approach to radiation therapy, which creates significant and potentially unpredictable challenges for us.

Our success depends on the successful development of our therapeutic product candidates, which are designed to treat solid tumors using a novel approach to radiation therapy. There are currently few approved radiopharmaceutical therapeutic products. In addition, there has been limited historical clinical trial experience, generally, for the development of radiopharmaceutical therapeutics. As a result, the design and conduct of clinical trials for these drugs is uncertain and subject to increased risk.

While the use of external beam radiation as a therapy for cancers has existed for decades, the use of systemic delivery of targeted radiopharmaceuticals in general is relatively new, including for both beta- and alpha-emitting therapies. It is difficult to accurately predict the challenges we may incur for our therapeutic product candidates as they proceed through clinical trials. In addition, assessments of the long-term safety of targeted beta- and alpha-emitting isotope therapies have been limited, and there may be long-term effects from treatment with our therapeutic product candidates that we cannot predict at this time.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our ongoing or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Before we can initiate clinical trials for any future product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing required for authorization to proceed with clinical development. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory filing, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing or planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs.

We do not know whether our planned and ongoing trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs or ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- delays in identifying, recruiting and training suitable clinical investigators;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of our product candidates for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from ongoing or future public health or geopolitical concerns;
- subjects choosing alternative treatments for the indications for which we are developing our therapeutic product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial or incurring greater costs than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- failure of a facility manufacturing our product candidates or any of their components to produce clinical trial materials in accordance with current good manufacturing practice requirements, or cGMP, regulations (and similar foreign requirements) or other applicable requirements;

- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations (and similar foreign requirements) or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any transfer of manufacturing processes to alternate facilities or any other changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice, or GCP, requirements or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or diagnostic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Such delays could also shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the availability and efficacy of approved drugs and diagnostics for the disease under investigation, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. The potential patient populations for our clinical trials may be narrow, and we may experience difficulties in identifying and enrolling a sufficient number of patients in our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities.

Other pharmaceutical or biotechnology companies targeting the same diseases and intended uses as our product candidates are recruiting for their clinical trials from these patient populations, which may make it more difficult to fully enroll our clinical trials. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, the process of finding eligible subjects may prove costly.

Moreover, we rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Due to their radioactive nature, Illuccix and our product candidates have time-limited stability, and as a result, we may encounter difficulties with fulfilment and logistics.

The radioactive components of Illuccix and our product candidates have short-half lives, which refers to the time it takes for the radioactivity to decrease by 50%. Radioactivity decay reduces the potential effectiveness of the radioactive component of Illuccix and our product candidates, which requires us to manufacture and deliver Illuccix and our product candidates for use in clinical trials to patients in a timely manner.

Illuccix is designed to provide, and has been approved in the United States, for four hours of stability following radiolabeling, meaning that the patient must intravenously receive Illuccix within four hours of radiolabeling, which refers to the final manufacturing step of adding a radioisotope to the product or product candidate. TLX101-CDx is designed to provide for ten hours of stability following radiolabeling. TLX250-CDx is designed to provide 96 hours of stability following radiolabeling and TLX007-CDx is designed to provide extended stability post-production due to its higher radioactivity, compared to currently approved Gallium-68 (^{68}Ga) PSMA-PET imaging agents, following radiolabeling. We expect our other product candidates to also have time-limited stability following radiolabeling based on applicable half-life.

Our product candidates are commonly manufactured as a cold-kit, enabling longer shelf storage of between 12-24 months prior to radiolabeling for specific patient administration on an as-needed basis. As such, our product candidates must be radiolabeled on an as-needed basis, and shipped almost immediately thereafter. Because of this, specific radiolabeled patient doses of Illuccix or our product candidates cannot be “stock-piled” and stored for even a small number of days ahead of shipment, we or any third-party pharmacy network or hospital must be able to radiolabel them on an as-needed rolling basis. Any delay, even if seemingly insignificant, could result in an immediate and substantial impact on our ability to deliver the product candidate to patients. Any significant delays in delivering Illuccix or our product candidates to patients could damage our reputation and result in deviations from our clinical trial protocols, which in turn could affect our ability to advance the clinical development of our current and future product candidates on a timely basis, or at all. In addition, we currently rely on our third-party radiopharmacy partners for the production of Illuccix for commercial supply in the United States. We cannot be sure that these manufacturers will be able to meet our demand for Illuccix on a timely basis.

With respect to our product candidates, as we continue to scale our operations and enroll larger clinical trials, and prepare for potential commercialization, we will need to scale our shipping abilities. Labor disputes, government restrictions, work stoppages, pandemics, derailments, damage or loss events, adverse weather conditions, other events beyond our control could interrupt or delay transportation, which could result in the loss or damage of Illuccix or any product candidates with similar stabilization restrictions. We have insurance which covers material loss or damage to Illuccix while in partner control or during transit, subject to customary insurance limitations and restrictions. Our insurance may not cover all instances worldwide.

If we or our manufacturers are unable to meet the challenges posed by the time-limitations inherent in the composition of Illuccix or any of our product candidates, it would adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to identify or discover additional product candidates or our decisions to prioritize the development of certain product candidates over others may later prove wrong.

Part of our strategy involves identifying and developing product candidates to build a pipeline of product candidates. Our diagnostic and therapeutic discovery or development efforts may not be successful in identifying compounds that are useful in diagnosing or treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive regulatory approval and/or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases or yield clinically significant outcomes.

We are currently advancing multiple imaging and therapeutic product candidates in clinical development, which may create a strain on our limited human and financial resources. As a result, we may not be able to provide sufficient resources to any single product candidate to permit the successful development and commercialization of such product candidate, which could result in material harm to our business. Further, we have limited financial and managerial resources, and we can only focus our research programs on developing product candidates for certain indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or the same product candidate for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our strategy involves pairing our diagnostic imaging product or product candidates with a complementary therapeutic product candidate, and we may not be successful in developing both the diagnostic and therapeutic product candidates that are designed to be paired, which could impact the successful development of both.

In connection with certain targets for which we are developing drug or biological candidates for treatment use, we are developing diagnostic imaging agents to help inform whether a particular patient's disease condition is appropriate for treatment with our drug or biological candidate. For example, we are using Illuccix as the paired diagnostic to our therapeutic product candidate, TLX591 (in addition to Illuccix being previously studied and used in the VISION trial as a diagnostic for Novartis' Pluvicto radioligand therapy) and we are developing TLX300-CDx as the paired diagnostic to evaluate the potential utility of TLX300, and similarly we are developing paired diagnostics for our other therapeutic product candidate development programs. We may not be successful in developing an appropriate diagnostic imaging agent or its development may cause a delay or result in expenditure of more funds than we currently anticipate. In addition, the development of a diagnostic imaging agent will be subject to FDA review and approval, which may be delayed or not obtained, or require additional development and testing than currently planned. If the FDA considers the diagnostic imaging agent to be required for the use of the therapeutic product candidate, the FDA may require the approval of the diagnostic imaging agent before it can approve the therapeutic product candidate. Equivalent foreign regulatory review and approval would also be required before the product could be supplied for use in patient treatment. Failure to successfully develop and obtain regulatory approval for a diagnostic imaging agent may delay FDA or foreign regulatory approval of a drug or biological candidate intended for therapeutic use and delay or adversely affect commercialization of that drug or biological candidate, or require us to engineer or identify alternative solutions to select patients who are most likely to benefit from our drug or biological candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The discovery, development and commercialization of new diagnostics and therapies is highly competitive, particularly in the cancer field. We face competition with respect to Illuccix and will face competition with

respect to any product candidates that we are developing and may seek to commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions worldwide, many of which have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. There are a number of major pharmaceutical, specialty pharmaceutical and biotechnology companies that currently market and sell therapies and/or are pursuing the development of therapies for the treatment of cancer and the other disease indications for which we are developing our product candidates.

With respect to Illuccix, our main competitors in the United States include companies with approved PSMA-PET diagnostics, including Novartis AG, Lantheus Holdings, Inc. and The Bracco Group (through its Blue Earth Diagnostics affiliate). Certain academic institutions, like University of California, Los Angeles and University of California, San Francisco, also hold a license for a commercial PSMA-PET diagnostic. Our main competitors also include companies developing PSMA imaging agents, including ABX, Isotopia Molecular Imaging Ltd., Itel Group, ITM Isotope Technologies Munich SE, Five Eleven Pharma Inc., Fortis Healthcare Limited, Radiomedix, Inc., HTA, and Jiangsu Hengrui Pharmaceuticals Company Ltd. Our competitors will also include companies developing other modalities to localize prostate cancer.

In the kidney and brain cancer imaging fields, there are no approved agents for molecular imaging for ccRCC or glioma. Our main future competitors in these fields are companies developing agents, including Debiopharm SA, Philogen S.p.A., ImaginAb, Inc., Precision Molecular, Inc., Five Eleven Pharma Inc., Novartis AG, Blue Earth Diagnostics, Inc., RadioPharm Theranostics Limited, Curasight A/S, Molecular Targeting Technologies, Inc. (MTTI), and EvaThera.

With respect to our therapeutic product candidates, we consider our most direct competitors to be companies developing targeted radiopharmaceuticals for the treatment of cancer. There are several companies with approved beta-based radiopharmaceuticals, including Lantheus Holdings, Inc., Novartis AG, Bayer AG, Sirtex Medical Limited, Boston Scientific Corporation and Q BioMed Inc. and other companies developing beta-based radiopharmaceuticals, including Eli Lilly and Company, ITM Isotope Technologies Munich SE and Y-mAbs Therapeutics, Inc. The beta emitting isotopes used by these companies include Iodine-131, Lutetium-177, Strontium-89 and Yttrium-90. A recently approved beta particle-based radiopharmaceutical is Pluvicto, which was developed by Novartis AG and approved by the FDA in 2022 for the treatment of patients with metastatic prostate cancer. There are also several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Bayer AG, Novartis AG, Johnson & Johnson, Abdera Therapeutics Inc., Actinium Pharmaceuticals, Inc., Aktis Oncology, Inc., Convergent Therapeutics, Inc., Debiopharm SA, Fusion Pharmaceuticals Inc., ITM Isotope Technologies Munich SE, Lantheus Holdings, Inc., Mariana Oncology, Inc., Perspective Therapeutics, Inc., POINT Biopharma Global Inc., RadioMedix, Inc., RayzeBio, Inc, and Y-mAbs Therapeutics, Inc. These companies are targeting a wide range of solid and hematologic malignancies using various alpha-emitting isotopes, including Radium-223, Lead-212, and Actinium-225. The first and only approved alpha particle-based therapy is Xofigo (Radium-223), which was developed by Bayer AG and approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

With respect to TLX591, our main competitors include Novartis AG, with Pluvicto as the only currently approved PSMA-targeted therapy. Our main competitors also include companies developing PSMA-targeted therapies, including Convergent, Therapeutics, Inc. Point Biopharma Global Inc., Lantheus Holdings, Inc., Curium Pharma, ArtBio, Blue Earth Therapeutics Ltd., Clarity Pharmaceuticals Ltd., Fusion Pharmaceuticals Inc., Bayer AG, Orano Med, Isotopia Molecular Imaging Ltd., ITM Isotope Technologies Munich SE, Janssen Pharmaceuticals, Inc., Advancell Isotopes Pty Ltd., Alpha-9 Theranostics Inc., Cancer Targeted Technology, FutureChem Co, Ltd., Beijing Sinotau Intl. Pharmaceutical Technology Co., Ltd., RadioPharm Theranostics Limited, Precision Molecular, Inc., StarPharma Holdings Limited, and AMBRX Biopharma Inc. Our competitors also include companies developing other modalities to treat patients in mCRPC. For TLX250, our main competitors include Debiopharm SA, Precision Molecular, Inc., Astellas Pharma US, Inc. and Bayer AG. Our competitors will also include companies developing other modalities to image renal cell carcinoma and carbonic anhydrase IX. For TLX101, our main competitors include ITM Isotope Technologies Munich SE, Molecular Targeting Technologies, Inc. (MTTI), EvaThera, Novartis AG, Radiopharm Theranostics Limited, Plus Therapeutics, Inc., and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to treat brain cancer.

We are currently focused on developing and commercializing Illuccix and our product candidates for the diagnosis and treatment of cancer and there are a variety of commercially available imaging and therapeutic products marketed for cancer. In many cases, cancer imaging products and therapeutics are administered in combination to enhance efficacy. Some of these products are branded and subject to patent protection, and others are available on a generic basis or prepared under the practice of pharmacy or pharmacy compounding exemptions in certain jurisdictions. Many of these products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic diagnostics and therapeutics. Illuccix is, and any other product for which we obtain marketing authorization will likely be, priced at a significant premium over competitive generic products or "home-brew" non-cGMP products, which may make it difficult for us to achieve our business strategy of using our products in combination with existing products or replacing existing products with our products, particularly if clinical differentiation or innovation contribution is more limited compared to currently available products.

Further, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are or are perceived to be more effective, safer, more tolerable, more convenient and/or less costly than any of our currently approved products or product candidates or that would render our products obsolete or non-competitive. Our competitors may also obtain regulatory approval from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position before we are able to enter the market or preventing us from entering into a particular indication at all.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, engaging clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

If we are not able to compete effectively against current or potential competitors, our business may be materially harmed and our financial condition and results of operations will be adversely affected.

We may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, of any products for which we obtain regulatory approval, including Illuccix, in which case we may not generate significant revenues or remain profitable.

We may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success of any products for which we obtain regulatory approval, including Illuccix. Oncologists may be reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their oncologists recommend switching products or they are required to switch therapies due to lack of coverage and reimbursement for existing therapies.

Efforts to drive adoption within the medical community and third-party payors based on the benefits of our products and product candidates require significant resources and may not be successful. The success of Illuccix and our current or future product candidates, whether alone or in collaboration with third parties, including achieving and maintaining an adequate level of market adoption, depends on several factors, including:

- our ability to successfully launch and achieve broad adoption of Illuccix or any other product for which we obtain approval, or any future indications for which Illuccix may be approved;
- the competitive landscape for Illuccix and our product candidates, including the timing of new competing products entering the market and the level and speed at which these products achieve market acceptance;
- actual or perceived advantages or disadvantages of Illuccix or any product candidates for which we obtain approval as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration, access or cost effectiveness;
- the effectiveness of our sales, marketing, manufacturing and distribution strategies and operations;

- the consistency of any new data we collect and analyses we conduct with prior results; whether they support a favorable safety, efficacy and effectiveness profile of Illuccix; and any potential impact on our FDA or any foreign regulatory approvals and/or labeling for Illuccix;
- our ability to comply with the FDA's and comparable foreign regulatory authorities' post-marketing requirements and commitments, including through successfully conducting, on a timely basis, additional studies that confirm clinical efficacy, effectiveness and safety of Illuccix (or any product candidates for which we obtain approval and are required to conduct such studies) and acceptance of the same by the FDA or similar foreign regulatory authorities;
- acceptance of current indications of Illuccix and future indications of Illuccix and other product candidates, if approved, by patients, the medical community and third-party payors;
- obtaining and maintaining coverage, adequate pricing and reimbursement by third-party payors, including government payors, for Illuccix and our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or as co-pay amounts under third-party coverage;
- our ability to enforce intellectual property rights in and to our products to prohibit a third party from marketing a competing product and our ability to avoid third-party patent interference or intellectual property infringement claims;
- current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions;
- the performance of our manufacturers, license partners, distributors, providers and other business partners, over which we have limited control;
- any significant misestimations of the size of the market and market potential for any of Illuccix or our product candidates;
- establishing and maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and effectiveness profile;
- maintaining an acceptable safety and tolerability profile of Illuccix or any of our product candidates for which we obtain approval, including the prevalence and severity of any side effects;
- the ability to offer Illuccix or any product candidates for which we obtain approval for sale at competitive prices;
- adverse publicity about our products or favorable publicity about competitive products; and
- our ability to maintain compliance with existing and new health care laws and regulations, including government pricing, price reporting and other disclosure requirements related to such laws and regulations, and the potential impact of such laws and regulations on physician prescribing practices and payor coverage.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize Illuccix or our product candidates, if approved, which would materially harm our business.

If we are unable to maintain or expand our sales, marketing and distribution capabilities, we may not be successful in commercializing Illuccix or any of our product candidates, if approved.

We have built a commercial infrastructure in Australia, New Zealand, the United States, Canada and the European Union for Illuccix. Prior to building this infrastructure, we did not previously have any experience in the sales, marketing or distribution of pharmaceutical products. If any of our product candidates are approved, we may need to evolve our sales, marketing and distribution capabilities and we may not be able to do so successfully or on a timely basis. In the future, we may choose to expand our sales, marketing and distribution

infrastructure to market or co-promote one or more of our product candidates, if and when they are approved, or enter into collaborations with respect to the sale, marketing and distribution of our product candidates. We are working with existing and may in the future work with additional partners to develop the commercial infrastructure to support the sale of Illuccix outside of the United States.

There are risks involved with establishing and maintaining our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any commercial launch of a product candidate or negatively impact ongoing commercialization efforts for our approved products. Further, we may underestimate the size of the sales force required for a successful product launch and we may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial launch of any of our product candidates is delayed or does not occur for any reason, including if we do not receive regulatory approval in the timeframe we expect, we may have prematurely or unnecessarily incurred commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to successfully commercialize Illuccix or any of our product candidates, if approved, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, market access, market analytics, operations and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe current or future products;
- the lack of complementary products, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales, marketing and distribution organization;
- our inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies;
- our ability to supply, manufacture and deliver sufficient inventory of our products for commercial sale on a timely basis; and
- existing or new competitors taking share from Illuccix or any other product candidate for which we obtain approval in the future, or preventing Illuccix or any such product from gaining share in its approved indications.

The commercial success of Illuccix and our product candidates, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, key opinion leaders, patients, healthcare payors and others in the medical community.

Adverse events in clinical trials of our product candidates, or in clinical trials or other studies conducted by others involving similar products, which may include the same radioisotopes as Illuccix and/or our product candidates, and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for Illuccix or any future product candidates that we may develop. If public perception is influenced by claims that radiopharmaceuticals or specific therapies within radiopharmaceuticals are unsafe, Illuccix or any product candidates for which we obtain regulatory approval may not be accepted by the general public or the medical community.

In particular, the commercial success of Illuccix and our product candidates, if approved, will depend upon, among other things, these products gaining and maintaining acceptance by physicians, key opinion leaders, patients, third-party payors, and other members of the medical community as efficacious and cost-effective alternatives to competing products and treatments. If Illuccix or any of our product candidates, once approved, do not achieve and maintain an adequate level of acceptance, we may not generate material sales of that product or be able to successfully commercialize it. The degree of market acceptance of Illuccix or our product candidates, if approved, will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;

- the prevalence and severity of any side effects in general, and differentiation relative to other treatments;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA;
- the size of the target patient population;
- advertising concerning our products or competing products and treatments;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our products for sale at competitive prices;
- the relative convenience and ease of administration of our products and product candidates, which may require coordination amongst multiple physicians across disciplines for administration;
- the willingness of the target patient population to try new products or product candidates and of physicians to prescribe these products and product candidates;
- strength of marketing and distribution support;
- publicity for our product candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- any restrictions on the use of our products together with other medications; and
- the sufficiency of coverage or reimbursement by third parties.

Manufacturing of radiopharmaceuticals is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of Illuccix or any of our product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

Manufacturing of radiopharmaceuticals is complex, highly regulated and must comply with cGMPs and similar foreign requirements. While we have manufacturing capabilities of our own, we also rely on third parties, such as contact manufacturing organizations, or CMOs, for the manufacture of Illuccix and our product candidates. If we are unable to obtain or maintain arrangements with CMOs, or to do so on commercially reasonable terms, we may not be able to commercialize Illuccix or develop our product candidates successfully. Our third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs on a timely basis or at all, and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of Illuccix or any of our product candidates.

Additionally, as we expect the market for Illuccix and PSMA-PET imaging to expand and our product candidates progress through preclinical studies and clinical trials towards potential approval and commercialization, it is possible that various aspects of manufacturing will be altered in an effort to optimize processes and results. Such changes may require new submissions to and approval from regulators, which may further delay the timeframes under which modified manufacturing processes can be used for Illuccix or any of our product candidates, and additional bridging studies or trials may be required. Any such delay could harm our business, financial condition, results of operations and prospects.

We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMPs or similar foreign requirements. Despite our efforts to audit and verify regulatory compliance, we or one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMPs or similar foreign

regulations. This may result in shutdown of our facility or that of the third-party vendor or invalidation of product lots or processes, which could adversely affect our business, financial condition, results of operations and prospects. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our products and could be costly and result in reputational damage.

We may be unable to generate and/or obtain a sufficient supply of radioisotopes to support clinical development or manufacturing at commercial scale.

As a radiopharmaceutical company, Illuccix and our product candidates are prepared for patient administration using radioisotopes. Gallium-68, or ^{68}Ga, is a necessary component isotope for radiopharmacies to radiolabel Illuccix for patient administration and is sourced by a radiopharmacy directly. Other important isotopes applicable to our current pipeline of diagnostic and therapeutic product candidates include Zirconium-89 or ^{89}Zr, Lutetium-177 or ^{177}Lu, Yttrium-90, or ^{90}Y, Fluorine-18 or ^{18}F, Iodine-131 or ^{131}I, and Technetium-99m or ^{99m}Tc. We procure supply of these isotopes from suppliers based predominately in Canada or Europe. Global isotope supply chains, including obtaining precursor or raw materials necessary to produce many of the synthetic radioisotopes used in nuclear medicine, are commonly sourced from countries such as Russia, Brazil, South Africa and Turkey that may, from time-to-time, be subject to instability, unrest, protests, intergovernmental conflicts and various international trade or monetary sanctions. Where isotopes or raw materials are procured under various medical or humanitarian exemptions, including countries that may, from time-to-time, be subject to instability, unrest, protests, intergovernmental conflicts and various international trade or monetary sanctions, those exemptions may be repealed or altered in a way that is detrimental to our ability to operate our business.

We aim to maintain multiple supply agreements with isotope suppliers and stockpiles to ensure adequate quantities to meet our current pipeline development needs. However, there is a limited supply of some radioisotopes due to the limited supply of starting radioactive raw materials to create the radioisotope or the complexity required to manufacture isotopes to the required quality and purity standards for effective radiolabeling. We aim to maintain supply relationships with all major current suppliers and for certain isotopes there are no or limited alternatives to our current suppliers. While we are making investments to secure additional access to and capabilities for manufacturing isotopes, we may encounter supply shortages which could affect our business operations and results of operations. There can be no assurance that our suppliers will renew existing contracts on acceptable terms, or even at all. Additionally, failure to acquire enough medical-grade isotopes for specific product candidates would make it impossible to effectively complete clinical trials, especially as we scale up for later-stage clinical trials, and to commercialize any product candidates that we may develop, which would materially harm our business.

Isotope suppliers may also have limited production capacity to meet future commercial demand, and there is no guarantee that production will start in the time frame we expect. Even where a contract exists, we may have limited recourse if a supplier is unable to meet its obligations. Suppliers may also be unable to meet their obligations for any number of reasons. For example, the U.S. Department of Energy has reserved its ability to cancel private orders when the supply is instead needed for national defense, environmental safety, or in the event of any other sort of lack of supply capacity or for a number of other reasons that are outside of our control.

Radioisotopes or radioactive raw materials may only be available from a limited number of countries, including Russia, Brazil, Turkey or South Africa. Our isotope suppliers obtain the radioactive materials from source material countries in accordance with applicable laws and export regulations, usually under medical exemption, and then use the raw materials to manufacture the radioisotopes for onward clinical sale and commercial sale to third parties, including governments, hospitals and pharmaceutical companies. We and our suppliers are exposed to a number of environmental and geopolitical risks beyond radioactive raw material availability, including restrictions on trade of certain items with Russia, and other unforeseen geopolitical factors that limit our ability to access our supply of raw material. The ongoing war in Ukraine and subsequent economic sanctions imposed on Russia, including by the United States, may impact our ability to procure supply of necessary isotopes and may impact our product development timelines. For example, while our current suppliers are not currently designated on any export or sanctions-related restricted party lists maintained by the U.S. government, there is no guarantee our suppliers (or their third-party suppliers of raw materials) will not be designated on such lists in the future. In addition, our dependence on international radioisotope suppliers is increased in the near term because the U.S. Department of Energy restricts usage for certain isotopes for clinical development outside the United States, and therefore, we must rely on our suppliers for our international operations. To date, the ongoing

war in Ukraine has not materially impacted the development of any of our product candidates, nor has it materially impacted the price at which we are able to purchase isotopes. Although we do not expect to encounter additional delays from our suppliers based on the ongoing war in the Ukraine, we may experience delays in the future, and any such delay could have an adverse material impact on our development plans and business. We expect to continue to monitor and adapt our development plans as necessary in response to environmental and geopolitical risks. Any difficulty that our suppliers have in procuring raw materials may also magnify the impact of other risks described in this registration statement.

Our ability to conduct clinical trials to advance our product candidates is dependent on our ability to either self-generate and/or obtain these radioisotopes and other isotopes we may choose to utilize in the future. While we intend to scale-up our manufacturing facilities to achieve vertical integration and the ability to self-manufacture our final diagnostics and therapeutics products, we are dependent on third-party manufacturers and suppliers for many of our isotopes, and our suppliers will be dependent on third parties to supply the raw radioactive materials. These parties may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies, and we have no control over our suppliers' compliance with these standards. Failure to comply with regulations and standards may result in their inability to supply an isotope that could result in delays in our clinical trials or commercialization, which could have a negative impact on our business.

Even if we are able to effectively commercialize Illuccix or any product candidates for which we obtain approval, the products may not receive coverage or may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, all of which would harm our business.

The legislation and regulations that govern regulatory approvals, pricing, coverage and reimbursement for new imaging and therapy products vary widely from country to country. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to pricing or reimbursement regulations that delay the commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from product sales in that country. In the United States and most other major markets internationally, approval and reimbursement decisions are not linked directly, but there is increasing scrutiny from the Congress, government or regulatory authorities, payors, patient organizations of the pricing or reimbursement of pharmaceutical products. Adverse pricing or reimbursement limitations may also hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to successfully commercialize Illuccix and any other products that we may develop or acquire will depend, in part, on the extent to which satisfactory pricing, coverage and reimbursement for these products is available from government payors, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Obtaining and maintaining adequate coverage and reimbursement for Illuccix and any of our product candidates, if approved, may be difficult. Moreover, the process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for our products. Even with payor coverage, patients may be unwilling or unable to pay the copay required and may choose not to take or use our products.

A primary trend in the healthcare industry in the United States and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek, with respect to an approved product, additional clinical evidence that goes beyond the data required to obtain regulatory approval. They may require such evidence to demonstrate clinical benefits and value in specific patient populations or they may call for costly pharmaceutical studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies before covering our products. Accordingly, we cannot be sure that reimbursement will be or will continue to be available for Illuccix and any product that we commercialize and, if reimbursement is available, we cannot be sure as to the level of

reimbursement and whether it will be adequate. Coverage and reimbursement may impact the demand for or the price of Illuccix or any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize Illuccix or any other approved products.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that Illuccix or any other product candidate for which we obtain approval will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our products and our overall financial condition.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of Illuccix or any other products that we may develop or acquire.

We face an inherent risk of product liability exposure related to our commercialization of Illuccix and the testing of our product candidates in human clinical trials as the administration of our products to humans may expose us to liability claims, whether or not our products are actually at fault for causing any harm or injury. As Illuccix is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying conditions, the likelihood of adverse product reactions or unintended side effects, including death, may increase. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities or may be required to limit commercialization of our products. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Illuccix and any other products that we may develop or acquire;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to successfully commercialize Illuccix and any other products that we may develop or acquire.

We currently hold clinical trial liability insurance of up to A$20 million per occurrence in the aggregate and general product liability insurance coverage in the amount of A$20 million in the aggregate, but that coverage may not be adequate to cover any and all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Regulatory Matters

Even if we complete the necessary preclinical studies and clinical trials for our product candidates, the regulatory approval process is expensive, time-consuming and uncertain and we or they may not receive approvals for the commercialization of some or all of our or their product candidates in a timely manner, or at all.

Our long-term success and ability to sustain and grow revenue depends on our ability to continue to successfully develop our product candidates and obtain regulatory approval to market our or their products both in and outside of the United States. In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country, impose substantial requirements on the development of product candidates to become eligible for marketing approval, have substantial discretion in the process, and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical studies, clinical trials or other studies and testing. The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. For example, in many countries outside of the United States, it is required that the drug also be approved for reimbursement before the drug can be sold in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

In addition, the FDA and foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that any product candidate is safe and effective. If we are required to conduct additional clinical trials of Illuccix prior to approval of any additional investigational indications we are developing it for, or of any other product candidates prior to approval, we may need substantial additional funds, and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each indication to establish the product candidate’s safety and efficacy.

In addition, changes in or the enactment of additional statutes, promulgation of regulations or issuance of guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a Diversity Action Plan, or DAP, for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

Further, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval.

The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the European Medicines Agency, or EMA, and available to clinical trial sponsors, competent authorities of the EU Member States and the public. We have not previously secured authorization to conduct clinical studies in the European Union pursuant to this new regulation and, accordingly, there is a risk that we may be delayed in commencing such studies.

The FDA or other regulatory authorities may determine that (i) our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; (ii) the dose used in a clinical trial has not been optimized and require us to conduct additional dose optimization studies; or (iii) the comparator arm in a trial is no longer the appropriate comparator due to the evolution of the competitive landscape or subsequent data of the comparator product, even if the FDA or other regulatory authority had previously approved the trial design, and we may be required to amend the trial or we may not receive approval of the indication.

Further, under the Pediatric Research Equity Act, or PREA, an NDA, BLA or supplement to an NDA or BLA for certain drugs and biological products must contain data to assess the safety and effectiveness of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services, or CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Finally, our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of mifepristone continues. On April 7, 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. On December 13, 2023, the U.S. Supreme Court granted these petitions for writ of certiorari for the appeals court decision. On June 13, 2024, the U.S. Supreme Court reversed the appeals court's decision and remanded the case after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA.

The approval of our product candidates for commercial sale could also be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including, but not limited to, the following:

- regulatory authorities may determine that our product candidates do not demonstrate safety and effectiveness in accordance with regulatory agency standards based on a number of considerations, including adverse events that are reported during clinical trials;
- regulatory authorities could analyze and/or interpret data from clinical trials and preclinical testing in different ways than we interpret them and determine that our data is insufficient for approval;
- regulatory authorities may require more information, including additional preclinical or clinical data or the conduct of new trials, to support approval;
- regulatory authorities could determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal or other laws or otherwise not properly managed, and we may be unable to obtain regulatory approval for a commercially viable manufacturing process for our product candidates in a timely manner, or at all;
- the supply or quality of our product candidates for our clinical trials may be insufficient, inadequate or delayed;
- the size of the patient population required to establish the efficacy of our product candidates to the satisfaction of regulatory agencies may be larger than we or they anticipated;
- our failure or the failure of clinical sites, and the records kept at the respective locations, including records containing clinical trial data, to be in compliance with the FDA's GCP, requirements or comparable regulations outside of the United States;
- regulatory authorities may change their approval policies or adopt new regulations;
- regulatory authorities may not be able to undertake reviews of our marketing applications, conduct applicable inspections or proceed through their approval processes in a timely manner;
- the results of our earlier clinical trials may not be representative of our future, larger trials;
- regulatory authorities may not agree with our regulatory approval strategies or components of our or their regulatory filings, such as the design or implementation of the relevant clinical trials; or
- a product may not be approved for the indications that we request or may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Accordingly, we may not be able to submit applications for marketing approvals/authorizations and may not receive necessary approvals to commercialize our products in any market. Any failure, delay or setback in obtaining regulatory approval for our product candidates could materially adversely affect our ability to generate revenue from a particular product candidate, which could result in significant harm to our financial position and adversely impact the price of our ordinary shares and ADSs.

Failure to obtain marketing approval in foreign jurisdictions would prevent our medicines from being marketed in such jurisdictions and any of our medicines that are approved for marketing in such jurisdiction will be subject to risk associated with foreign operations.

In order to market and sell our medicines in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

Further, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, or GB, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland is currently subject to EU rules. The United Kingdom and European Union have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. From January 1, 2025 forward, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the U.K. market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States. In addition, we do not have experience commercializing products outside of the United States and such efforts may depend on our ability to find a suitable collaborator.

We intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable

jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

We may seek approval of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated development pathways. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay or prevent the receipt of, necessary marketing approvals. Moreover, even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional NDAs or BLAs seeking accelerated approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval. Furthermore, for any submission of an application for accelerated approval, there can be no assurance that such submission will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation (i) authorized FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; (ii) requires a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months until the study is completed; and (iii) authorizes FDA to use expedited procedures to withdraw accelerated approval of an NDA or a BLA if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required

post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will ultimately not be legally binding even when finalized, we will need to observe the FDA's guidance closely to ensure that our products qualify for accelerated approval.

In the European Union, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Products utilizing our technology may need to be approved or cleared by the FDA and similar regulatory agencies or certified by notified bodies worldwide as medical devices. We may not receive, or may be delayed in receiving, the necessary approval, clearance or certification for our future medical device products, which would adversely affect business, financial condition, results of operations and prospects.

We are developing artificial intelligence, or AI, and surgical assistance offerings that may be subject to regulation as medical devices in the United States and other jurisdictions. We have not yet utilized our AI platform in the development of Illuccix or our product candidates. To date, we have not had any discussion with the FDA or other regulatory authorities or notified bodies regarding the regulatory pathways required to market these technologies. The FDA or similar regulatory agencies may subject these offerings to medical device requirements, including premarket review, lengthier or more rigorous processes than we expected that may include the performance of one or more clinical trials. Efforts to achieve requisite governmental clearances and approvals could be costly and time consuming, and we may not be able to obtain any such required clearances or approvals in accordance with our anticipated timeline or in a cost-efficient manner. Any delay or failure to obtain necessary regulatory clearances, approvals or certifications could have a material negative impact on our ability to generate revenues.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a premarket approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical

trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is generally much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device or other restrictions or requirements, which may limit the market for the device.

The FDA, comparable foreign regulatory authorities or notified bodies can delay, limit or deny clearance, approval or certification of a medical device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory authority or notified body that our product candidates are safe or effective for their intended uses or are substantially equivalent to a predicate device;
- the disagreement of the FDA or the applicable foreign regulatory authority with the design or implementation of our clinical studies or the interpretation of data from pre-clinical studies or clinical studies;
- serious and unexpected adverse effects experienced by participants in our clinical studies;
- the data from our pre-clinical studies and clinical studies may be insufficient to support clearance, approval or certification where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Subject to the transitional provisions and in order to sell our products in EU member states, our products must also comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces the Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the European Union. All medical devices placed on the market in the European Union must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Even if regulatory clearance, approval or certification is obtained, such products will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions. In addition, the cost of compliance with new laws or regulations governing our technology or future products could adversely affect our business, financial condition, results of operations and prospects. New laws or regulations may impose restrictions or obligations on us that could force us to redesign our technology or other future products or services, and may impose restrictions that are not possible or practicable to comply with, which could cause our business to fail.

Illuccix and any of our product candidates for which we obtain marketing approval in the future are subject to post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. Illuccix and any of our product candidates for which we obtain marketing clearance or approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other U.S. and foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and related compliance requirements such as price reporting, transparency reporting and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing authorization is granted, it may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including in the case of drug or biological products, the requirement to implement a REMS, which could include requirements for a restricted distribution system.

The FDA and comparable foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug or biological product. There are similar potential requirements for medical devices. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive requirements by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA or foreign regulatory authorities to monitor and ensure compliance with cGMPs (and similar foreign requirements) or other regulations.

If the FDA or another regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- refuse to approve pending applications or supplements to approved applications;
- require us to change the way a product is distributed, conduct additional clinical trials, change the labeling of a product or require us to conduct additional post-marketing studies or surveillance;
- restrict our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- require additional warnings on the product label, such as a "black box" warning or a contraindication;
- impose restrictions on the products, manufacturers or manufacturing process;
- require warning or untitled letters;
- seek injunctions or civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- seize or detain products or implement import bans;
- impose voluntary or mandatory product recalls and publicity requirements;
- totally or partially suspend production; and
- impose restrictions on operations, including costly new manufacturing requirements.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

In connection with our currently approved products and assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, our ability to market any future products could be limited, which could adversely affect our ability to sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other U.S. or foreign agencies, including the Department of Justice, or DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs and biological products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we communicate about any of our product candidates for which we, or they, receive marketing approval in a way that regulators assert goes beyond their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Alleged violations of the FDCA or other statutes, including the False Claims Act, or the FCA, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products and any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may seek certain designations for our product candidates in the United States, including breakthrough therapy, fast track and priority review designations, and PRIME designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A breakthrough therapy-designated product candidate is defined as a product candidate that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. We have received breakthrough therapy designation for our kidney cancer imaging product candidate, TLX250-CDx. Breakthrough therapy designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that any product candidate that receives a breakthrough therapy designation will receive marketing approval.

The FDA may also issue fast track designation to a product candidate if it is intended, alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it

demonstrates the potential to address unmet medical needs for such a disease or condition. We have received fast track designation for our glioma imaging product candidate, TLX101-CDx. For fast track-designated product candidates, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product candidate's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective.

We may also seek priority review for one or more of our product candidates. If the FDA determines that a product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition, the FDA may designate the product candidate for priority review upon submission of a marketing application seeking approval of that product. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and reject our request for designation. Further, even if we receive a designation, such as the breakthrough therapy designation for our kidney cancer imaging product TLX250-CDx or the fast track designation for our glioma imaging candidate TLX101-CDx, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures, and the designation does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the sponsor intends to apply for an initial MAA through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria with respect to its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables a sponsor to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we or our collaborators receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of the EMA's grant of a marketing authorization.

We may not be able to obtain orphan drug designation or exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or foreign regulatory authorities from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, meaning that the product is intended for a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States the drug or biologic will be recovered from sales in the United States for that drug or biologic. For example, we have received orphan drug designations from the FDA for TLX101 for the treatment of glioma, for TLX101-CDx for the imaging of glioma and for TLX66 as a conditioning treatment prior to hematopoietic stem cell transplant. TLX090 (^{153}Sm-DOTMP) and TLX102 (4-[^{211}At] astato-l-phenylalanine, or ^{211}At-APA) have also been granted orphan drug designation by the FDA for the treatment of osteosarcoma and multiple myeloma, respectively. In addition, in the European Union, a medicinal

product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than 5 in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. For example, TLX101 and TLX66 have been granted orphan drug designation in Europe. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that any product candidate that receives an orphan drug designation will receive marketing approval.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities, as applicable, from approving another marketing application for the same product for the same disease or condition for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for Orphan Designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain the designation and if, upon approval, we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same disease or condition. In addition, even after an orphan drug or biologic is approved, the FDA and comparable foreign regulatory authorities, such as the European Commission, can subsequently approve the same product for the same condition if the FDA or such other authorities conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or comparable foreign regulatory authorities determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future or whether Congress will take legislative action, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or Congress may make to orphan drug regulations and policies, our business could be adversely impacted.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing certain product candidates for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA’s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities (or notified bodies) to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA, other agencies, and authorities (or notified bodies) may also slow the time necessary for new product candidates to be reviewed and/or approved (or certified), which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other agencies, and authorities (or notified bodies) may also slow the time necessary for new product candidates to be reviewed and/or approved (or certified) by necessary government agencies, foreign regulatory authorities (or notified bodies), which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities.

In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the

future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our or their product candidates, if approved, and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell or commercialize Illuccix or any product candidate for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the ACA) was enacted. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS, an agency within the U.S. Department of Health and Human Services, or HHS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least US$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers, which went into effect in April 2013 and will remain in effect through 2032. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, with the passage of the Inflation Reduction Act, or the IRA, in August 2022, Congress extended the expansion of ACA premium tax credits through 2025.

These and other laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products or product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. The Trump Administration also took executive actions to undermine or delay implementation of the PPACA, including directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In January 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care,

and consider actions that will protect and strengthen that access. Under this Executive Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the PPACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the health insurance marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the PPACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

In the European Union, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and new payment methodologies that govern Illuccix or any other approved product and/or the level of reimbursement physicians receive for administering Illuccix or any other approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from Illuccix or from product candidates for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The insurance coverage and reimbursement status of newly approved products is uncertain. Illuccix and product candidates, if approved, may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for Illuccix or any other product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs and other medical products vary widely from country to country. In the United States, healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our products and product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford

treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our products and product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products or product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products and product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products, As noted above, in the United States, we plan to have various programs to help patients afford our products, including patient assistance programs and co-pay coupon programs for eligible patients.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is

available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard-of-care drugs, including lower-priced generic versions of standard-of-care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. Additionally, we may develop companion diagnostic tests for use with our product candidates. We may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when approved.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, former President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, several states had submitted Section 804 Importation Program proposals to the FDA. On January 5, 2023, the FDA approved Florida's plan for Canadian drug importation. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

In July 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs the HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." In September 2021, the HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (i) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (ii) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (iii) foster scientific

innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

On August 16, 2022, the IRA was enacted. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated US$4,000 a year in 2024 and, thereafter beginning in 2025, at US$2,000 a year. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 and the second cycle will commence in the fall of 2024.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Finally, outside of the United States, in some countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, official list price country pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies.

These measures, as well as others adopted in the future, may result in additional downward pressure on the price that we receive for Illuccix or any other approved product we or our collaborators might bring to market. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from Illuccix or from product candidates that we may successfully develop and for which we, or they, may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Our relationships with radiopharmacies, healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare professionals, including but not limited to physicians, nurses, medical directors, hospitals, pharmacies, pharmacy benefit managers, group purchasing organizations, wholesalers, insurers, and all individuals employed by such entities, which we refer to collectively as HCPs, may influence the recommendation and prescription of our approved products. Our arrangements with HCPs and others who have the ability to improperly influence the recommendation and prescription of our products may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our approved products. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, arranging for or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the FCA imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or service. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS, information related to payments and other transfers of value to physicians (as defined by statute), other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and
- international, federal or state laws, regulations, or rules that oversee the compounding, administration or distribution of radiopharmaceutical products by licensed pharmacists.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain advisory agreements we have entered into with physicians who are paid, in part, in the form of shares or share options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, we are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. We are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect our liability to federal and state payors and also adversely impact our reported financial results of operations in the period of such restatement. Further, a number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to significant penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If we become subject to investigations, restatements, or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of our products and thus have an adverse impact on our financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in us having to carry a liability on our consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, our financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, we may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for our covered outpatient drugs.

Additionally, if we overcharge the government in connection with the Federal Supply Schedule pricing program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our collaborators are also subject to similar requirements outside of the United States and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, Australia, European Union, United Kingdom and other countries in which we may conduct business. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be

sure how these regulations will be interpreted, enforced or applied to our operations in the future. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the European General Data Protection Regulation, or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of the "sale" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, many other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws that will go into effect in 2025 and beyond. Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Other states have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to

the United States. This CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business. Following the withdrawal of the United Kingdom from the European Union, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the United Kingdom and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the U.K. Data Protection Act and the GDPR, respectively. The United Kingdom and the United States have also agreed to a U.S.-U.K. "Data Bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the United Kingdom to the United States. In addition to the United Kingdom, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-U.K. Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world, including Australia which has had its current detailed stringent privacy laws in place since 1988. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Our employees, independent contractors, consultants, collaborators and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and/or requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, collaborators and vendors. Misconduct by these partners could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations or similar regulations of comparable foreign regulatory authorities; provide inaccurate information to the FDA or comparable foreign regulatory authorities; fail to comply with manufacturing standards, federal and state healthcare fraud and abuse laws and regulations

and similar laws and regulations established and enforced by comparable foreign regulatory authorities; fail to comply with state drug pricing transparency filing requirements; fail to report financial information or data accurately; or fail to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of foreign jurisdictions, including GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from significant penalties, governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

If we fail to comply with environmental, health and safety laws and regulations, including those governing radiopharmaceutical products and radioactive materials, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and radiation safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. While most of the activities are conducted by third party partners on our behalf or by pharmacists or healthcare professionals consistent with their own professional obligations on their own behalf, our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Our use of facilities that use and produce radioactive materials subjects us to compliance with decommissioning and decontamination, or D&D, requirements when we close those facilities, exposing us to potentially significant costs. Our product candidates are manufactured using radioactive components. When a cyclotron reaches the end of its useful life at one of our facilities or if we need to abandon such facility for any other reason, we are obligated under the laws and regulatory rules of the various jurisdictions in which we operate to decommission and decontaminate such facility or cyclotron. Estimating the amount and timing of such future D&D costs includes, among other factors, country-specific requirements and projections as to when a facility will retire or the useful life of a cyclotron. If we do not conduct D&D properly at any of our sites, we may suffer significant additional costs to remediate any D&D deficiencies, fines, regulatory or criminal charges or other sanction or legal action, any of which could have a material adverse effect upon our business, financial condition and results of operations. Although we have estimated our future D&D costs and recorded a liability for such costs, there can be no assurances that we will not incur material D&D costs beyond such estimates or our provisions.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioisotopes. We and our third-party

manufacturers are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste products.

Our use of chemicals in the manufacturing process for our product candidates is also subject to chemicals approvals, registrations and regulations around the world, including a regulation in the European Union known as Registration, Evaluation, Authorisation and Restriction of Chemicals, and similar laws and regulations in certain other jurisdictions in which we operate. In addition, we are required to obtain and maintain a hazardous materials license, pursuant to which we are required to perform annual self-audits, and that may result in random inspections by regulators. If such audit or inspection were to result in adverse findings, it may impact our ability to maintain our license, which would in turn adversely affect our ability to conduct our business.

Additionally, we cannot completely eliminate the risk of contamination or injury from these materials, and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

Although we intend to validate that any third-party manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Comparable restrictions and related risks regarding the use of potentially hazardous substances are also applicable outside the United States. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, financial condition, results of operations and prospects.

Laws and regulations governing international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside of the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. The FCPA is enforced by the DOJ and the SEC.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals, clinics, universities and similar institutions are operated by the government, and doctors and other healthcare professionals are considered foreign officials. Certain payments to healthcare professionals in connection with clinical trials, regulatory approvals, sales and marketing, and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Because the FCPA applies to indirect payments, the use of third parties and other collaborators can increase potential FCPA risk, as we could be held liable for the acts of third parties that do not comply with the FCPA's requirements.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant

civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Like the FCPA, the Australian Criminal Code, the U.K. Bribery Act and other anti-corruption laws throughout the world similarly prohibit offers and payments made to obtain improper business advantages, including offers or payments to healthcare professionals and other government and non-government officials. These other anti-corruption laws also can result in substantial financial penalties and other collateral consequences.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States, has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

With the passage of the CREATES Act, we are exposed to possible litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of their abbreviated new drug applications, or ANDAs, 505(b)(2) NDAs and biosimilar product applications.

In December 2019, former President Trump signed legislation intended to facilitate the development of generic and biosimilar products. The bill, previously known as the CREATES Act, authorizes sponsors of ANDAs, 505(b)(2) NDAs, or biosimilar product applications to file lawsuits against companies holding NDAs or BLAs that decline to provide sufficient quantities of an approved reference drug or biological product on commercially reasonable, market-based terms. Drug or biological products on FDA's drug shortage list are exempt from these new provisions unless the product has been on the list for more than six continuous months or the FDA determines that the supply of the product will help alleviate or prevent a shortage.

To bring an action under the statute, the developer of a product candidate that seeks to develop the product and seek approval under an ANDA, 505(b)(2) NDA, or biosimilar product application must take certain steps to request the reference product from the reference product manufacturer, which, in the case of products covered by a REMS with elements to assure safe use, include obtaining authorization from the FDA for the acquisition of the reference product. If the reference product manufacturer does not provide the reference product and the ANDA, 505(b)(2) NDA, or biosimilar product sponsor does bring an action for failure to provide a reference product, there are certain affirmative defenses available to the reference product manufacturer, which must be shown by a preponderance of evidence, including that the NDA or BLA holder sells the reference product through agents, distributors, or wholesalers and has placed no restrictions, explicit or implicit, on selling the reference product to ANDA, 505(b)(2) or biosimilar sponsors. If the sponsor prevails in litigation, it is entitled to a court order directing the reference product manufacturer to provide, without delay, sufficient quantities of the applicable product on commercially reasonable, market-based terms, plus reasonable attorney fees and costs.

Additionally, the new statutory provisions authorize a federal court to award the product developer an amount "sufficient to deter" the reference product manufacturer from refusing to provide sufficient product quantities on commercially reasonable, market-based terms, up to a certain maximum amount based on revenue earned while in noncompliance, if the court finds, by a preponderance of the evidence, that the reference product manufacturer did not have a legitimate business justification to delay providing the product or failed to comply with the court's order. For the purposes of the statute, the term "commercially reasonable, market-based terms" is defined as (i) the nondiscriminatory price at or below the most recent wholesale acquisition cost for the product, (ii) a delivery schedule that meets the statutorily defined timetable, and (iii) no additional conditions on the sale.

Although we intend to comply fully with the terms of these statutory provisions, we are still exposed to potential litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of ANDAs, 505(b)(2) NDA applications or biosimilar product applications. Such litigation would subject us to additional litigation

costs, damages and reputational harm, which could lead to lower revenues. The CREATES Act may facilitate future competition with Illuccix and any of our product candidates, if approved, which could impact our ability to maximize product revenue.

We are required to comply with governmental economic and trade sanctions and export and import controls that could impair our or our collaborators' ability to compete in international markets due to licensing requirements and subject us or them to liability if we or they are not in compliance with applicable laws.

Our products are subject to international, national and state export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and we are required to comply with these laws as well as various economic and trade sanctions, including those administered by the U.S. Treasury Department's Office of Foreign Assets Controls. These laws and regulations restrict our ability to transact or deal with certain countries, regions, governments, persons and entities. Our activities, including our procurement of materials and exports of our products, must be in compliance with these laws and regulations. While we have policies and procedures designed to ensure that we maintain compliance with these laws and regulations, there is a risk that our employees, agents, or business partners may take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us or our collaborators and the respective responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. Investigations of alleged violations can be expensive and disruptive, and such violation (or allegation of a violation) could materially adversely affect our reputation, business, financial condition and results of operations.

In addition, changes in our products or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products in international markets, prevent customers from using our products or, in some cases, prevent the export or import of our products to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products could adversely affect our business, financial condition and results of operations.

Risks Related to Our Dependence on Third Parties

We depend on collaborations with third parties for certain aspects of the development, marketing and/or commercialization of Illuccix and our product candidates. If those collaborations are not successful, or if we are not able to maintain our existing collaborations or establish additional collaborations, we may have to alter our development and commercialization plans and may not be able to capitalize on the market potential of Illuccix or our product candidates.

Our product development programs and the commercialization of our products and product candidates, if approved, require local expertise and substantial additional cash to fund expenses. We expect to maintain our existing collaborations and collaborate with additional pharmaceutical and biotechnology companies for certain aspects of the development, marketing and/or commercialization of our products and product candidates. For example, we expect to rely on additional partners to develop and commercialize our products outside of the United States, including our ongoing partnership with Grand Pharmaceutical Group Limited for our imaging and therapeutic product candidates in Greater China. In addition, we intend to utilize collaborators to aid in the further development, marketing and/or commercialization of our product candidates as well, including our collaboration with Merck KGaA for clinical trials of TLX250. We also have a license agreement with Eli Lilly and Company for the exclusive worldwide rights to develop and commercialize radiolabeled forms of olaratumab together with our linker and our other proprietary licensed technology, for the diagnosis and treatment of human cancers.

Potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies and we face significant competition in seeking appropriate collaborators, including as a result of a significant number of recent business combinations among large pharmaceutical companies that have reduced the number of potential collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon the assessment of the potential collaborator's expertise, its current and expected resources and competing priorities, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or foreign regulatory

authorities, the potential market for the product or product candidate, the costs and complexities of manufacturing and delivering such product or product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. A potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate, document and manage. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all, or we may be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. If we are unable to maintain our current collaboration agreements or enter into new collaboration agreements, we may have to curtail, reduce or delay the development or commercialization programs for our products or product candidates, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements, and our collaboration agreements may not lead to the development or commercialization of our products or product candidates in the most efficient manner, or at all, and may result in lower product revenues or profitability to us than if we were to market and sell these products ourselves. In connection with any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, marketing and/or commercialization of our products or product candidates. Further, if our collaborations do not result in the successful development and commercialization of our products or product candidates or if any one of our collaborators terminates its agreement with us, we may not receive any future milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development and commercialization of our products or product candidates could be delayed and we may need additional resources to develop product candidates.

Collaborations involving our products and product candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or in compliance with applicable local and national laws and regulatory requirements;
- collaborators may de-emphasize or may not pursue development, marketing and/or commercialization of our products or product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products or product candidates may not commit sufficient resources to the marketing and distribution of our products or product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities for us with respect to our products or product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and/or commercialization of the applicable products or product candidates or to enter into new collaboration agreements;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- the number and type of our collaborations could adversely affect our attractiveness to other collaborators or acquirers.

If any of these events occurs, the market potential of our products and product candidates, if approved, could be reduced, and our business could be materially harmed.

If we are unable to establish and maintain our agreements with third parties to distribute Illuccix to patients, our results of operations and business could be adversely affected.

We rely on third parties to commercially distribute Illuccix to patients. For example, we have contracted with a distribution network of specialty pharmacies, which sell Illuccix directly to patients, and specialty distributors, which sell Illuccix to healthcare entities who then resell Illuccix to patients. While we have entered into agreements with each of these pharmacies and distributors to distribute Illuccix in the United States, they may not perform as agreed or they may terminate their agreements with us. We may also need to enter into agreements with additional pharmacies or distributors, and there is no guarantee that we will be able to do so on a timely basis, at commercially reasonable terms, or at all. If we are unable to maintain and, if needed, expand, our network of specialty pharmacies and specialty distributors, we would be exposed to substantial distribution risk. In addition, and particularly as we expand into less-mature markets or into countries where corruption may be more prevalent, we will need to conduct robust due diligence with third-party collaboration partners to best ensure that Illuccix and our other products are able to be manufactured, compounded, or distributed on a timely basis that complies will all applicable laws, regulations, and rules, including but not limited to, those that deal with anti-corruption, anti-kickback, marketing authorization and distribution of pharmaceutical products, the environment, and the safe use of the products with patients.

The use of specialty pharmacies and specialty distributors involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using Illuccix or serious adverse reactions, events and/or product complaints regarding Illuccix;
- not effectively sell or support Illuccix or communicate publicly concerning Illuccix in a manner that is contrary to FDA rules and regulations;
- reduce their efforts or discontinue to sell or support, or otherwise not effectively sell or support, Illuccix;
- not devote the resources necessary to sell Illuccix in the volumes and within the time frames that we expect;

- be unable to satisfy financial obligations to us or others;
- not be able to obtain or maintain all necessary licenses; or
- cease operations.

Any such risks may apply to future products we develop, and such events may result in decreased product sales, which would harm our results of operations and business.

We rely on third parties as we conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We rely on third parties, such as strategic partners, CROs, clinical data management organizations, medical institutions and clinical investigators, as we conduct our clinical trials. For example, in China, we are conducting a Phase 3 study of TLX591-CDx (the same compound approved in the United States as Illuccix) in collaboration with our strategic partner for the Greater China region, Grand Pharmaceutical Group Limited, and we aim for this study to support future marketing authorization applications for Illuccix in China. We also currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time in accordance with agreements or applicable laws. If we need to enter into alternative arrangements, our product development activities may be delayed.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards when conducting, recording and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA and TGA also require us to comply with comparable standards. Regulatory authorities ensure compliance with these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of the third parties that we rely on in connection with our clinical trials fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with such requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. In such an event, our financial results and the commercial prospects for our products or product candidates, if approved, could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of such third parties could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

In addition, as discussed above, the third parties upon whom we rely to conduct our clinical trials could be negatively impacted as a result of disruptions caused by pandemics or epidemics including difficulties in initiating clinical sites or enrolling participants, travel or quarantine policies, and other factors, including ongoing and future environmental or geopolitical concerns. If these third parties are so affected, our business prospects and results of operations could be severely adversely impacted.

We rely on third parties to conduct investigator-sponsored clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We partly rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We do not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or foreign regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design, execution of the trials, safety concerns or other trial results.

Such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, such as access to and the ability to use and reference the data resulting from the investigator-sponsored trials, including for our own regulatory submissions and marketing authorization applications. However, we do not have control over the timing for patient recruitment and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to rely on the data from the investigator-sponsored trials in our clinical development plans may be adversely affected.

Additionally, the FDA or foreign regulatory authorities may disagree with the sufficiency of our right to reference the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, our right for exclusive commercial use of the data or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or foreign regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

We are currently dependent on third parties for the manufacture, distribution and patient dose preparation of our products and product candidates and any difficulties, disruptions, delays or unexpected costs, or the need to find alternative sources, could adversely affect our results of operations, profitability and future business prospects.

While we have acquired some laboratory capability with Optimal Tracers in Sacramento and IsoTherapeutics in Angleton and completed Stage 1 of the buildout of our European manufacturing site in Brussels South, which is operational for selected research and development activities, we currently rely, and expect to continue to rely, on third-party contract manufacturers to manufacture our products and product candidates for our commercial and clinical use.

Facilities used by our third-party manufacturers may be inspected by the FDA or applicable foreign regulatory authorities after we submit a marketing application and before potential approval of the product candidate and are also subject to ongoing periodic unannounced inspections by the FDA or applicable foreign regulatory authorities for compliance with cGMPs (or similar foreign requirements) and other regulatory requirements following approval. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing processes of, and are completely dependent on, our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our products and product candidates. Third-party manufacturers may not be able to comply with cGMPs or similar regulatory requirements outside of the United States. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture or are not able to maintain approval, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates as alternative qualified manufacturing facilities may not be available on a timely or cost-efficient basis, or at all. Failure by any of our manufacturers to comply with applicable cGMPs (and similar foreign requirements) or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines,

injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our products or product candidates and have a material adverse impact on our business, financial condition and results of operations.

We currently have long-term supply agreements with our third-party contract manufacturers to manufacture the clinical and commercial supplies of Illuccix and for our product candidates. Our ability to have our products manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturers' facilities. Reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach, termination or nonrenewal of a manufacturing agreement by the third party, including at a time that is costly or inconvenient to us;
- the possible failure of the third party to manufacture Illuccix or our product candidates according to our schedule, or at all, including if the third-party manufacturer gives greater priority to the supply of other products over Illuccix or our product candidates, or otherwise does not satisfactorily perform according to the terms of the manufacturing agreement;
- equipment malfunctions, power outages or other general disruptions experienced by our third-party manufacturers or distributors to their respective operations and other general problems with a multi-step manufacturing or distribution process;
- the possible disruptions to supply chain and logistics processes that are required to store, transport, and deliver our products to customers that require timely delivery given the need to inject a dose of our products within a specific window of radioactivity; and
- the possible misappropriation or disclosure by the third party or others of our proprietary information, including our trade secrets and know-how.

We currently rely on a single source supplier for our active pharmaceutical ingredient for Illuccix and our related product manufacturing requirements, although additional sources and back-up suppliers are being validated and implemented. Any performance failure on the part of our existing or future manufacturers could delay clinical development, regulatory approval or commercialization of our product candidates. If our suppliers or contract manufacturers are so affected, our supply chain could be disrupted, our product shipments could be delayed, our costs could be increased and our business could be adversely affected. If our current contract manufacturers cannot perform as agreed, we may be required to replace those manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture Illuccix or our product candidates, we could incur added costs and delays in identifying and qualifying any such replacement. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could negatively impact revenues from sales of Illuccix or delay commercialization of any product candidates that are subsequently approved.

If, because of the factors discussed above, we are unable to have Illuccix or our product candidates manufactured on a timely or sufficient basis, we may not be able to meet clinical development needs or commercial demand for Illuccix or our product candidates or we may not be able to manufacture Illuccix or our product candidates in a cost-effective manner. As a result, we may lose sales, fail to generate projected revenues or suffer development or regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

We are currently party to and may seek to enter into additional collaborations, licenses and other similar arrangements and may not be successful in maintaining existing arrangements or entering into new ones, and even if we are, we may not realize the benefits of such relationships.

We are currently parties to license and collaboration agreements with a number of pharmaceutical companies and universities and expect to enter into additional agreements as part of our business strategy. The success of our current and any future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- we may not be able to enter into critical strategic collaborations or enter into them on favorable terms;

- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations, and they may not perform their obligations as agreed, expected, or in compliance with applicable legal requirements;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, which may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Additionally, we may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our R&D pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Risks Related to Our Intellectual Property

If we are unable to obtain and/or maintain commercially valuable regulatory exclusivity and patent claims or to protect our patents, trademarks, know-how and trade secrets, our ability to successfully commercialize our products and product candidates would be adversely impacted.

We rely on effective exclusivity and IP protection and our success will depend in part on our ability to obtain and/or maintain commercially valuable regulatory exclusivity and patent claims and to protect our patents, trademarks, know-how and trade secrets. We and our collaboration partners face numerous risks and uncertainties with respect to our licensed patents and those that may subsequently be licensed or issued to us, including that:

- lodged regulatory filings may not result in intended market or data exclusivity;
- governments may change data and market exclusivity provisions;
- know-how and trade secrets may be published removing protections;
- patent or trademark applications may not result in issued patents or trademarks or may take longer than expected to be issued;
- the claims of any patents or trademarks that are issued may not provide meaningful protection;
- patent term extensions may not be granted or, if granted, may be subject to revision;
- we and our research partners may not be able to develop additional proprietary technologies that are patentable or otherwise protectable under regulatory exclusivity principles;
- patents issued to us, or our industry partners, may not provide a competitive advantage;
- other companies may challenge our issued patents or trademarks;
- other companies may independently develop similar or alternative technologies to ours or duplicate or design around our technology;
- other companies may hold patents or trademarks that are relevant to our technology or activities and enforce their rights against us; and
- if patents are not issued, then the value of our patent rights may be significantly diminished.

Additionally, any information contained in our licensed patents could become part of the public domain, so that it will not be protected as confidential information or trade secrets. As legal regulations and standards relating to the validity and scope of regulatory exclusivity and IP continue to evolve around the world, the degree of future protection for our proprietary rights is uncertain. We may also be subject to arbitrary compulsory licenses or governmental acts reducing IP protection outside our reasonable control. We may incur significant costs in asserting any patent or trademark IP rights and in defending legal action against us relating to IP rights. Such disputes could delay our product development or commercialization activities. Parties making claims against us may be able to obtain injunctive or other equitable relief that could prevent us from further developing discoveries or commercializing products or require the payment of damages or royalties.

In addition, in the event a successful claim of infringement is made out against us, we may be required to pay damages and obtain one or more licenses from the prevailing third party. If we are not able to obtain these licenses at a reasonable cost, if it all, we may encounter delays and lose substantial resources while seeking to develop or commercialize alternative products.

There is a risk that third parties may have IP that is relevant to our proposed activities which could prevent us conducting these activities or may require us to license in the third party's IP, find alternatives for the third-party IP, or seek to challenge the third-party IP, either at an administrative stage or through the courts. We may need to acquire or license IP from third parties to develop and commercialize our own pipeline of IP and products. There is no guarantee such acquisitions or licenses can be obtained or, if obtained, that they will be on reasonable commercial terms. Additionally, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, there can also be no assurance that any of these parties will not breach confidentiality, or infringe or misappropriate our IP, which could cause material loss to us.

If we are unable to obtain and maintain patent protection for our products or product candidates and other discoveries, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and other discoveries similar or identical to ours, and our ability to successfully commercialize our products or product candidates and other discoveries may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary products and product candidates and other discoveries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel products and product candidates and other discoveries that are important to our business. For a description of our patent portfolio, see "Item 4. Information on the Company — B. Business Overview." We intend to continue to apply for patents with claims covering our key products, product candidates or other discoveries when and where we deem it appropriate to do so.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As such, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally, which could result in substantial costs and divert our efforts and attention from other aspects of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our product candidates or other discoveries, or which effectively prevent others from commercializing competitive products and discoveries. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the United States Patent and Trademark Office, or the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Composition of matter patents for biological and pharmaceutical products and product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering compositions of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, in some foreign jurisdictions, our ability to secure patents based on our filings in the United States may depend, in part, on our ability to timely obtain assignment of rights to the invention from the employees and consultants who invented the technology. Publications of discoveries in the scientific literature often lag behind

the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside of the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States transitioned to a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, or post-grant or inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our discoveries or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative discoveries or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical discoveries and products, or limit the duration of the patent protection of our products, product candidates and discoveries. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

We cannot be certain that we are aware of all third-party patents and pending applications in the United States and abroad that are relevant to or necessary for the commercialization of our product candidates in any jurisdiction. We may not be able to conduct complete and thorough searches, we may not be able to identify all relevant third-party patents, and we may not be able to fully predict the scope of the patent claims or the expiration of relevant third-party patent applications that may issue as patents. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual

property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Our rights to develop and commercialize our products and product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our products and product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain intellectual property rights and proprietary technologies from third parties that are important or necessary to the development of our proprietary technologies, including technologies related to Illuccix and our product candidates. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property and proprietary technologies in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our competitive position, business, financial condition, results of operations and prospects significantly.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents are or may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain and enforce the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our products or product candidates and proprietary technologies. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize product candidates, we may be unable to maintain profitability. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property rights that are subject to our existing licenses. Any of these events could have a material adverse effect on competitive position, business, financial conditions, results of operations, and prospects.

Our technology licensed from third parties may be subject to retained rights.

Any license we may enter into could provide for the retention by the licensor of certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether any future licensors will limit their use of the technology to these uses, and we may incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. The Bayh-Dole Act also imposes other obligations, including the requirement that products covered by the government funded patents be manufactured in the United States. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. In the future, we may own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act. If the federal government exercises its rights under the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to various agreements that we depend on to develop Illuccix and our product candidates and various proprietary technologies, and our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. For example, under certain of our license agreements we are required to use commercially reasonable efforts to develop and commercialize product candidates covered by the licensed intellectual property rights, maintain the licensed intellectual property rights, and achieve certain development milestones, each of which could result in termination in the event we fail to comply.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the licensing agreement;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under our collaboration agreements;
- our rights to transfer or assign the license;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, certain provisions in our and our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products or product candidates, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. We are generally also subject to all of the same risks with respect to protection of intellectual property that we may license as we are for intellectual property that we own, which are described herein. If we or any of our current or future licensors fail to adequately protect this intellectual property, our ability to commercialize product candidates could suffer.

Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in courts or patent offices.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one or more of our products or product candidates, the defendant could counterclaim that the patent covering the relevant product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including subject matter eligibility, novelty, non-obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection would have a material adverse impact on our business. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors or commercial supply companies or others may infringe our patents and other intellectual property rights. To counter infringement, we may be required to file infringement actions, which can be expensive and time-consuming. In an infringement proceeding, a defendant may assert and a court may agree with a defendant that a patent of ours is invalid or unenforceable (or both), or may refuse to stop the other party from using the intellectual property at issue.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly and could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of any current and future collaborators to develop, manufacture, market and sell Illuccix and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products or product candidates and technology, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. No litigation asserting such infringement claims is currently pending against us, and we have not been found by a court of competent jurisdiction to have infringed a third party's intellectual property rights.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. If such patent claims were to survive an invalidity challenge, and if they were asserted against us, we could incur substantial costs in the resulting litigation, including possible payment of treble damages for willful infringement and an injunction requiring us to cease sale of our products.

If we are found to infringe or think there is a risk we may be found to infringe, a third party's intellectual property rights, we could be required or choose to obtain a license from such third party to continue developing, marketing and selling our products, product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us. We could be forced, including by court order, to cease commercializing the infringing intellectual property or product or to cease using the infringing technology. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble

damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares and ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings which typically last for years before they are concluded. Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees when due. Additionally, the USPTO and various foreign patent offices require

compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with such provisions, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, a patent's life can be increased based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

If our product candidates or any of our future product candidates obtain regulatory approval, additional competitors could enter the market with generic or similar versions of such products, which may result in a material decline in sales of our competing products.

Under the Hatch-Waxman Act, a company may submit an ANDA, seeking approval of a generic version of an approved innovator product. Under the Hatch-Waxman Act, a company may also submit an NDA under section 505(b)(2) of the FDCA that references the FDA's prior approval of the innovator product or preclinical studies and/or clinical trials that were not conducted by, or for, the sponsor and for which the sponsor has not obtained a right of reference. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA.

In certain circumstances, third parties may submit an ANDA or NDA under Section 505(b)(2) as early as the so-called "NCE-1" date that is one year before the expiry of the five-year period of New Chemical Entity exclusivity or more generally four years after NDA approval. The third parties may rely on certain safety and efficacy data of the innovator's product, may not need to conduct clinical trials and can market a competing version of a product after the expiration or loss of patent exclusivity or the expiration or loss of regulatory exclusivity and often charge significantly lower prices. Upon the expiration or loss of patent protection or the expiration or loss of regulatory exclusivity for a product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. If we are not successful in defending our patents and regulatory exclusivities, we will not derive the expected benefit from them.

In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in

the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for the applicable, approved innovator product, a generic or 505(b)(2) sponsor that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our product candidates that are regulated as drugs are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA sponsor does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

If we do not successfully extend the term of patents covering our product candidates under the Hatch-Waxman Act and similar foreign legislation, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval, if any, of our products or product candidates, one or more of our U.S. patents may be eligible for patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years for one patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. The total patent term, including the extension period, may not exceed 14 years following FDA approval. Accordingly, the length of the extension, or the ability to even obtain an extension, depends on many factors.

In the United States, only a single patent can be extended for each qualifying FDA approval, and any patent can be extended only once and only for a single product. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family.

If we are unable to obtain a patent term extension for a product or product candidate or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product or product candidate, if any, in that jurisdiction will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue could be materially reduced.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, product candidates and other discoveries, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third

parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also may not have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. To the extent that we are unable to timely enter into confidentiality and invention or patent assignment agreements with our employees and consultants, our ability to protect our business through trade secrets and patents may be harmed. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. To the extent inventions are made by a third party under an agreement that does not grant us an assignment of their rights in inventions, we may choose or be required to obtain a license.

Not all of our trademarks are registered. Failure to secure those registrations could adversely affect our business.

In total, as of August 23, 2024, we own 13 registered U.S. trademarks, 16 pending U.S. trademark applications, 137 foreign trademarks registered in jurisdictions such as Australia, Europe, China, Brazil and Japan, and 94 pending foreign trademark applications applied for in jurisdictions such as Australia, Europe, China, Brazil and Japan. For a description of our registered and pending trademarks, see "Item 4. Information on the Company — B. Business Overview."

If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

In addition, any proprietary name we propose to use with our key product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed drug names, including an evaluation of potential for confusion with other drug names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug names for any of our product candidates, if approved, we may be required to expend significant additional resources in an effort to identify a suitable proprietary drug name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent,

conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our or our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own or license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct R&D activities in countries where we do not have patent rights, or in countries where R&D safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key members of our management team and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, technical and scientific expertise of principal members of our management and scientific teams, including Christian Behrenbruch, our Group Chief Executive Officer. Although we have entered into formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time by providing notice within the notice period specified in such agreements, subject to certain exceptions. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of our key employees could impede the achievement of our research, development, commercialization and other business objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to continue to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced rapid growth since our inception in 2017. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our clinical operations, preclinical and IND-enabling studies or studies approved by comparable foreign authorities and to establish regulatory, quality, and manufacturing supply chain logistics and facility operations.

To manage our anticipated future growth, we will continue to seek to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, we are completing the commissioning of a European manufacturing facility in Brussels South and have limited experience in managing the manufacturing processes necessary for delivering potent therapeutic radioisotopes. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating new employees; managing our internal development efforts effectively, including the clinical and FDA, or comparable foreign regulatory authority, and review process for Illuccix and any other product candidates, while complying with our contractual obligations to third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed or on reasonable terms, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants, CROs, or CMOs is compromised for any reason,

our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain and/or maintain regulatory approval of Illuccix or any of our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new qualified employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize Illuccix and any other product candidates we develop and, accordingly, we may not achieve our research, development, and commercialization goals.

Our business and operations may be materially adversely affected in the event of information technology system failures or security breaches, and the costs and consequences of implementing data protection measures could be significant.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber incidents initiated by malicious third parties. Cyber incidents are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect, respond to and recover from. Cyber incidents could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company, including personal data of our employees, patients and clinical trial participants. In addition, we face other kinds of risks related to our commercial and personal data, including lost or stolen devices or other systems (including paper records) that collect and store our personal and commercial information, including clinical trial data.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development and commercialization programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our reputation or competitive position could be damaged, and the further development and commercialization of our products or product candidates could be delayed or halted. In addition, we may in certain instances be required to provide notification to individuals or others in connection with the loss of their personal or commercial information.

If a material breach of our security or that of our vendors occurs, our financial or other confidential information could be compromised and could adversely affect our business or result in legal proceedings. In addition, the cost and operational consequences of implementing further data protection measures could be significant. The development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, the possibility of these events occurring cannot be eliminated entirely.

Our employees, independent contractors, consultants, collaborators and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and/or requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, collaborators and vendors. Misconduct by these partners could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations or similar regulations of comparable foreign regulatory authorities; provide inaccurate information to the FDA or comparable foreign regulatory authorities; fail to comply with manufacturing standards, federal and state healthcare fraud and abuse laws and regulations

and similar laws and regulations established and enforced by comparable foreign regulatory authorities; fail to comply with state drug pricing transparency filing requirements; fail to report financial information or data accurately; or fail to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of foreign jurisdictions, including GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from significant penalties, governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Legal claims and proceedings could adversely impact our business.

We have been in the past the subject of employment-related claims, and may in the future be a party to employment-related litigation, and any future litigation related to such actions could materially adversely affect us. We consider our historical experiences with such claims and proceedings to be in the normal course of our business or typical for our industry; however, it is difficult to assess the outcome of these matters, and we may not prevail in any future proceedings or litigation. Regardless of their merit, any threatened or actual claims or proceedings can require significant time and expense to investigate and defend. Since litigation is inherently uncertain, there is no guarantee that we will be successful in defending ourselves against such claims or proceedings, or that our assessment of the materiality of these matters, including any reserves taken in connection therewith, will be consistent with the ultimate outcome of such matters.

Risks Related to an Investment in the ADSs

There has been no prior market for the ADSs and an active and liquid market for our securities may fail to develop, which could harm the market price of the ADSs.

While our ordinary shares have been listed on the ASX since 2017, prior to the anticipated listing of the ADSs on Nasdaq, there has been no public market on a U.S. national securities exchange for our ordinary shares or ADSs, and the ADS being registered in connection with this registration statement constitutes the first opportunity for investors to purchase our ADS in the United States. We have applied to have our ADSs listed on Nasdaq, and we expect our ADSs to be quoted on Nasdaq, subject to completion of customary procedures in the United States. An active trading market for the ADSs may never develop or be sustained should the ADS be approved for listing on Nasdaq. We cannot be certain that holders of our ordinary shares will deposit their ordinary shares for ADSs that are listed on Nasdaq. In the absence of an active trading market for the ADSs, investors may not be able to sell their ADSs.

Future sales of ordinary shares or ADSs by existing holders could depress the market price of the ordinary shares or ADSs.

Sales of a substantial number of shares or ADSs in the public market, or the perception that such sales could occur, could adversely affect the market price of our ordinary shares or ADSs. As of June 30, 2024, we had 334,231,398 outstanding ordinary shares, and approximately 9,568,292 in ordinary shares underlying outstanding share options and other equity securities convertible into or exercisable for ordinary shares. In addition, as of the date of this registration statement, there were approximately 26,233,477 ordinary shares underlying outstanding Convertible Bonds, which may be converted at the option of the holders, subject to the conditions in the trust deed, at any time on or after September 9, 2024, at an initial conversion price of A$24.78 per ordinary share, subject to adjustment. Ordinary shares underlying these securities may become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the ordinary shares in the public market could depress the market price of the ordinary shares or the ADSs. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ordinary shares and ADSs could decline substantially, which could impair our ability to raise additional capital through the issuance of ordinary shares, ADSs or other securities in the future.

Our shareholders may experience dilution if we issue ordinary shares or ADSs in future financings, and, as a result, the price of the ordinary shares or ADSs may decline.

We may from time-to-time issue additional ordinary shares or ADSs and such issuance may occur at a discount from the trading price of the ordinary shares or ADSs. Additionally, we have in the past issued debt securities convertible into equity, and we may do so again in the future. For example, in July 2024, we issued the Convertible Bonds, which may be converted into ordinary shares. As a result, holders of the ADSs could experience immediate dilution upon the issuance of any of our ordinary shares, including as a result of the conversion of some or all of the Convertible Bonds. As opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preference shares or shares. If we issue ordinary shares or other equity or equity-linked securities, holders of ADSs would experience additional dilution and, as a result, the trading price of the ordinary shares or ADSs may decline.

Your right as a holder of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in ordinary shares may be limited, which may cause dilution to your holdings.

The deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

As of June 30, 2024, our executive officers, directors, holders of 5% or more of our outstanding equity interests and their respective affiliates beneficially owned approximately 15.78% of our outstanding ordinary shares. These shareholders may be able to determine all matters requiring shareholder approval and they may have interests that differ from yours and may be adverse to your interests. For example, these shareholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction.

ADS holders may not be entitled to a trial by jury with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing our ADSs provides that, to the fullest extent permitted by applicable law, ADS holders, including holders who acquire ADSs in the secondary market, irrevocably waive the right to a trial by jury for any claim they may have against us or the depositary arising out of or relating to the deposit agreement, the shares or the ADSs, including claims under U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the U.S. Supreme Court. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a trial by jury. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We

believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before acquiring any ADS(s) and thereby becoming subject to the terms of the deposit agreement.

If any owner or holder of our ADSs, including purchasers of ADSs in secondary market transactions, brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, such owner or holder may incur increased costs of bringing a claim and may not be entitled to a trial by jury with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in any such action. The deposit agreement governing our ADSs provides that any legal suit, action or proceeding against or involving us brought by the depositary or any holder or beneficial owner of ADSs, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may be instituted only in any state or federal court in New York, New York. This forum provision may increase your costs and limit your ability to bring a claim in a judicial forum that you find favorable for disputes with the depositary or us, or the depositary's or our respective directors, officers or employees, which may discourage such lawsuits against the depositary, us and the depositary's and our respective directors, officers or employees. However, it is possible that a court could find this choice of forum provision to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings. Any legal suit, action or proceeding against or involving the depositary brought by us, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may only be instituted in a state or federal court in New York, New York. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

Limitations in the deposit agreement may not be effective to waive claims against the Company based on compliance with the federal securities laws.

Although the deposit agreement provides a waiver of trial by jury as described above, we have been advised that no condition, stipulation or provision of the deposit agreement or ADSs can serve as a waiver by any owner or holder of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

The market price and trading volume of the ADSs may be volatile and may be affected by economic conditions beyond our control.

The market price of the ADSs may be highly volatile and subject to wide fluctuations. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition, the trading volume of the ADSs may fluctuate and cause significant price variations to occur. If the market price of the ADSs declines significantly, you may be unable to resell the ADSs at or above the purchase price, if at all. We cannot assure you that the market price of the ADSs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the ADSs or result in fluctuations in their price and trading volume include:

- adverse results or delays in our preclinical studies or clinical trials;
- reports of adverse events or other negative results in clinical trials of third parties' product candidates that target our products' or product candidates' target indications;
- an inability for us to obtain additional funding on reasonable terms or at all;
- any delay in submitting an IND, BLA or NDA (or similar foreign application) for our product candidates and any adverse development or perceived adverse development with respect to the FDA's (or comparable foreign regulatory authority's) review of that IND, BLA or NDA (or similar foreign application);
- failure to develop successfully and commercialize our products and product candidates;

- announcements we make regarding our current products and product candidates, acquisition of potential new products/product candidates and companies and/or in-licensing;
- failure to maintain our existing license arrangements or enter into new licensing and collaboration agreements;
- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to current and future products;
- inability to obtain adequate clinical or commercial supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions, including failure to reach agreement with applicable regulatory authorities on the design or scope of our planned clinical trials;
- failure to obtain and maintain regulatory exclusivity for our products and product candidates;
- regulatory approval or commercialization of new products or other methods of treating our target disease indications by our competitors;
- failure to meet or exceed financial projections we may provide to the public or to the investment community;
- publication of research reports or comments by securities or industry analysts;
- the perception of the pharmaceutical and biotechnology industries, and especially the radiopharmaceutical industry, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions to or departures of our key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation, against us;
- changes in the market valuations of similar companies;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- changes in trading volume of ADSs on Nasdaq and of our ordinary shares on the ASX;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, executive officers or our shareholders in the future;
- announcement or expectations of additional financing efforts; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

ADS holders are not our shareholders and do not have shareholder rights.

JPMorgan Chase Bank, N.A., as depositary, will issue, register and deliver the ADSs. After purchasing an ADS, you will become a holder of ADSs with underlying ordinary shares in an Australian publicly listed company. ADS holders will not be treated as our shareholders and will not have shareholder rights. The depositary will be the holder of our ordinary shares underlying the ADSs. Holders of ADSs will have ADS holder rights, which are solely contractual in nature. A deposit agreement among us, the depositary, ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. We and the depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders. For a description of ADS holder rights, see "Item 12. Description of Securities Other than Equity Securities — D. American Depositary Shares." Our shareholders have shareholder rights. Australian law and our Constitution govern shareholder rights. For a description of our shareholders' rights, see "Item 10. Additional Information — B. Memorandum and Articles of Association."

ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to receive our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions that may be attached to any shares. ADS holders may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. ADS holders may instruct the depositary to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders will not be entitled to exercise their right to vote unless they surrender their ADSs and withdraw the ordinary shares underlying their ADSs prior to both the ordinary share and ADS record dates for such meeting. However, ADS holders may not have sufficient advance notice about the meeting to surrender their ADSs and withdraw the shares. If we ask for ADS holders' instructions, the depositary will notify registered holders of ADSs of the upcoming vote and arrange to deliver our voting materials and form of notice to them. If we ask the depositary to solicit voting instructions, the depositary will try, as far as practical, subject to Australian law and the provisions of the depositary agreement, to vote the shares as ADS holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of ADS holders. We cannot assure ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, there may be other circumstances in which ADS holders may not be able to exercise voting rights.

ADS holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to any shares, the directors may determine that a dividend will be payable on our ordinary shares and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends in the foreseeable future). Dividends may be paid on our ordinary shares of one class but not another and at different rates for different classes. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares represented by ADSs will be paid to the depositary, which has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Before the depositary makes a distribution to you in respect of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADS depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution. ADS holders will receive these distributions in proportion to the number of ordinary shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to ADS holders amounts distributed by us as a dividend or distribution.

There are circumstances where it may be unlawful or impractical to make dividends or other distributions to the holders of the ADSs.

The deposit agreement requires the depositary to convert foreign currency distributions it receives on deposited ordinary shares into U.S. dollars and distribute the net U.S. dollars to ADS holders if it can do so on a reasonable basis and transfer the money to the United States. If it cannot make that conversion and transfer, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. If a dividend or other distribution is payable by us in Australian dollars, the depositary will hold the foreign currency it cannot convert for the account of ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, ADS holders may lose some of the value of the dividend or other distribution. The depositary is not responsible if it decides that it is unlawful or impractical to make a dividend or other distribution available to any ADS holders. This means that ADS holders may not receive the dividends or other distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to them.

You will have limited ability to bring an action against us or against our directors and executive officers, or to enforce a judgment against us or them, because we are incorporated in Australia and certain of our directors and executive officers reside outside of the United States.

We are incorporated under the laws of Australia. Certain of our directors and executive officers are residents of countries other than the United States and a portion of our and their assets are located outside of the United States. As a result, it may not be possible or practicable for you to effect service of process within the

United States upon such persons or to enforce against us or them judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the United States. An award for monetary damages under U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. As a result, our holders of our ADSs may have more difficulty in protecting their interests through actions against us, our management or our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States. In addition, as a company incorporated in Australia, the provisions of the Corporations Act 2001 (Cth), or the Australian Corporations Act, regulate the circumstances in which shareholder derivative actions may be commenced, which may be different to the circumstances for companies incorporated in the United States.

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Following the effectiveness of this registration statement and the listing of the ADSs on Nasdaq, our ordinary shares will continue to be listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and the ADSs. However, the dual listing of our ordinary shares and the ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

Our ordinary shares are quoted in Australian dollars on the ASX and the ADSs will be quoted in U.S. dollars. In the past year, the Australian dollar has generally weakened against the U.S. dollar; however, this trend may not continue and may be reversed. As such, any significant change in the value of the Australian dollar may have a negative effect on the value of the ADSs in U.S. dollars. In addition, if the Australian dollar weakens against the U.S. dollar, then, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. While we engage in limited hedging transactions to manage our foreign exchange risk, these activities may not be effective in limiting or eliminating foreign exchange losses. Consequently, appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers.

As a foreign private issuer listed on Nasdaq, we are permitted to, and intend to, follow certain home country corporate governance practices in lieu of certain Nasdaq practices. In particular, we expect to follow home country law instead of Nasdaq practice regarding the following:

- We expect to rely on an exemption from the requirement that our independent directors meet regularly in executive sessions. The ASX Listing Rules and the Australian Corporations Act do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we expect to rely on this exemption.
- We expect to rely on an exemption from the requirement that the responsibility for the appointment of the independent registered public accounting firm be made by the audit committee. While our Audit and Risk Committee is directly responsible for remuneration and oversight of the independent registered public accounting firm, the ultimate responsibility for the appointment of the independent registered public accounting firm rests with our shareholders in accordance with Australian law and our

Constitution. In accordance with the Rule 10A-3, our Audit and Risk Committee will be responsible for the annual auditor engagement and if there is any proposed change to the independent registered public accounting firm, the committee would make a recommendation to our board of directors, which would then be considered by our shareholders at an annual meeting of shareholders.

- We expect to rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq rules. Our Constitution provides that two shareholders present and entitled to vote on a resolution at the meeting shall constitute a quorum for a general meeting. Nasdaq requires that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares, which quorum may not be less than 33 1/3% of the outstanding shares of an issuer's voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from Nasdaq's quorum requirements, we expect to rely on this exemption.
- We expect to rely on an exemption from the requirement prescribed by Nasdaq that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, changes of controls or private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for the ability to seek prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12 month period (but, in determining the available issue limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties, certain substantial shareholders and their respective associates (as defined in the ASX Listing Rules) and (iii) directors or their associates acquiring securities under an employee incentive plan. Due to differences between Australian law and rules and the Nasdaq shareholder approval requirements, we expect to rely on this exemption.

As long as we remain subject to the rules of the ASX, we will be unable to access equity capital without shareholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and, consequently, we could be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite shareholder approvals.

Our ability to access equity capital is subject to ASX Listing Rules 7.1 and 7.4, which provides that a company must not, without shareholder approval, issue or agree to issue any equity securities, or other securities with rights to conversion to equity, if such issue of securities, when aggregated with securities issued by the company during the previous 12-month period, would be an amount that would exceed 15% of the number of ordinary shares on issue at the commencement of the 12-month period, subject to certain adjustments and permitted exceptions.

Our equity issuances are subject to limitations under ASX Listing Rule 7.1 as long as we continue to be listed on the ASX and this constraint may prevent us from raising the sufficient equity capital needed to conduct our operations as planned without shareholder approval.

As a foreign private issuer, we are permitted to file less information with the SEC than a company that files as a domestic issuer.

As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act. Under Australian law, we prepare financial statements on an annual and semi-annual basis, and we are not required to prepare or file quarterly financial information.

For as long as we are a "foreign private issuer," we intend to file our annual financial statements on Form 20-F and furnish our semi-annual financial statements on Form 6-K to the SEC as long as we are subject to the reporting requirements of Section 13(g) or 15(d) of the Exchange Act. However, the information we file or furnish is not the same as the information that is required in annual reports on Form 10-K for U.S. domestic issuers. Accordingly, there may be less information publicly available concerning us than there is for a company that files as a U.S. issuer.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur additional legal, accounting and other expenses.

While we currently qualify as a foreign private issuer, we will be required to determine our status as a foreign private issuer on an annual basis at the end of our second fiscal quarter. In order to maintain our current status as a foreign private issuer, either (i) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (ii) (a) a majority of our executive officers or directors must not be U.S. citizens or residents, (b) more than 50 percent of our assets cannot be located in the United States and (c) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and Nasdaq listing standards. Further, we would be required to comply with U.S. GAAP, as opposed to IFRS Accounting Standards, in the preparation and issuance of our financial statements for historical and current periods. If we are required to comply with the reporting requirements applicable to a U.S. domestic issuer, the regulatory and compliance costs to us may be higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs.

We are an emerging growth company, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies may make the ADSs less attractive to investors and, as a result, adversely affect the price of the ADSs and result in a less active trading market for the ADSs.

We are an "emerging growth company," or EGC, as defined in the JOBS Act. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than US$1.235 billion in annual revenue; (ii) the last day of the fiscal year in which we qualify as a "large accelerated filer"; (iii) the date on which we have, during the previous three-year period, issued more than US$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year in which the fifth anniversary of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act occurs. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. Applicable exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) certain reduced disclosure obligations regarding executive compensation in our periodic reports and, proxy statements and registration statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We cannot predict whether investors will find the ADSs less attractive if we rely on certain or all of these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for the ADS and the trading price of the ADS may be more volatile.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act, or Sarbanes-Oxley, will require our management to assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting and may require our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting.

We have not completed an assessment to determine whether these controls and procedures would be considered effective for purposes of Sarbanes-Oxley, and there is no guarantee that these requirements will not adversely affect the cost or timing of preparing our financial statements.

In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant

period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control and preventing fraud.

If we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Sarbanes-Oxley, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Sarbanes-Oxley, we may not be able to remain listed on Nasdaq.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We identified a material weakness related to a lack of appropriately designed, implemented and documented procedures and controls at both the entity-level and process-level to allow us to achieve complete, accurate and timely financial reporting. These controls are necessary to ensure the accuracy and reliability of our financial reporting and compliance with applicable regulations. The material weakness has a pervasive impact on the financial statements, and if left unaddressed, could in the future impact our ability to safeguard assets, prevent and detect errors or fraud, and ensure the integrity of financial information.

We also identified a material weakness related to segregation of duties, which have not been sufficiently established across the key business and financial processes to maintain appropriate segregation of duties over certain manual and IT business controls. Segregation of duties is an internal control principle that helps prevent errors and fraud by dividing tasks and responsibilities among different individuals. In our current control environment, due to the size of our finance team, this segregation has not been adequately maintained. A consequence of the lack of segregation of duties is a heightened risk of fraud or material misstatement where no appropriate mitigating controls are in place. In particular, our IT business processes lack the necessary controls to ensure proper segregation of duties.

We have taken steps designed to mitigate the impact of the identified material weaknesses, including hiring additional accounting and financial reporting personnel, investing in technology to enhance our financial systems and processes, introducing a formalized governance framework across the organization and establishing a compliance register to support accurate financial reporting and compliance with regulatory bodies.

We are in the process of developing a remediation plan designed to improve our internal control over financial reporting to remediate these material weaknesses. These remediation measures are ongoing and include (i) efforts to enhance risk and control documentation practices related to internal control over financial reporting, (ii) strengthening, monitoring and management testing of controls and oversight mechanisms to ensure ongoing compliance with internal control policies and procedures, (iii) investing in training programs, (iv) conducting a comprehensive review of our existing roles and responsibilities to identify areas where segregation of duties is lacking or inadequate, (v) updating and enhancing process documentation to define roles, responsibilities, and segregation of duties requirements and (vi) exploring technology solutions and automation tools that can assist in achieving segregation of duties within our IT systems.

We cannot assure you that the measures we have taken to date, and measures we plan to implement, will be sufficient to remediate the control deficiencies that led to the identified material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable

to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our ADSs may decline as a result.

We will incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a company whose ADSs are publicly traded in the United States, we will incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and internal controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company in the United States. we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

We do not anticipate paying dividends in the foreseeable future.

We do not anticipate paying dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance the development of our business. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors on the basis of our earnings, financial requirements and other relevant factors, and subject to Australian law. As a result, a return on your investment will only occur if the ADS price appreciates. We cannot assure you that the ADSs will appreciate in value or even maintain the price at which you purchase the ADSs. You may not realize a return on your investment in the ADSs and you may even lose your entire investment in the ADSs.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price and trading volume of our ordinary shares or ADSs could decline.

The trading market for our ordinary shares and ADSs will be influenced by the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on us, to the extent such coverage currently exists, or in other cases, may never publish research on us. If no or too few securities or industry analysts cover our Company, the trading price for our ordinary shares and the ADSs would likely be negatively affected. If one or more of the analysts who cover us downgrade the ADSs or publish inaccurate or unfavorable research about our business, the market price of the ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs could decrease, which might cause our ADS price and trading volume to decline.

You may be subject to limitations on transfers of the ADSs.

The ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders and ADS holders.

As an Australian company listed on the ASX, we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Australian

Corporations Act and ASX Listing Rules, set forth various rights and obligations that are applicable to us as an Australian company listed on the ASX. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under the section entitled "Item 10. Additional Information — B. Memorandum and Articles of Association," as well as our Constitution, which is included as an exhibit to this registration statement, prior to investing in the ADSs.

Australian takeover and foreign investment laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.

We are incorporated in Australia and are subject to the takeover and foreign investment laws of Australia. Among other things, we are subject to the Australian Corporations Act and Foreign Acquisitions and Takeovers Act. Subject to a range of exceptions (including a takeover bid, scheme of arrangement or with shareholder approval), the takeover provisions in the Australian Corporations Act prohibit the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover and foreign investment laws may discourage takeover offers being made for us or may discourage or prevent the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may limit the ability of our shareholders and ADS holders to obtain a premium from a control transaction.

We currently report our financial results under IFRS Accounting Standards, which differs in certain significant respect from U.S. GAAP.

Currently we report our financial statements under IFRS Accounting Standards. There have been and there may in the future be certain significant differences between IFRS Accounting Standards and U.S. GAAP, and those difference may be material. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS Accounting Standards and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS Accounting Standards with those companies that prepare financial statements under U.S. GAAP.

There can be no assurance that we will not be a passive foreign investment company for any taxable year, which could result in adverse U.S. federal income tax consequences to U.S. investors.

In general, a corporation organized outside the United States will be classified for U.S. federal tax purposes as a passive foreign investment company, or PFIC, for any taxable year in which either (i) 75% or more of its gross income consists of "passive income," or (ii) 50% or more of the value of its assets (generally determined on an average quarterly basis) consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a foreign corporation that owns (or is treated as owning) at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of that other corporation and received directly its proportionate share of the income derived by that other corporation. "Passive income" generally includes dividends, interest, rents, royalties and certain gains. Cash is a passive asset for these purposes.

Based on the expected nature and amount of our estimated gross income, the anticipated nature and estimated average value of our gross assets, the anticipated cash needs of our group's operations and the nature and extent of the active businesses conducted by our "25% or greater" owned subsidiaries, we do not expect that we will be classified as a PFIC in the current taxable year or for the foreseeable future. However, our PFIC status for any taxable year can be determined only after the end of such year and will depend on the composition of our income and assets and the value of our assets from time to time (which may be determined, in part, by reference to the market price of our ADSs or ordinary shares, which could be volatile). Furthermore, the composition of our income and assets for the current and future taxable years will be affected by how, and how quickly, we spend the cash we have on hand. Accordingly, there can be no assurance that we will not be a PFIC for our current or any future taxable year. If we were a PFIC for any taxable year during which a U.S. investor is treated as owning our ADSs or ordinary shares, the U.S. investor generally would be subject to adverse U.S. federal income tax consequences, possibly including increased tax liability on disposition gains and "excess distributions," and additional reporting requirements. See "Item 10. Additional Information — E. Taxation."

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

Our tax treatment is subject to the enactment of, or changes in, tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related to the Organization for Economic Co-Operation and Development's Base Erosion and Profit Shifting Project, the imposition of a minimum global effective rate for multinational businesses (Pillar Two) and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reforms may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

We are subject to taxation in multiple jurisdictions. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, although we believe we are compliant with applicable transfer pricing requirements in various countries, a tax authority could challenge our allocation of income and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. In the event a tax authority assesses a deficiency, contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

General Risk Factors

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations and prospects and the trading price of our ordinary shares and the ADS.

Global credit and financial markets have experienced extreme disruptions over the past several years. Such disruptions have resulted, and could in the future result, in diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be compromised by economic downturns, a volatile business environment and unpredictable and unstable market conditions, such as pandemics or epidemics of infectious diseases, ongoing or future wars or other geopolitical conflicts, rising inflation, increasing interest rates and slower economic growth or recession. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy and financial performance and could require us to delay or abandon plans with respect to our business, including clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including the current global situation resulting from epidemics or pandemics, ongoing or future wars or other geopolitical conflicts, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and the operations of our suppliers, CROs, CMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers to produce Illuccix and our product candidates and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our product candidates. Our ability to obtain sufficient supplies for Illuccix and our product candidates could be disrupted if the operations of these suppliers were affected by a

man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Global climate change, as well as increasing laws, regulation and litigation in the area of climate change, may have an adverse effect on our results of operations, financial condition or liquidity.

There is widespread consensus in the scientific community that there is a long-term upward trend in global air and sea temperatures that, along with shifting demographic trends in catastrophe exposed regions, has increased the severity and frequency of severe weather events and other natural catastrophes, and is likely to further increase the average economic value of expected losses in the future. Rising sea levels are also expected to increase the risk of coastal flooding in many geographical areas. Extreme weather events can disrupt business continuity by negatively impacting our infrastructure, systems and processes including, but not limited to, manufacturing and supply arrangements in geographical locations exposed to severe weather events. In addition, global climate change could impair our ability to predict the costs associated with future weather events. We cannot predict with certainty the frequency or severity of hurricanes, tropical cyclones, wildfires or other natural catastrophes, and our risk assessments may not accurately reflect shifting environmental and climate related risks. Unanticipated factors could lead to additional insured losses that exceed our current estimates, resulting in disruptions to or adverse impacts on our business, the market or our third-party collaborators.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal name is Telix Pharmaceuticals Limited. Our company was incorporated under the laws of Australia in January 2017. In November 2017, we completed an initial public offering of our ordinary shares and the listing of our ordinary shares on the ASX. Our corporate headquarters and registered offices are located at 55 Flemington Road, North Melbourne, Victoria, 3051, Australia. Our reception telephone number is +61 3 9093 3855. Our agent for service of process in the United States is Telix Pharmaceuticals (US) Inc., located at 11700 Exit 5 Pkwy, Suite 200, Fishers, Indiana 46037. Our website address is www.telixpharma.com. The reference to our website is an inactive textual reference only and information contained in, or that can be assessed through, our website is not part of this registration statement or incorporated by reference herein. All information we file with the SEC is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at www.sec.gov.

A substantial portion of our workforce is based in the United States with our United States office in Indianapolis, Indiana and a research and development facilities in Angleton, Texas and Sacramento, California. We have facilities in Australia (Melbourne, Sydney and Brisbane), Belgium (Brussels and Liège), Switzerland (Geneva), Japan (Kyoto) and Canada (Vancouver).

See "— B. Business Overview" (below) for a discussion of significant events and developments relating to our business and "Item 5. Operating and Financial Review and Prospects — B. Liquidity and Capital Resources" for a discussion of our capital expenditures.

B. Business Overview

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals. Our mission is to be the global leader in radiopharmaceuticals by combining therapeutic and diagnostic modalities for the benefit of patients, an innovative precision medicine concept generally referred to as "theranostics". We have an extensive pipeline of theranostic radiopharmaceutical product candidates with a focus in urologic oncology (prostate and kidney), neuro-oncology (glioma), musculoskeletal oncology (sarcoma) and bone marrow conditioning. Our theranostic approach is intended to use imaging and therapy together to "see and treat" cancer and rare diseases, to both better inform treatment decisions and deliver personalized therapy for patients.

Our products are designed to deliver targeted radiation to cancer cells with precision via a systemic radioactive infusion in order to treat tumors regardless of where they are in the body. This targeted radiation uses a radioactive isotope as a payload, which is attached to a targeting agent (such as a small molecule or antibody) with an affinity for targeted biomarkers on the surface of cancerous or diseased cells. Depending on the choice of radioisotope payload, we can deliver the payload as an imaging agent or as a therapy. The specificity of the targeting agent is designed to concentrate radiation at the tumor sites and to limit off-target tissue exposure.

We select our clinical targets based on our deep understanding of radiation biology and radiopharmaceutical development. Our objective is to develop theranostic products with a targeting agent and isotope-agnostic approach. We choose our targeting agents for the specific biological target and clinical application and then aim to optimize the radio-biology accordingly. We believe this approach allows for efficient drug development and gives us the ability to select the optimal targeting strategy and isotope for the tumor(s) being evaluated.

Our central objective is to "pharmaceuticalize" the field of radiation oncology and transition from external beam radiation to an injection that efficiently delivers targeted radiation to a tumor. We believe that therapeutic and diagnostic radiopharmaceuticals can become a fundamental pillar of cancer care that may deliver transformative survival and quality of life outcomes for patients, building upon recent practice-changing advances in immuno-oncology, targeted oncology and antibody-drug conjugates (as well as the advent of cell and gene therapies). To succeed in our objective, we will need to (i) convince oncologists to utilize the systemic delivery of radiopharmaceuticals as a cancer treatment along with other forms of treatment, (ii) continue to build or otherwise secure access to supply chain and manufacturing capabilities to ensure access to raw materials and overcome the challenges associated with the short-shelf life of radiopharmaceuticals and (iii) establish radiopharmaceuticals as a safe and effective means to treat cancer.

Our prostate cancer portfolio includes Illuccix, our commercially available ^{68}Ga-labelled PSMA prostate cancer imaging agent. Illuccix was approved by the TGA in November 2021, the U.S. Food and Drug Administration, or FDA, in December 2021, and Health Canada in October 2022. We have built a highly effective, specialist commercial team, which we believe has been integral to the commercial success of Illuccix to date.

As of June 30, 2024, we have generated A$1.0 billion in revenue from product sales of Illuccix since the commercial launch in April 2022 and 98% of this revenue has been generated from sales in the United States. The revenues generated from sales of Illuccix, the costs associated with such sales and our operating and other expenses resulted in a loss of A$104.1 million and a profit of A$5.2 million for the years ended December 31, 2022 and 2023, respectively, and a loss of A$14.3 million and a profit of A$29.7 million for the six months ended June 30, 2023 and 2024, respectively. In the year ended December 31, 2021, which was prior to commercial launch of Illuccix, we had a loss of A$80.5 million.

We intend to leverage our commercial revenues as a source of funding for the development of additional therapeutic and diagnostic product candidates in our pipeline. These product candidates include TLX591, a therapeutic rADC, being evaluated in a Phase 3 clinical trial for the treatment of patients with prostate cancer and three innovative imaging agents, TLX250-CDx for kidney (renal) cancer, TLX101-CDx for brain (glioma) cancer and TLX007-CDx for prostate cancer. In December 2023, we submitted a BLA to the FDA for TLX250-CDx for the characterization of renal masses as ccRCC, the most common and aggressive sub-type of kidney cancer. TLX250-CDx was granted breakthrough therapy designation from the FDA in 2020 and the BLA for TLX250-CDx has been granted on a rolling review process. Breakthrough therapy designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX250-CDx will receive marketing approval. We completed the BLA submission in May 2024, and in July 2024, the FDA declined to review the BLA and issued an RTF determination. The denial of acceptance for filing was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment. While we believe that TLX250-CDx has met all sterility requirements of product release and that we will be able to complete the required remedial actions within 90 days and resubmit the BLA, even if we satisfy the requirements of the RTF determination, there can be no assurance that FDA will accept the BLA for review or that we will obtain regulatory approval from the FDA.

In May 2024, we submitted an NDA for TLX007-CDx. In July 2024, the FDA accepted the NDA for TLX007-CDx and assigned a PDUFA goal date of March 24, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all.

In August 2024, we submitted an NDA for TLX101-CDx for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all. TLX101-CDx was granted fast track designation by the FDA for this indication in April 2024. Fast track designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX101-CDx will receive marketing approval.

Beyond these programs, we are developing a pipeline of therapeutic product candidates with an initial focus on large oncology indications, as well as rare diseases, which represent areas of high unmet medical need. This includes two additional therapeutic radiopharmaceutical candidates that are being evaluated in Phase 2 clinical trials: TLX250, a late-stage product candidate for the treatment of kidney cancer, and TLX101 for the treatment of brain cancer, each of which we are developing as an integrated theranostic with the corresponding imaging agent.

In addition to our deep pipeline of theranostics, we aim to complement our theranostic product candidates with innovative nuclear medicine solutions spanning the patient treatment continuum from diagnosis and staging, through surgical intervention, to therapy. We believe this complementary approach will enable us to build deeper relationships with key opinion leaders and physicians who use our products, and to better support patients through their treatment journey.

Our complementary portfolio approach is best exemplified by our offering in urologic oncology for the medical specialists managing the treatment of patients with prostate and kidney cancer. In prostate cancer, our offering includes Illuccix, surgical tools to guide cancer-detection, two therapeutic product candidates, TLX591 and TLX592, currently being evaluated in clinical trials, and we are developing a complementary AI platform to

provide image reader and clinical decision support. The goal of our AI platform is to increase the efficiency and reproducibility of imaging assessments and it has not been used in the development of Illuccix or our product candidates. We are currently building a similar portfolio of complementary products in kidney cancer and intend to expand this approach into other oncology indications.

We believe the impact of our investment into supply chain, manufacturing, distribution, and commercial capabilities is demonstrated through the successful commercial launch of Illuccix. Leveraging our extensive network of partners, we have expanded manufacturing capabilities to support the scale-up of commercial sales of Illuccix. Furthermore, our widespread distribution network, encompassing over 220 radiopharmacies across the United States, is designed to ensure flexibility and reliability in delivering Illuccix imaging doses to patients.

In 2023, we opened our manufacturing facility located in Brussels South, Belgium. At approximately 30,000 square feet, it is one of the largest radiopharmaceutical production facilities in Europe, with nine good manufacturing practice, or GMP, lines, clean rooms, a radiopharmacy and provisions for the installation of two cyclotrons. We expect this facility to deliver significant flexibility and reliable supply for our growing commercial production requirements. In 2022, we acquired Optimal Tracers, which expanded our translational radiochemistry capability and established a U.S.-based laboratory and production footprint for manufacturing radiopharmaceutical doses to support clinical trials.

In April 2024, we acquired IsoTherapeutics Group, LLC, which we believe will enable us to internalize select aspects of our development programs, with the goal of reducing cost and time to achieve technical milestones.

In April 2024, we acquired ARTMS Inc., which we expect will further enhance the vertical integration of our supply chain and manufacturing by providing a greater level of control and security over each of our diagnostic isotopes, with the goal of facilitating broader patient access to therapeutic and diagnostic radiopharmaceuticals through ARTMS Inc.'s high-yield production techniques.

In May 2024, we acquired QSAM Biosciences, Inc., a clinical-stage company developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer, and Samarium-153-DOTMP, which is a novel kit-based bone-seeking targeted radiopharmaceutical candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. Samarium-153-DOTMP, which we have designated as TLX090, has two potential applications – pain management of bone metastases and osteosarcoma therapy, including in pediatric patients.

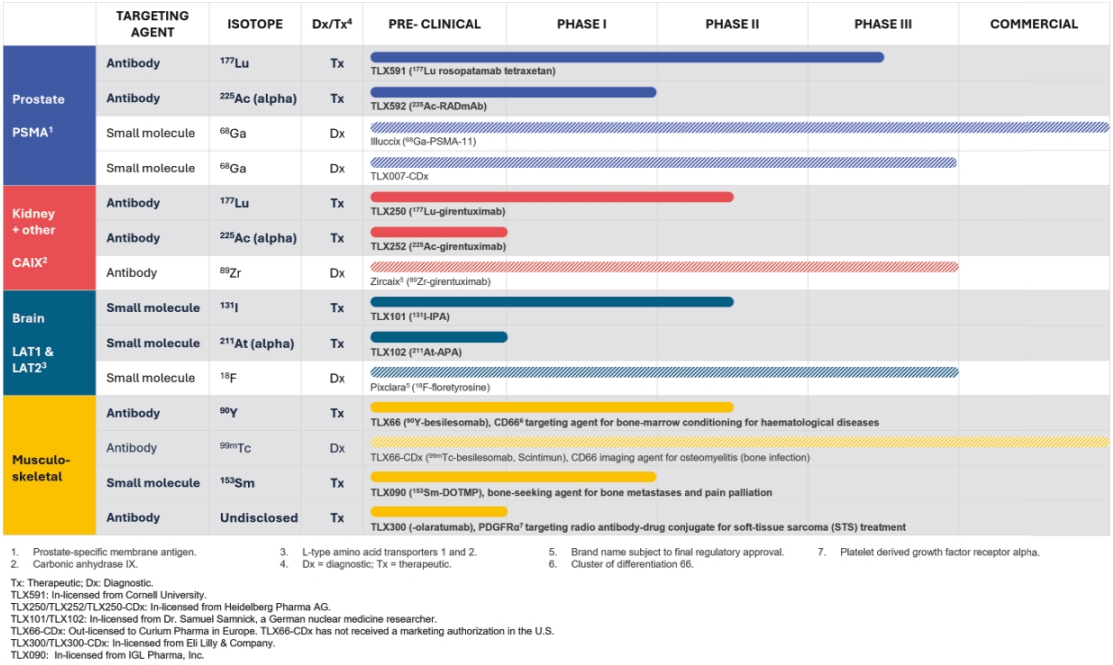
Our Product Pipeline

Overview

Our portfolio includes both therapeutic and diagnostic radiopharmaceutical product candidates designed for use throughout the continuum of the patient journey, from diagnosis and staging to treatment and ongoing care. We also intend to use our therapeutic and diagnostic radiopharmaceutical product candidates in combination with one another, as a theranostic treatment approach. Our clinical programs include several product candidates that are being evaluated in Phase 2 and Phase 3 clinical trials with multiple expected upcoming data readouts and regulatory filings.

For most of our programs, particularly the prostate and kidney programs, we have generated extensive clinical data that we believe demonstrate the potential of our product candidates to offer meaningful benefits to patients. We believe the targets and indications we are pursuing are well validated and are well suited for the delivery of therapeutic and diagnostic targeted radiation. We believe that our use of imaging to select patients for therapy is also a differentiated aspect of our commercial strategy. We believe that this precision medicine or theranostic approach may increase the potential of our therapeutic development programs, as patients can be selected for therapy with greater confidence that the drug target is sufficiently present to potentially confer therapeutic benefit. This may, in turn, lead to more streamlined and efficient clinical trials, and enable improved patient outcomes.

A summary of our core development pipeline is illustrated below.



1. Prostate-specific membrane antigen.
2. Carbonic anhydrase IX.
3. L-type amino acid transporters 1 and 2.
4. Dx = diagnostic; Tx = therapeutic.
5. Brand name subject to final regulatory approval.
6. Cluster of differentiation 66.
7. Platelet derived growth factor receptor alpha.

Tx: Therapeutic; Dx: Diagnostic.
TLX591: In-licensed from Cornell University.
TLX250/TLX252/TLX250-CDx: In-licensed from Heidelberg Pharma AG.
TLX101/TLX102: In-licensed from Dr. Samuel Samnick, a German nuclear medicine researcher.
TLX66-CDx: Out-licensed to Curium Pharma in Europe. TLX66-CDx has not received a marketing authorization in the U.S.
TLX300/TLX300-CDx: In-licensed from Eli Lilly & Company.
TLX090: In-licensed from IGL Pharma, Inc.

In addition to the development pipeline above, we are also exploring product and indication expansion opportunities with our late-stage diagnostic portfolio through our lifecycle management programs, including TLX007-CDx, which is a new ^{68}Ga-based PSMA-PET imaging agent for prostate cancer with its own NDA. TLX007-CDx contains a different formulation and higher radioactivity compared to Illuccix and TLX007-CDx is expected to have an extended distribution profile compared to currently approved 68Ga-based PSMA-PET imaging agents due to the higher radioactivity and the use of 68Ga sourced from newer high activity generators and cyclotrons. Our lifecycle management program also includes two substantial prostate cancer indications for Illuccix, a staging indication for TLX250-CDx, and an expansion into brain metastases for TLX101-CDx.

Prostate Cancer and PSMA

Our prostate cancer programs target PSMA, a well-validated protein target for the delivery of both therapeutic and diagnostic radiopharmaceuticals that is highly expressed on prostate cancer cells with low expression on healthy cells. We believe that our approach to targeting PSMA is unique because we use a small molecule targeting ligand for imaging and an antibody for our therapeutic product candidate. Our use of a small molecule targeting ligand for imaging enables rapid targeting and clearance of the payload to produce sharp images for PET scanning in the diagnostic setting. In contrast, using an antibody in the therapeutic setting is intended to allow for specific targeting of tumor tissue, differentiated pharmacokinetics and excretion profiles and prolonged treatment effect enabled by efficient irradiation of tumors.

Our lead therapeutic product candidate TLX591 (^{177}Lu rosopatamab tetraxetan) is a lutetium-labelled rADC that we believe has the potential to deliver improved patient outcomes with an efficient dosing regimen. The targeting and pharmacology of TLX591 differs significantly from PSMA-targeting small molecules used in commercially available compounds, and was designed for high internalization, long retention and to be highly selective for tumor-expressed PSMA. This profile was designed with the goal of enabling a short, patient-friendly dosing regimen that delivers a meaningful therapeutic index and low occurrence of the off-target side effects that are common with currently marketed small molecule PSMA radiopharmaceuticals.

TLX591 has been evaluated in 242 patients across eight clinical trials. An open-label, single-arm Phase 1/2 clinical trial with six experimental dose cohorts of TLX591 reported a 42.3 month median survival in 17 patients with advanced metastatic castrate-resistant prostate cancer, or mCRPC, treated at the higher dose level when TLX591 was delivered under a fractionated dosing regimen. Median survival was 19.6 months at the lower dose

level and was 27.8 months across those dose cohorts. At the higher dose level, 23.5% and 35.3% of patients had Grade 3 and 4 neutropenia, respectively, and 29.4% and 58.8% of patients had Grade 3 and 4 thrombocytopenia, respectively. The trial met its primary endpoint, which was to identify the maximum tolerated dose of TLX591 when administered in two doses two weeks apart. The survival benefits were a secondary endpoint. This trial did not contain a control group and was not powered to measure statistical significance of the survival benefit, which is a limitation of single-arm trials.

In November 2023, we initiated a randomized, multinational, multicenter, open-label Phase 3 trial, which we refer to as the ProstACT GLOBAL trial, to evaluate TLX591 for the treatment of PSMA-positive mCRPC patients in combination with the standard of care compared to the standard of care alone. We expect this trial to enroll 30 patients in a dosimetry and safety lead-in portion replicating the prior study using the product candidate specifications intended for commercial release and then proceed to a randomized treatment expansion portion, in up to approximately 490 patients. We dosed the first patient in the trial in Australia in November 2023. We received authorization to conduct the trial in the United States in April 2024 and have opened clinical trial sites in the United States. We dosed the first patient in a Phase 1 trial evaluating the safety and tolerability profile of TLX591 in combination with the standard of care in mCRPC patients in January 2022, which we refer to as the ProstACT SELECT trial. In October 2023, we reported interim data from 28 evaluable patients out of 30 patients enrolled in two cohorts in the ProstACT SELECT trial of TLX591 with two doses administered 14 days apart. Based on the interim data, the trial appears to have achieved its primary safety and tolerability objectives. In May 2024, we reported that the trial demonstrated a median radiographic progression-free survival of 8.8 months, a secondary objective of the trial, based on an evaluable patient population of 23 patients who each received two 76 mCi doses of TLX591.

As the primary goal of a Phase 1 study is to demonstrate safety and tolerability criteria in a small patient population, these studies are not powered for or designed to demonstrate efficacy. Early-stage trial results should be interpreted with caution and efficacy outcomes should be evaluated for statistical and clinical significance in a larger Phase 3 randomized controlled trial.

TLX592 (^{64}Cu/^{225}Ac-RADmAb), is our next generation prostate cancer therapy candidate for targeted alpha therapy and is our first clinical program based on our proprietary RADmAb-engineered antibody technology. The engineered antibody vector is designed for faster elimination from circulation than standard antibodies and slower elimination than small molecules that may result in side effects. It is also designed to enable reduced bone marrow residence time to mitigate the risk of hematologic toxicity while retaining PSMA-mediated tumor localization and exertion of cytotoxic activity. TLX592 is designed to be cleared by the liver without exocrine uptake.

We conducted the Phase 1 CUPID trial in which we evaluated TLX592 with a beta-emitting isotope (^{64}Cu) in 12 patients with advanced prostate cancer prior to commencing therapeutic studies with ^{225}Ac, an alpha-emitting isotope. We treated patients with PSMA avid disease based on Illuccix imaging, across three dose levels to assess safety profile, pharmacokinetics, biodistribution and dosimetry. In May 2024, we reported that, based on preliminary results from 11 evaluable patients, we observed accelerated elimination from blood circulation compared to the standard antibody used with TLX591 and observed similar on-target and off-target biodistribution and liver clearance, which we believe are important characteristics for an alpha-emitting agent. The trial established a baseline dosing schedule for future trials of TLX592 using ^{225}Ac. The goal of this Phase 1 trial was to evaluate safety and demonstrate proof-of-concept in a small patient population. Phase 1 proof-of-concept trial results should be interpreted with caution. We plan to initiate a Phase 1/2 trial designed to evaluate the safety profile of TLX592 by the end of 2024, subject to regulatory approval.

Our prostate cancer portfolio also includes Illuccix, our commercially available ^{68}Ga-labelled PSMA-PET imaging agent. The “cold kit” format of Illuccix enables rapid radiolabeling at room temperature with high radiochemical purity and production consistency, suited to the commercial and hospital radiopharmacy setting. Illuccix is approved in the United States, Australia, and Canada, and we anticipate receiving approval in the European Union, the United Kingdom and Brazil beginning in 2024. Approved indications for patients with prostate cancer include staging of high-risk patients, identification of suspected recurrence, and selection for PSMA-directed radioligand therapy. We are also exploring potential future utilization in additional indications for prostate cancer patients through our lifecycle management program. These include monitoring progression in metastatic and non-metastatic castration resistant patients and monitoring response to PSMA-directed radioligand therapy.

We are developing TLX007-CDx, a new cold kit for the preparation of PSMA-PET imaging for prostate cancer. TLX007-CDx is designed to have an extended distribution profile compared to currently approved ^{68}Ga PSMA-PET imaging agents due to the use of ^{68}Ga sourced from newer high activity generators and cyclotrons.

We believe that TLX007-CDx may further expand the availability and distribution of PSMA-PET imaging due to its longer shelf life and resulting expanded distribution radius. We believe that TLX007-CDx has the potential to address unmet needs by extending availability of PSMA-PET imaging to substantially all PET/CT locations in the United States. Many PET/CT imaging sites that are not served by approved PSMA-PET imaging agents are located in rural and underserved areas.

We conducted a Phase 1 clinical trial of TLX007-CDx to compare the biodistribution of TLX007-CDx and Illuccix in normal tissues and major organs, and in prostate cancer deposits. This trial met its primary objective by demonstrating that there were no differences between TLX007-CDx and Illuccix in the biodistribution in normal tissues and organs, or in prostate cancer deposits, based on 11 evaluable patients. In May 2024, based on the results of such trial, we submitted an NDA to the FDA for TLX007-CDx for the imaging of patients with prostate cancer. As the primary goal of a Phase 1 study is to demonstrate biodistribution and clinical equivalency in a small patient population, these studies are not powered for or designed to demonstrate efficacy.

Kidney Cancer and CAIX

Our target for kidney cancer is carbonic anhydrase IX, or CAIX, a scientifically validated target in ccRCC, which is the most prevalent and aggressive form of kidney cancer. CAIX is a cell surface protein that is highly expressed in ccRCC, and in many other solid tumors in the hypoxic tumor microenvironment. We believe the correlation between hypoxia and disease progression, along with therapeutic resistance, underscores the potential of this target. Whereas normal endogenous expression of CAIX is very low, CAIX has been found to be differentially expressed on regulatory T-cells, or Tregs, in the tumor microenvironment across a number of solid tumors. To target CAIX, we use a monoclonal antibody, girentuximab, which is designed to have a high degree of selectivity and affinity for the target and can be used for both imaging and therapy. We are using the same hepatically cleared agent for both the imaging and therapeutic applications due to avoidance of kidney excretion, which is an advantage when assessing or treating primary kidney disease. We believe the target profile and properties of girentuximab make the ccRCC phenotype promising as the first therapeutic indication for TLX250, our targeted radiation therapeutic product candidate.

Our CAIX-targeting therapeutic candidate is TLX250 (^{177}Lu-DOTA-girentuximab), an rADC that we are developing for the treatment of advanced metastatic kidney cancer. In a Phase 1 clinical trial of TLX250 we observed a mean progression free survival, or PFS, of 11.1 months in 23 patients with advanced ccRCC. As the primary goal of a Phase 1 study is to demonstrate safety and tolerability criteria in a small patient population, these studies are not powered for or designed to demonstrate efficacy.

TLX250 is being evaluated in two Phase 2 investigator-sponsored clinical trials for the treatment of kidney cancer, STARLITE-1 and STARLITE-2, in combination with checkpoint inhibitors in a total of 129 patients. We are also evaluating TLX250 in combination with peposertib (M3814), a DNA-dependent protein kinase, or DNA-PK, inhibitor, in collaboration with Merck KGaA, Darmstadt, Germany, or Merck KGaA, in a Phase 1b trial, STARSTRUCK, for the treatment of patients with ccRCC as well as other selected solid tumors that commonly express CAIX at an advanced stage of disease. We expect the STARSTRUCK trial to enroll 85 patients.

We believe the combined diagnostic and therapeutic potential of TLX250 may also extend into other cancers that significantly express CAIX, including certain Von Hippel Landau, or VHL, induced cancers, ovarian cancer, triple-negative breast cancer and bladder cancer. We believe that our preliminary clinical data in patients with triple-negative breast and bladder cancer supports future development of TLX250 in these indications.

TLX252 is a CAIX-targeting rADC alpha therapy candidate (^{225}Ac-DOTA-girentuximab) that we are developing as a potential complement to the TLX250 (beta) program. TLX252 has demonstrated pre-clinical proof-of-concept in several published preclinical imaging and efficacy animal studies, and comparable *in vivo* characteristics (binding, pharmacokinetics and biodistribution) to non-radiolabeled girentuximab, which we believe supports the initiation of initial dose-finding trials of TLX252 for the treatment of patients with advanced metastatic kidney cancer.

Our imaging candidate TLX250-CDx (Zircaix) is a PET diagnostic imaging agent that is under development to characterize indeterminate renal masses as ccRCC or non-ccRCC in a non-invasive manner. We recently completed the pivotal Phase 3 ZIRCON trial evaluating TLX250-CDx in 300 patients, of which 284 were evaluable. The trial met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% positive-predictive value, or PPV, for ccRCC across three independent readers. We believe this demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

We submitted a BLA for TLX250-CDx to the FDA for regulatory approval in December 2023 for characterization of masses as ccRCC. The BLA was granted on a rolling review process. We completed the BLA submission in May 2024, and in July 2024, the FDA declined to review the BLA and issued an RTF determination. The denial of acceptance for filing was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment. While we believe that TLX250-CDx has met all sterility requirements of product release and that we will be able to complete the required remedial actions within 90 days and resubmit the BLA, even if we satisfy the requirements of the RTF determination, there can be no assurance that FDA will accept the BLA for review or that we will obtain regulatory approval from the FDA. If approved, TLX250-CDx would be the first targeted radiopharmaceutical imaging agent for kidney cancer to be approved in the United States. We also intend to conduct a label-expanding Phase 3 trial of TLX250-CDx for the imaging of patients with metastatic ccRCC. We believe TLX250-CDx is a natural follow-on product to Illuccix as it is targeted at the same clinician users, the urologist and urologic oncologist, and leverages our existing commercial infrastructure.

In July 2023, we dosed the first patient in the Phase 2 STARBURST trial of TLX250-CDx exploring CAIX expression in patients with a diverse range of solid tumors for potential therapeutic and diagnostic applications. This trial, which aims to enroll 100 patients, may enable us to identify new therapeutic indications for TLX250 through the use of molecular imaging with TLX250-CDx.

Glioma and LAT1/LAT2

Our targets for glioma are large amino acid transporters 1 and 2, or LAT1 and LAT2 (respectively), validated targets that are highly expressed in several solid tumors, including malignancies of the central nervous system, or CNS. We believe that the LAT1 and LAT2 receptors, which are expressed on both sides of the blood-brain barrier, are suitable targets for the delivery of radiation to both primary CNS malignancies and metastases from non-CNS cancers such as lung and breast cancer. As such, we believe there are several potential indications for theranostic radiopharmaceuticals targeting LAT1 and LAT2.

Our therapeutic product candidate, TLX101, is a systemic therapy directed at the LAT1 receptor for the treatment of glioblastoma. We are using a small molecule for this therapy due to the need to cross the blood-brain barrier to reach its target. TLX101 has received orphan drug designation in the United States and Europe for the treatment of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101 will receive marketing approval.

We are evaluating TLX101 in the front-line and recurrent disease settings where we have observed preliminary clinical evidence of anti-tumor effect and disease stabilization. We completed the IPAX-1 trial of TLX101 in combination with external beam radiation therapy in patients with recurrent glioblastoma. The IPAX-1 trial enrolled ten patients, met its primary endpoint of safety and tolerability of TLX101 and demonstrated preliminary efficacy data that supports continued development. As the primary goal of a Phase 1 study is to demonstrate safety and tolerability criteria in a small patient population, these studies are not powered for or designed to demonstrate efficacy. The Phase 1 IPAX-2 trial is designed to enroll 15 patients to evaluate the safety of treatment of patients with newly diagnosed glioblastoma with TLX101 as a front-line treatment. We dosed the first patient in August 2023. TLX101 is also being evaluated in the investigator-led Phase 2 IPAX Linz trial, which is enrolling patients with recurrent glioblastoma.

TLX102 is a LAT1-targeting small molecule-based alpha therapy candidate (211At-APA) that we are developing as a potential complement to the TLX101 and TLX101-CDx programs. TLX102 has demonstrated pre-clinical proof-of-concept and we believe that TLX102 has the potential to have a favorable efficacy and safety profile in future human clinical trials in patients with glioblastoma and multiple myeloma. Due to comparable target binding and molecular structure, we expect that data from our existing LAT1 theranostic programs, TLX101-CDx

and TLX101, will complement and inform the clinical and regulatory development strategy for TLX102. In August 2020, TLX102 was granted orphan drug designation from the FDA in the United States for the treatment of multiple myeloma. Orphan drug designation may not lead to a faster development or regulatory review or approval process in multiple myeloma or glioblastoma and does not increase the likelihood that TLX102 will receive marketing approval in either of these disease areas.

Our imaging candidate, TLX101-CDx (Pixclara), also known as ^{18}F-floretyrosine or ^{18}F-FET, is a PET diagnostic agent designed to image cancerous lesions in the brain by targeting the LAT1 and LAT2 receptors. ^{18}F-FET is widely used in many jurisdictions and is recommended by the joint guidelines from the European Association of Nuclear Medicine, European Association of Neuro-Oncology, Society of Nuclear Medicine and Molecular Imaging, Response Assessment in Neuro-Oncology, The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients. In October 2020, TLX101-CDx was granted orphan drug designation by the FDA in the United States for the imaging of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-CDx will receive marketing approval. In August 2024, we submitted an NDA to the FDA for TLX101-CDx for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients through the 505(b)(2) NDA regulatory pathway. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all. TLX101-CDx was granted fast track designation by the FDA for this indication in April 2024. Fast track designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX101-CDx will receive marketing approval. We also intend to conduct a label-expanding Phase 3 trial of TLX101-CDx for the imaging of patients with brain metastases from non-brain cancers, including lung and breast cancer.

Soft Tissue Sarcoma and PDGFRα

Our product candidates TLX300 and TLX300-CDx employ antibody-directed targeted radiation for both therapeutic and diagnostic applications against platelet-derived growth factor receptor alpha, or PDGFRα, which is a tyrosine kinase receptor involved in fibrogenesis. We believe that the targeting of activated fibroblasts in the tumor micro-environment is a promising strategy to drive durable treatment responses in certain solid tumors. Eli Lilly & Company, or Lilly, provided us with a license for olaratumab, a naked antibody that was formerly marketed as Lartruvo. We re-purposed olaratumab as a radiopharmaceutical product candidate.

We have completed pre-clinical studies evaluating TLX300 and have received ethics approval to initiate a clinical trial in Australia. We expect to initiate a proof-of-concept targeting and biodistribution trial in humans in the fourth quarter of 2024. We intend to develop the therapeutic application of TLX300 for the treatment of soft tissue sarcoma, or STS, using an alpha-emitting isotope. We have not yet determined the specific alpha-emitting isotope that we will use in clinical trials of TLX300.

TLX300-CDx (^{89}Zr-DFOsq-olaratumab, including our proprietary DFO-squaramide chelator) is an investigational imaging agent that we are developing for use with TLX300 as a theranostic pair. We plan to conduct a Phase 1 trial to evaluate the safety profile and establish the optimal dose, biodistribution, dosimetry and pharmacokinetics of TLX300-CDx in patients with advanced STS. We plan to conduct this trial using a beta-emitting isotope in order to evaluate the safety profile, pharmacology and dosimetry prior to use of an alpha-emitting isotope in subsequent clinical trials. We have not yet determined the specific isotopes that we will use in these trials.

Bone Marrow Conditioning and CD66

Our efforts in bone marrow conditioning, or BMC, are designed to explore the potential utility of targeted radiation to ablate bone marrow as part of a pre-conditioning regimen for bone marrow transplantation, novel stem cell therapies and gene therapies, each of which requires conditioning prior to treatment. The standard of care involves using highly toxic chemo-ablation techniques that require long hospitalization times and significant treatment-related morbidity and mortality risks, which considerably limit patient access to these therapeutic interventions. We believe that a safe, durable and short internment treatment could be transformative to many facets of cancer and autoimmune disease treatments that require BMC.

Our product candidate TLX66 (^{90}Y-DTPA-besilesomab) is designed to target cluster of differentiation 66, or CD66, a well-validated leukocyte and neutrophil target. TLX66 has been evaluated as a therapeutic bone marrow

conditioning agent in approximately 100 patients with results that support continued development, both as a monotherapy and in combination with low dose chemotherapy conditioning regimes. We plan to evaluate TLX66 in a Phase 2 clinical trial as a BMC agent in patients with acute myeloid leukemia who are not suitable for conventional BMC regimes. We expect to submit an IND to the FDA for this trial and to commence the trial in 2025. In March 2022, TLX66 was granted orphan drug designation by the FDA in the United States as a conditioning treatment prior to hematopoietic stem cell transplant, or HSCT. TLX66 was granted orphan drug designation in Europe in October 2019. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX66 will receive marketing approval.

We believe that the imaging application of besilesomab could support patient selection for TLX66 by informing healthcare providers whether sufficient activity will be absorbed by a patient's bone marrow. TLX66-CDx, an imaging application of besilesomab, has already been commercialized and is sold under license by Curium Pharma as an approved product (marketed as Scintimun) for imaging osteomyelitis (bone infection) in approximately 30 countries. TLX66-CDx has not received marketing approval in the United States. In parallel to the therapeutic applications of TLX66, we are exploring several indication expansions, as well as geographic expansion to key commercial markets.

Manufacturing TLX66 and TLX66-CDx utilizes a small amount of Triton X-100, which is a non-ionic surfactant, in the antibody manufacturing process. Triton X-100 is subject to a regulation in the European Union known as Registration, Evaluation, Authorisation and Restriction of Chemicals, or REACH. Outside of the United States, Curium Pharma is responsible for the manufacturing and commercialization of TLX66-CDx. We are permitted to manufacture TLX66 for research and clinical development in the European Union pursuant to a self-certified exemption applicable to research and development activity. We would need to obtain authorization under REACH in order to use Triton X-100 for the future commercial manufacturing of TLX-66 or re-design the commercial manufacturing process for TLX66 such that Triton X-100 is not used. We are currently planning to re-design the commercial manufacturing process for TLX66 and potentially for TLX66-CDx. We believe that any improvements to the manufacturing process we may make could also result in an increase in productivity and a potential reduction in manufacturing costs. If we re-design the manufacturing process for TLX66, we may be required to conduct additional clinical trials of TLX66 or meet alternative regulatory standards.

Bone Metastases and Pain Palliation

TLX090 (^{153}Sm-DOTMP) is a novel kit-based bone-seeking targeted radiopharmaceutical product candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. It is a combination of patented, lower specific activity form of Samarium-153, a beta-emitting radioisotope with a 46-hour half-life, and the chelating agent DOTMP, which selectively targets sites of high bone mineral turnover, a known characteristic of bone metastases, and minimizes off-target migration. We believe that TLX090 may be administered as a single dose, multiple doses and higher dose regimens for pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090 is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma

Operations and Manufacturing Activities

Our corporate headquarters is located in Melbourne, Australia. The majority of our workforce is based in the United States at our office in Indianapolis, Indiana and our R&D facilities in Angleton, Texas and Sacramento, California. Our international operations include Australia (corporate headquarters in Melbourne and regional offices in Sydney and Brisbane), Belgium (Brussels and Liège), Switzerland (Geneva), Japan (Kyoto) and Canada (Vancouver). We are investing significantly to build a world-class vertically integrated supply chain, superior manufacturing and distribution capabilities, and the ability to deliver radiopharmaceuticals to all major global markets.

We believe the impact of our investment into supply chain, manufacturing, distribution, and commercial capabilities to date is clearly demonstrated through the successful commercial launch of Illuccix. Leveraging our extensive network of partners, we have expanded manufacturing capabilities to support the scale-up of commercial sales of Illuccix. Furthermore, our widespread distribution network, encompassing over 220 radiopharmacies across the United States, is designed to ensure flexibility and reliability in delivering Illuccix imaging doses to patients.

We continue to invest to strengthen our vertically integrated supply chain and manufacturing model. In 2023 we opened our manufacturing facility located in Brussels South, Belgium. At approximately 30,000 square feet, it is one of the largest radiopharmaceutical production facilities in Europe, with nine GMP lines, clean rooms, a radiopharmacy and provisions for the installation of two cyclotrons. We expect this facility to deliver significant flexibility and reliable supply for our growing commercial production requirements. It also serves as a vital hub for research and development, specifically in manufacturing scale-up and production of next generation radiopharmaceuticals, including both alpha-emitters and beta-emitters. In 2022, we acquired Optimal Tracers, a Sacramento-based company that provides radiochemistry process development services and research tracers for use in clinical trials. The acquisition of Optimal Tracers expanded our translational radiochemistry capability and establishes a U.S.-based laboratory and production footprint for manufacturing doses of radiopharmaceutical to support clinical trials. We are also obtaining planning and regulatory approvals for a hotlab and dosimetry facility in Melbourne, Australia.

In April 2024, we acquired IsoTherapeutics Group, LLC, which we believe will enable us to internalize select aspects of our development programs, with the goal of reducing cost and time to achieve technical milestones.

In April 2024, we acquired ARTMS Inc., which we expect will further enhance the vertical integration of our supply chain and manufacturing by providing a greater level of control and security over each of our diagnostic isotopes, with the goal of facilitating broader patient access to therapeutic and diagnostic radiopharmaceuticals through ARTMS Inc.'s high-yield production techniques.

Our Opportunity and Strategy

The global radiopharmaceutical industry is undergoing a period of transformative growth with theranostics emerging as a key pillar in the armamentarium of oncology treatment. We believe that with increasing integration of nuclear medicine and traditional oncology clinical practice, radiopharmaceuticals will become a core component of the multi-disciplinary approach to cancer treatment with a proportionate benefit to patients.

Our therapeutic radiopharmaceutical platform harnesses the power of radioactive isotopes combined with multi-platform targeting agents to deliver targeted radiation directly to the tumor site. These therapies have the potential to be stand-alone treatments or as complements to existing treatment modalities to address areas of high unmet medical need. Due to our expertise in the multiple components of radiopharmaceuticals we are able to create theranostics in an "agnostic" manner, pairing the right delivery mechanism with the right isotope most likely to be suited for the tumor being treated.

We pair each therapeutic with a diagnostic imaging agent, this underpins the "theranostic" approach whereby two conjugates are used to target the same cell-surface receptor, one for detection, localization or staging, and the other for selective destruction of target cancer cells. When used in tandem to plan and execute treatment, and then to assess response and monitor for progression, this approach allows the delivery of truly personalized therapy to patients.

Our Strategy

Our strategy is to launch innovative imaging agents in our core disease areas in order to finance and prepare the market for our therapeutic product candidates as well as our next-generation radiopharmaceuticals. This strategy is underpinned by using a vertically integrated approach to supply and manufacturing, and is supported by a first-class commercial organization ensuring global patient access to our products.

The four central strategic pillars to achieve our mission are:

Grow our commercial footprint in urology. Our first commercial product, Illuccix, has provided an important entry point into the field of urology through our specialized field force. We intend to broaden our commercial footprint in urology by (i) expanding Illuccix into new indications, (ii) obtaining approval for synergistic products, including TLX250-CDx, that may enable us to deepen our clinical and commercial relationship with clinical decision-makers and (iii) evaluating lifecycle management, including TLX007-CDx, a ^{68}Ga-based PSMA-PET imaging agent for prostate cancer, for which we submitted an NDA in May 2024. In July 2024, the FDA accepted the NDA for TLX007-CDx and assigned a PDUFA goal date of March 24, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all. We also intend to develop an AI solution for reader and clinical decision-making support and radio-guided surgery probes and tracers.

Invest to commercialize our pipeline of therapeutic product candidates. We aim to build both breadth and depth in oncology and to address areas of significant unmet medical need, both for large oncology indications such as prostate cancer and kidney cancer, as well as rare oncology applications such as glioma. This is based on a robust target selection process that is aligned with our expertise in radiation biology. We intend to advance TLX591, TLX250 and TLX101 into late-stage clinical trials for the treatment of prostate cancer, kidney cancer and gliomas, respectively.

We are currently evaluating TLX591 in our ProstACT GLOBAL trial in patients with advanced prostate cancer. We believe that TLX591 is the most advanced rADC in this disease area and has potential to be the first approved rADC for the treatment of advanced prostate cancer. Our clinical data suggests that our targeting approach could enable high on-target PSMA tumor-binding with low rates of off-target organ exposure and with a potentially favorable safety profile.

We plan to advance TLX250 and TLX101 into late-stage clinical trials for the treatment of kidney cancer and glioblastoma, respectively. We believe that each of our product candidates is currently the most advanced systemic radiotherapy in its respective indication. We are continuing to initiate earlier-stage clinical trials of our therapeutic product candidates as monotherapies and in combinations, including of TLX300 for the treatment of STS, and TLX250 in combination with peposertib, a DNA-PK inhibitor, with Merck KGaA for the treatment of ccRCC and various CAIX-positive tumors. We believe that these trials provide opportunities to generate further clinical data and demonstrate the differentiated positioning of our clinical product candidates.

Advance and augment our pipeline and progress development of next generation radiopharmaceuticals. We have established a track-record in identifying validated clinical product candidates that can be optimized as radiopharmaceutical therapies to develop them through to commercial products. We are leveraging this capability to expand our pipeline with next-generation radiopharmaceuticals, particularly targeted alpha-emitting therapies, through business development, as well as internal R&D programs and collaborations. These efforts focus on product candidates with a validated clinical rationale, a scientific profile to support efficacy as a radiopharmaceutical and which are complementary to our existing pipeline.

Through our existing clinical programs and dedicated research facilities located in Angleton, Texas, Sacramento, California and Brussels South, Belgium, we are focused on the development of alpha therapy candidates as a future pipeline expansion opportunity, and on building supply and manufacturing capabilities required to support an eventual commercial launch.

Vertically integrate manufacturing and supply chain activities. Radiopharmaceutical companies have particularly onerous manufacturing, supply chain, distribution and logistical requirements due to radiopharmaceuticals typically having a short shelf-life and the need to be manufactured in proximity to the patient. Radiopharmaceuticals begin to decay as soon as they are produced and are stable for hours to days. Since inception, we have invested in our supply and manufacturing and distribution capabilities, working with industry-leading partners.

We continue to invest in this area with the goal of completing the vertical integration of our business, adding manufacturing and process development as a core capability, and continuing to build on our production capabilities, both in-house and through partners, to ensure a high level of control and redundancy in our supply chain. We believe this is an essential foundation for long-term commercial success across the breadth of our product pipeline.

Our Theranostic Approach

Our approach enables us to design and develop product candidates to deliver targeted radiation to cancer cells, regardless of where the cancer is in the body, via a systemic radioactive infusion. We aim to use imaging and therapy together to “see and treat” cancer. We refer to this approach as theranostic, which we believe is a powerful way to tackle unmet need in cancer and rare diseases.

We believe that our ability to harness the power of targeted radiation throughout the patient journey to enhance patient outcomes is a key differentiator.

Targeted Radiation Overview

We are developing targeted radiation across the continuum from diagnosis and staging to treatment, both as stand-alone and combination therapies.

Many existing cancer therapies are non-selective and as a result can act against healthy tissue and vital organs while treating disease. Existing external beam radiation therapy, or EBRT, approaches are effective but typically only deliver localized treatment and cause damage to surrounding tissue. Localized therapeutic approaches rely on the treating physician making assumptions about the extent of disease and can result in imprecise application of treatment. Treatments that miss small amounts of cancer cells can lead to a recurrence of the cancer or disease.

Targeted radiation uses a radioactive isotope as a payload that is attached to a targeting agent, such as a small molecule or antibody, with an affinity for specific biomarkers found on the surface of cancerous or diseased cells. Depending on the choice of radioisotope payload, these target agents can deliver either imaging or therapy.

The targeted radiation drug or antibody is administered into the bloodstream and circulates throughout the body. Once administered, the targeted radiation seeks cancerous or diseased cells, including primary tumors and small metastases (where the cancer has spread), upon which it is designed to bind selectively to its target. Some radioactive isotopes have physical properties that may be used to image cancer or rare diseases, for diagnosis and staging purposes. Higher dose radiation with different alpha- and beta-emitting radioisotopes can be used as therapies to kill cancerous or diseased cells.

The Targeting Agent

The targeting agent guides the radiation payload to the targeted cancer cells. The agent is designed to be cancer-specific due to selective affinity for tumor targets that are prevalent in tumors but not healthy tissues. The targeting agents can be either an antibody, peptide or small molecule, and the choice of targeting agent can impact the other properties of the drug, including:

- *Pharmacokinetics*: Peptides and small molecules have a short circulation time (several hours) and therefore require a higher dose of radiation payload to sufficiently irradiate the tumor in therapeutic contexts, which comes at the expense of a resulting higher exposure to the kidney. Antibodies have a longer circulation time (several days), are cleared though the liver and are lost slowly, which can transiently impact the levels of blood cells but results in higher amounts of radiation payload in tumors to maximize the therapeutic effect. The calculations and study required to determine the optimal dose of radiation to be delivered for maximum therapeutic effect with an acceptable safety profile are referred to as dosimetry.
- *Binding and cancer specificity*: Antibodies have evolved in the immune system to be highly selective and, as a well-known class of agents, can be generated to be highly specific to their target. Small molecules and peptides are not as predictable as a delivery platform, however they can be engineered for high selectivity and affinity; their metabolism properties and off-target toxicity are unique to each molecule.
- *Internalization and residualization in the tumor*: Once bound to their biological targets, targeting agents can be taken up by cancer cells through a process called ‘internalization’. Peptides tend to be returned to the blood or otherwise degraded relatively quickly after internalization. By contrast, antibodies tend to be retained within cancer cells and, with their sustained presence in the blood, tend to accumulate or ‘residualize’ their radiation payload over time which can favor the localization of higher amounts of radiation to the tumor than peptides or small molecules. The slow excretion of antibodies and their ability to highly effectively residualize radiation in tumors means that lower doses of radiation are needed to treat patients; thereby improving supply chain capability and cost of goods.
- *Route of excretion from the body*: Small molecules and peptides are primarily excreted in the urine rapidly passing through from the blood into the bladder via the kidneys. Antibodies are cleared via the liver, which is a more radio-tolerant organ.

In general, the properties of small molecules and peptides suit diagnostic targeted radiation agents, as the excess or unbound radiation drug is rapidly lost from the body, resulting in a good contrast between the tumor and background tissues and enabling favorable imaging within hours, allowing patients to be dosed and imaged within the same day. Conversely, the high specificity of antibodies, along with their well validated, predictable characteristics in the body and long retention in the tumor largely favor therapeutic use.

The Radiation Payload

The radioisotope is strongly bound to the target agent molecule either using traditional chemistry or trapping it using a 'chemical cage' called a "linker" or "chelator." Different chelators are paired with certain isotopes, such as deferoxamine, a linker that selectively binds with ^{89}Zr (which we use in TLX250-CDx), and the tetraxetan chelator, which binds isotopes like ^{177}Lu (which we use in TLX591) and ^{225}Ac (which we use in TLX592).

The choice of radioisotope and its decay profile impacts properties of the targeted radiation drug.

- *Diagnostic radioisotopes for imaging*: Radioisotopes emitting positrons can be detected by a PET camera. Gamma emissions can be detected by a single photon emission computed tomography, or SPECT. These are commonly referred to as "scanners."
- *Diagnostic radioisotopes for surgery*: Both gamma and beta emitting radioisotopes can be used for the interoperative detection of tumors, using a handheld or robotic probe. The most commonly used radioisotope in radio-guided surgery is ^{99m}Tc.
- *Radioisotopes for therapy*: Radioisotopes with the ability to kill cells for therapeutic effect are classified as either beta- or alpha-emitters, based on their emission profile. Beta emitters (such as ^{177}Lu and ^{131}I) have a longer penetration and may be more suitable for bulky metastatic disease. Alpha-emitters are substantially bigger isotopes than beta-emitters and have the potential to deliver very high amounts of energy to cancer cells in closer proximity to these particles, which can decrease the risk of damage to surrounding healthy cells and increase the selectivity and potency of the radiation treatment. Alpha and beta therapies are often complementary, with alpha therapies being more suitable for smaller or disseminated tumors (including micro metastatic disease) and beta therapies being more suitable for treatment of bulkier tumors.

Radio Antibody-Drug Conjugate (rADC)

We refer to our antibody-based agents as rADCs. These rADCs are radiopharmaceuticals that use an antibody as both a homing device and a carrier to deliver a therapeutic radiation payload to a specific target. This property distinguishes them from chemotherapy, which cannot distinguish between healthy cells and tumor cells. rADCs are designed to combine the targeting properties of monoclonal antibodies, which are designed to discriminate between healthy and cancerous tissue, with the cancer-killing capabilities of cytotoxic radiation.

Like conventional non-radioactive ADCs, the potential for rADCs to precisely target cancer cells is designed to enable improved efficacy as more of the therapeutic molecule acts on the tumor cells rather than healthy cells, which has the potential to lead to fewer side effects due to the reduction of off-target activity.

We are pioneering a novel technology platform designed to optimize the therapeutic window for rADCs, which we refer to as RADmAb. This proprietary technology uses antibody engineering to modulate the pharmacokinetics of 'full length' antibodies such that they are designed to clear faster from the blood while maintaining the same high specificity to their target and tumor localization properties. Since they retain the same overall structure as traditional antibodies, they also share similar characteristics important for commercial development including a standard manufacturing pathway, biological stability, immunogenicity and regulator familiarity. We believe that this technology, alongside our other radiolabeling knowhow and technologies, can be applied to any existing cancer-targeting antibody agent to potentially provide new intellectual property and a life-cycle management option for prospective partners.

Our Programs

Our Prostate Cancer and PSMA programs

Overview

Our prostate cancer portfolio programs target PSMA, a protein that is overexpressed on the surface of prostate cancer cells and is low or absent on most normal healthy cells. PSMA has become a major breakthrough in the staging, treatment and management of prostate cancer. Imaging with targeted radiation can identify prostate cancer wherever it is in the body and help guide patient treatment. The PSMA receptor is expressed in over 80% of prostate cancer tumors. This expression of PSMA provides a specific target to design therapeutic and diagnostic agents for the treatment and imaging of prostate cancer.

Market and Opportunity for Prostate Cancer Treatment

According to Pharma Intelligence, global incidence of prostate cancer was estimated to be 1,349,000 in 2022 and is expected to reach approximately 1,455,000 by 2027 and in the United States, the incidence of prostate cancer was estimated to be 244,000 in 2022 and is expected to reach approximately 268,000 by 2027. The U.S. market opportunity for PSMA-PET imaging agents in their approved indications is estimated to represent over US$2.4 billion per year. The U.S. market opportunity for PSMA-targeted therapeutic agents is estimated at several billion dollars per year.

High rates of screening in developed countries mean many men are diagnosed and treated early before their disease has spread. These men receive local therapy, either prostatectomy or EBRT, and may be cured of their disease. However, approximately 15% of patients develop advanced forms of the disease that can spread to other parts of the body. This is known as metastatic prostate cancer.

According to a study published in 2015, the incidence of mCRPC in the United States was modeled to be 42,970 cases in 2020 and diagnosed cases are estimated to be increasing at a rate of 5% per year, which implies an estimated incidence of approximately 52,000 cases in 2024. Approved treatment options for patients with mCRPC include androgen deprivation therapy, androgen receptor pathway inhibitors, docetaxel chemotherapy, Radium-223 for patients with bone-only metastases, PSMA-targeted lutetium-therapy for patients having received prior docetaxel, and poly (ADP-ribose) polymerase (PARP) inhibitors for patients with deleterious germline or mutated somatic homologous recombination repair gene. The global market for systemic treatments for patients with mCRPC is estimated at over US$5.5 billion per year.

Pluvicto (^{177}Lu vipivotide tetraxetan), marketed by Novartis, was approved by the FDA for the treatment of patients with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy in March 2022. Pluvicto is the only FDA-approved PSMA-targeted therapy for the treatment of prostate cancer. Novartis disclosed that Pluvicto recorded net sales of US$980 million in 2023 and reported net sales of US$655 million in the first half of 2024. Pluvicto uses a small-molecule approach to target the PSMA receptor and is administered in up to six cycles. In a pivotal clinical trial, patients treated with Pluvicto showed an overall response rate of 30%, a median progression-free survival of 8.7 months, and a median overall survival of 15.3 months. There is not a PSMA-targeted lutetium therapy approved in the pre-chemotherapy setting.

Several other systemic radiotherapies are being investigated in clinical trials in the mCRPC setting and across other stages of prostate cancer, and potentially could be commercialized in the future. We consider our most direct potential competitors to be companies developing PSMA-targeted therapies in the mCRPC space, including Novartis, Convergent, Point Biopharma, Lilly, Lantheus Holdings, Inc, Curium Pharma, ARTBIO, Inc., Blue Earth Therapeutics, Clarity Pharmaceuticals, Fusion Pharmaceuticals, Bayer, Orano Med SAS, Isotopia Molecular Imaging Ltd, ITM Isotope Technologies Munich SE, Janssen Pharmaceuticals, AdvanCell Isotopes Pty Ltd, Alpha-9 Theranostics, Cancer Targeted Technologies, FutureChem Co Ltd., Sinotau Pharmaceutical Group, RadioPharm Theranostics, Precision Molecular, StarPharma, Ambrx Biopharm, Inc., Amgen Inc., Crescendo Therapeutics, Poseida Therapeutics, Regeneron Pharmaceuticals, BioXcel Therapeutics, Lava Therapeutics, Janux Therapeutics, Bivision Pharmaceuticals and Full-Life Technologies. Our competitors also include companies developing other modalities to treat patients with mCRPC. (See “Business—Competition” for additional information).

Market and Opportunity for Prostate Cancer Imaging

PSMA-PET imaging is used by clinicians to locate prostate cancer lesions and inform clinical decisions for patients. PSMA-PET imaging is indicated in the United States for prostate cancer patients:

- with suspected metastasis who are candidates for initial definitive therapy;
- with suspected recurrence based on elevated serum PSA level; and
- for selection of patients with metastatic prostate cancer, for whom Pluvicto is indicated.

We estimate that, based on current guidelines and clinical practice, the PSMA-PET imaging market opportunity in the United States for these indications represents over 605,000 scans per year, which we estimate may be more than US$2.4 billion.

Guidelines and clinical research suggest potential future utilization of PET-PSMA imaging for:

- monitoring for progression in non-metastatic and mCRPC patients; and
- monitoring response to PSMA-directed radioligand therapy,

We estimate that these areas represent over 225,000 scans per year. We estimate that combined addressable market based on existing and future indications may be more than US$3.3 billion per year.

Our competitors in the prostate cancer imaging market are companies with approved PSMA-PET diagnostics, including Novartis, Lantheus Holdings, Inc., or Lantheus, and Bracco Imaging S.p.A. (through its Blue Earth Diagnostics affiliate). Certain academic institutions, such as UCLA and UCSF, also hold a license for a commercial PSMA-PET diagnostic.

In 2020, UCLA and UCSF obtained FDA approval for ^{68}Ga-PSMA-11, which was the first PSMA-PET imaging agent to be approved by the FDA. Pylarify (^{18}F-piflufolastat), marketed by Lantheus, and Illuccix were subsequently approved by the FDA in 2021. Locametz (^{68}Ga-PSMA-11), marketed by Novartis, received FDA approval in 2022 and Posluma (^{18}F-flotufolastat), marketed by Blue Earth Diagnostic, received FDA approval in 2023. Several other PSMA-PET product candidates are being evaluated in clinical trials for prostate cancer imaging and may be commercialized in the future. Companies developing PSMA-PET imaging agents include ABX-CRO, Isotopia Molecular Imaging Ltd, Itelpharma, ITM Isotope Technologies Munich SE, Five Eleven Pharma, Fortis Therapeutics, RadioMedix, HTA Co. Ltd and Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Currently approved PSMA-PET imaging compounds use either a Gallium-68 isotope (^{68}Ga), such as Illuccix, or a Fluorine-18 isotope (^{18}F) for PET imaging. New scientific publications illustrate evidence of important clinical differences between ^{68}Ga and ^{18}F based imaging agents, including a lower rate of false positives with ^{68}Ga imaging agents, which can potentially provide more accurate interpretation and understanding of the extent of disease. Also, ^{68}Ga-based imaging agents have been shown to help clinicians detect prostate cancer in patients with low disease burden. This early detection can lead to a change in management and better outcomes for patients. Additionally, approved ^{68}Ga-based imaging agents can use a lower radiation dose than approved ^{18}F-based agents, reducing exposure to nuclear medicine physicians and patients.

Therapy – TLX591

TLX591 (^{177}Lu rosopatamab tetraxetan) is a rADC directed at PSMA. We are evaluating the safety and efficacy of TLX591 in the ProstACT series of clinical trials.

The key evidence from Phase 1 and Phase 2 studies supporting the development of TLX591 include:

- evidence that treatment with TLX591 is well tolerated, including data from the Phase 1 ProstACT SELECT trial, common grade 3 and 4 hematological events included thrombocytopenia, lymphopenia and neutropenia. All hematological events were transient. All drug-related non-hematologic events were grade 1 or 2, with no grade 3 or 4 events;
- evidence of efficacy demonstrated following treatment of 242 patients across eight Phase 1 and Phase 2 clinical trials, including up to 42.3 months median survival in a single-arm Phase 2 clinical trial in 17 patients with mCRPC when delivered under a fractionated dosing regimen;
- evidence of low rates of off-target organ exposure observed in the ProstACT SELECT trial; and
- convenient two-dose regimen administered over 14 days with low radiation exposure.

As an rADC with an antibody targeting agent, we believe that TLX591 may be differentiated from PSMA-targeted therapies leveraging a small molecule approach as it has the potential for:

- functionally specific to tumor-expressed PSMA, whereas small-molecule PSMA is taken up by endogenous PSMA;
- reduced off-target radiation, with reduced potential for undesirable effects including dry eye, xerostomia, and back pain from ganglia irradiation;
- longer circulation time and tumor retention, while small molecule PSMA is rapidly excreted with approximately 70% of activity lost after 12 hours; and

- shorter dosing regimen of two doses, 14 days apart compared to dosing regimens lasting up to 36 weeks with small molecule PSMA.

Imaging – TLX591-CDx

Illuccix (also referred to as TLX591-CDx in some territories where approval has not yet been granted, ^{68}Ga-PSMA-11) is a preparation for imaging prostate cancer with PET (now approved in the United States, Australia and Canada). The "cold kit" format of Illuccix enables rapid radiolabeling at room temperature with high radiochemical purity and production consistency, suited to the commercial and hospital radiopharmacy setting. Illuccix is approved in the United States, Australia, and Canada, and we anticipate receiving approval in the European Union, the United Kingdom and Brazil beginning in 2024. Approved indications for patients with prostate cancer include staging of high-risk patients, identification of suspected recurrence, and selection for PSMA-directed radioligand therapy. We are also exploring potential future utilization in additional indications for prostate cancer patients through our lifecycle management program. These include monitoring progression in metastatic and non-metastatic castration resistant patients, and monitoring response to PSMA-directed radioligand therapy.

The key evidence supporting the use of Illuccix include:

- broad availability in the United States through over 220 radiopharmacies and with flexible scheduling;
- validated accuracy compared to other PSMA imaging agents, including lower rate of false positives and efficacy in patients with low disease burden; and
- potential for expanded clinical utility based on guidelines and clinical research.

Illuccix was granted transitional pass-through payment status by CMS, effective July 2022 for a three-year period. This status enables CMS to provide separate payments for Illuccix and the PET-CT scan when performed with Illuccix in the hospital outpatient setting.

Imaging – TLX007-CDx

We are developing TLX007-CDx, a new cold kit for the preparation of PSMA-PET imaging for prostate cancer. TLX007-CDx is designed to have an extended distribution profile compared to currently approved ^{68}Ga PSMA-PET imaging agents due to the use of ^{68}Ga sourced from newer high activity generators and cyclotrons.

We believe that TLX007-CDx may further expand the availability and distribution of PSMA-PET imaging due to its longer shelf life and resulting expanded distribution radius. We believe that TLX007-CDx has the potential to address unmet needs by extending availability of PSMA-PET imaging to substantially all PET/CT locations in the United States. Many PET/CT imaging sites that are not served by approved PSMA-PET imaging agents are located in rural and underserved areas.

We conducted a Phase 1 clinical trial of TLX007-CDx to compare the biodistribution of TLX007-CDx and Illuccix in normal tissues and major organs, and in prostate cancer deposits. This trial met its primary objective by demonstrating that there were no differences between TLX007-CDx and Illuccix in the biodistribution in normal tissues and organs, or in prostate cancer deposits, based on 11 evaluable patients. In the trial, each patient received a single dose of Illuccix followed by PET imaging and within seven days, received TLX007-CDx followed by PET imaging. There were no serious adverse events reported in the trial. In May 2024, based on the results of such trial, we submitted an NDA to the FDA for TLX007-CDx for the imaging of patients with prostate cancer. In July 2024, the FDA accepted the NDA for TLX007-CDx and assigned a PDUFA goal date of March 24, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all.

Clinical Data – TLX591

To date, 242 patients have been treated across eight Phase 1 and 2 trials of TLX591. We believe these data cumulatively support the clinical validity of our intended fractionated dosing, which is designed to split a dose over a longer treatment cycle to decrease toxicity without compromising efficacy. In an open-label, single-arm Phase 2 clinical trial with six experimental dose cohorts of TLX591 of 33 patients, we reported a 42.3 month median survival in 17 patients with advanced mCRPC treated at the higher dose level when TLX591 was delivered under a fractionated dosing regimen. Median survival was 19.6 months at the lower dose level and was

27.8 months across those dose cohorts. At the higher dose level, 23.5% and 35.3% of patients had Grade 3 and 4 neutropenia, respectively, and 29.4% and 58.8% of patients had Grade 3 and 4 thrombocytopenia, respectively. The trial met its primary endpoint, which was to identify the maximum tolerated dose of TLX591 when administered in two doses two weeks apart. The survival benefits were a secondary endpoint. This trial did not contain a control group and was not powered to measure statistical significance of the survival benefit, which is a limitation of single-arm trials.

The purpose of the ProstACT SELECT trial is to evaluate the utility of PSMA imaging to select patients for rADC-based PSMA therapy and to confirm the biodistribution of TLX591 with two doses administered 14 days apart. The primary clinical objectives are to determine whole body distribution and organ radiation dose and assess the safety and tolerability profile of TLX591, when administered in combination with standard of care in second-line mCRPC. The evaluable population was 28 patients of a total 30 enrolled in the trial. The first cohort of five patients each received a 27 millicurie dose followed by a 76 mCi dose for accuracy of biodistribution determination. The second cohort of 23 patients each received two 76 mCi doses. These patients included a heterogeneous patient population of low, medium and high disease burden, with the majority of patients having undergone two prior lines of therapy. Based on the interim data, the trial appears to have achieved its primary safety and tolerability objectives.

Interim data from the ProstACT SELECT trial suggested evidence of radiation delivery to bone, nodal, and visceral metastases while minimizing uptake and toxicity concerns in kidney and salivary glands. We believe this biodistribution is significant when compared to small molecule therapeutic and diagnostic PSMA agents, as uptake may not be strictly limited to PSMA cancerous tissue.

We also observed evidence of consistent lesion delineation between TLX591 and ^{68}Ga-PSMA-11 imaging, within the detection sensitivity and resolution limits of SPECT, evidence of uptake and retention in tumor and metastases up to 14 days post injection, the highest absorbed dose being in the liver (clearance organ) with minimal uptake in salivary glands, and a long retention period that was evidence of internalization.

The interim ProstACT SELECT data also provided evidence of the potential clinical advantage of the short, simple treatment regimen of two doses administered 14 days apart.

In this interim data, 21% of patients experienced grade 3 thrombocytopenia and (6/28), 32% experienced grade 3 neutropenia (9/28), 21% experienced grade 4 thrombocytopenia (6/28) and 4% experienced grade 4 neutropenia (1/28). Four patients received intervention in the form of platelets, growth factors or both. All hematologic events were transient and reversible. Four patients (13%) received intervention in the form of platelets, growth factors or both. All treatment related non-hematologic events were grade 1 or grade 2 and generally mild. The most prevalent non-hematological events were fatigue (76%), nausea (23%) and loss of appetite (20%).

In May 2024, based on interim data, we reported that the trial demonstrated a median radiographic progression-free survival of 8.8 months, a secondary objective of the trial, based on an evaluable patient population of 23 patients who each received two 76 mCi doses of TLX591.

We are also investigating TLX591 in the ProstACT GLOBAL clinical trial. We expect this trial to enroll 30 patients in a dosimetry and safety lead-in portion replicating the prior study using the product candidate specifications intended for commercial release and then proceed to a randomized treatment expansion portion, in up to approximately 490 patients. The trial is a multi-national, multi-center, prospective, randomized, controlled, open label study designed to investigate and confirm the benefits and risks associated with TLX591 a high-affinity PSMA-targeted rADC that delivers DNA breaking radiation directly to PSMA-positive bone, nodal, or visceral metastases in patients with mCRPC. The trial will enroll patients that have PSMA-positive mCRPC who have experienced disease progression following treatment with an androgen receptor pathway inhibitor (abiraterone or enzalutamide) that was received in either the metastatic castration-sensitive prostate cancer or first-line mCRPC treatment setting. The primary endpoint of the randomized portion of the trial is radiographic progression-free survival and secondary endpoints include overall survival, objective response rate, time to first symptomatic skeletal events, PFS, PSA decline of more than 50%, quality of life and safety and tolerability.

This is the first Phase 3 trial to evaluate TLX591 in combination with the standard of care (androgen receptor pathway inhibition or docetaxel) compared to the standard of care alone. The use of TLX591 with current real-world standard of care was intended to differentiate the ProstACT GLOBAL trial from other PSMA trials and reflects our continued innovation in prostate cancer care and commitment to patient outcomes.

We began dosing patients at Australian sites in November 2023. We received authorization to conduct the trial in the United States in April 2024 and have opened clinical trial sites in the United States. We expect to expand the trial into Europe, subject to regulatory approvals.

TLX592 – Alpha-PSMA

Through our TLX592 program, we are also exploring how the conjugation of an antibody vector with an alpha-emitting isotope might deliver a next generation rADC with a different therapeutic profile. We believe that TLX592 may be suitable for patients with early-stage mCRPC with a low disease burden and for patients with late-stage mCRPC who are no longer responding to PSMA-therapy.

TLX592 (^{64}Cu/^{225}Ac-RADmAb), is our next generation prostate cancer therapy candidate for targeted alpha therapy and is our first clinical program based on our proprietary RADmAb-engineered antibody technology. The engineered antibody vector is designed for faster elimination from circulation than standard antibodies and slower elimination than small molecules that may result in side effects. It is also designed to enable reduced bone marrow residence time to mitigate the risk of hematologic toxicity while retaining PSMA-mediated tumor localization and exertion of cytotoxic activity. TLX592 is designed to be cleared by the liver without exocrine uptake.

We have conducted *in vivo* animal studies using an LNCaP (PSMA positive) tumor model and observed that treatment with TLX592 resulted in a significant improvement in survival time of nude mice compared to a phosphate buffered saline treated control group. We studied the toxicological profile in CD1 mice and did not observe any treatment-related toxicity up to the highest dose level.

We conducted the Phase 1 CUPID trial in which we evaluated TLX592 with a beta-emitting isotope (^{64}Cu) in 12 patients with advanced prostate cancer prior to commencing therapeutic studies with ^{225}Ac, an alpha-emitting isotope. We do not intend to develop diagnostic imaging applications with TLX592. We used ^{64}Cu to understand safety, pharmacology and dosimetry prior to use of an alpha-emitting isotope as ^{64}Cu is detectable by PET whereas ^{225}Ac is not detectable by PET. We treated patients with PSMA avid disease based on Illuccix imaging, across three dose levels to assess safety profile, pharmacokinetics, biodistribution and dosimetry. In May 2024, we reported that, based on preliminary results from 11 evaluable patients, we observed accelerated elimination from blood circulation compared to the standard antibody used with TLX591 and observed similar on-target and off-target biodistribution and liver clearance, which we believe are important characteristics for an alpha-emitting agent. The trial established a baseline dosing schedule for future trials of TLX592 using ^{225}Ac. There were no serious adverse events observed in the trial. We plan to initiate a Phase 1/2 trial designed to evaluate the safety and efficacy of TLX592 by the end of 2024, subject to regulatory approval.

Our Kidney Cancer and CAIX programs

Overview

CAIX is a protein expressed on the surface of ccRCC and other solid tumors, including bladder or urothelial, breast, brain, cervix, colon, esophagus, head and neck, lung, ovarian, pancreatic and vulval cancers. CAIX is overexpressed in over 94% of ccRCC tumor cells and has limited expression on healthy tissue.

CAIX is often expressed in hypoxic (oxygenated) tumor cells, which are characteristic of advanced disease with typically poor treatment outcomes. Hypoxic tumors are also typically more aggressive and less responsive to current treatments, particularly immunotherapies. A published study has shown that tumor sections from patients that failed to respond to PD-1 blockade therapy showed significantly higher CAIX expression than those that responded (n = 19), suggesting that CAIX expression is associated with poor response to immunotherapy. Furthermore, a published study has demonstrated that in 117 hepatocellular carcinoma patients, positive CAIX expression correlated with reduced disease-free survival and overall survival.

We believe the correlation between hypoxia and disease progression, along with therapy resistance, underscores the potential of this target. Whereas normal endogenous expression of CAIX is very low, CAIX has been found

to be differentially expressed on Tregs in the tumor microenvironment in a number of solid tumors. We are developing products for the detection and treatment of ccRCC and investigating the potential of CAIX as a pan-cancer target in multiple tumor types.

Market and Opportunity for Kidney Cancer Therapy

We estimate that over 25% of ccRCC patients, equivalent to over 16,000 patients per year in the United States, have metastatic RCC. Approved treatment options for ccRCC patients include immunotherapy, tyrosine kinase inhibitors, and mTOR inhibitors. The global market for systemic RCC treatment is estimated to be over US$8 billion per year.

We are exploring the use of TLX250 for the treatment of ccRCC, either in combination with an immunotherapy or as a monotherapy, to treat metastatic disease expressing the CAIX receptor. There is a significant need for new therapeutic options for patients with advanced kidney cancer, given its inherent resistance to conventional chemotherapy and radiotherapy. Despite the transformative impact of immunotherapies on the prognosis of patients with metastatic kidney cancer, a considerable number fail to respond adequately and eventually progress.

An increasing body of scientific evidence suggests low doses of targeted radiation can potentially overcome immune resistance. This approach, known as immunological “priming,” has the potential to render tumors more susceptible to cancer immunotherapy. Several pre-clinical studies have shown an enhanced therapeutic outcome of checkpoint inhibitors when they are administered after a systemic radiotherapy, including rendering immunologically inert tumors sensitive to treatment.

There is currently no CAIX-targeted lutetium therapy approved to treat ccRCC. Several other systemic radiotherapies are being investigated to treat ccRCC targeting CAIX, and potentially could be commercialized in the future.

We consider our most direct competitors to be companies developing CAIX-targeted systemic radiotherapies, including Debiopharm SA, Precision Molecular, Inc. Bayer AG and RayzeBio, Inc. Our competitors will also include companies developing other modalities to treat ccRCC.

Market and Opportunity for Kidney Cancer Imaging

According to the Global Cancer Statistics 2020: GLOBOCAN survey, global incidence of kidney cancer was 431,288 in 2020. In the United States, the incidence of kidney cancer was 81,800 in 2022 according to the American Cancer Society. Approximately 80-90% of malignant kidney tumors are ccRCC. It is one of the subtypes with the worst prognosis and survival often depends on how early it is detected.

Kidney cancer is typically discovered incidentally and diagnosed using a number of modalities including CT scanning, MRI scanning, ultrasound, and biopsy.

The detection of renal masses is increasing due to widespread use of cross-sectional imaging. Many of these are small and represent a diagnostic challenge as current imaging techniques, including ultrasound and MRI, cannot reliably distinguish benign or malignant lesions from renal cell carcinoma, leading to invasive biopsy or partial nephrectomy (kidney removal) to confirm the diagnosis. These procedures are cumbersome and often lead to complications.

Currently, there are major unmet needs for the improvement in diagnosis of ccRCC from indeterminate renal masses as well as improving the staging of more advanced ccRCC through more accurate and specific imaging techniques. In the United States, we estimate that there are at least 113,000 patients per year with renal masses that could require a biopsy or nephrectomy. We believe that an additional 57,000 patients with ccRCC could benefit from more accurate staging or improved identification of recurrence using molecular imaging. This market is estimated to represent approximately US$750 million per year. We also believe that there may be patients that may benefit from more than one scan and from active surveillance.

Currently, there is no approved agent for CAIX imaging. We consider our most direct competitors to be companies developing ccRCC or CAIX-targeted imaging agents, including Debiopharm SA, Philogen S.p.A., ImaginAb, Inc. Precision Molecular, Inc. Astellas Pharma Inc. and Five Eleven Pharma. Our competitors will also include companies developing other modalities to image ccRCC and CAIX.

Therapy – TLX250

TLX250 (^{177}Lu-DOTA-girentuximab) is a rADC therapeutic product candidate for the treatment of kidney cancer. TLX250 is being evaluated for the treatment of patients with ccRCC in investigator-initiated Phase 2 trials in combination with checkpoint inhibitors (STARLITE-1 and STARLITE-2) and in a company-sponsored Phase 1 trial in combination with peposertib (M3814), a DNA-dependent protein kinase, or DNA-PK, inhibitor, in collaboration with Merck KGaA. The clinical trials of TLX250 are designed to evaluate the safety and effectiveness of treating CAIX-expressing tumors with targeted radiation and immunologically "prime" them, making them more susceptible to cancer immunotherapy. Our pre-clinical data in animal models indicates TLX250 could enhance the effect of immuno-oncology agents.

We are using girentuximab to target CAIX as it is designed to have a high degree of selectivity and affinity for the target and is cleared from the body by the liver. The lack of kidney excretion is an advantage for patients with primary kidney disease. We believe the target profile and the properties of girentuximab make the ccRCC phenotype promising as the first therapeutic indication for TLX250.

The key attributes supporting development of TLX250 include:

- two clinical trials have investigated TLX250 in patients with advanced ccRCC in which TLX250 has been well tolerated and has shown the potential to stabilize progressive disease as a monotherapy;
- animal models indicated combination with checkpoint inhibitors can improve therapeutic response; and
- potential application in range of carcinomas that are known to over-express CAIX.

We believe the therapeutic potential of TLX250 may also extend into other cancers that significantly express CAIX, including certain VHL-induced cancers, ovarian cancer, triple-negative breast cancer and bladder cancer. We believe that our preliminary clinical data in triple-negative breast cancer and bladder cancer supports future development of TLX250 in these indications.

Therapy – TLX252

In our TLX252 program, we are exploring how girentuximab radiolabeled with the alpha-emitting isotope Actinium-225 might complement the TLX250 (beta) program by addressing unmet need in radiation-resistant CAIX-positive disease. TLX252 has demonstrated pre-clinical proof-of-concept in several published preclinical imaging and efficacy animal studies, and comparable *in vivo* characteristics (binding, pharmacokinetics and biodistribution) to a non-radiolabeled girentuximab, which we believe supports the initiation of initial dose-finding trials of TLX252 for the treatment of patients with advanced metastatic kidney cancer. We expect that data from our existing CAIX program Zircaix diagnostic and TLX250 therapy will complement and inform the clinical and regulatory development strategy for TLX252.

Imaging – TLX250-CDx

TLX250-CDx (^{89}Zr-DFO-girentuximab) is a PET diagnostic imaging agent for the characterization of renal masses as ccRCC. We evaluated TLX250-CDx in the recently completed Phase 3 ZIRCON trial in 300 patients, of which 284 were evaluable. The trial met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a mean positive predictive value of 93% for ccRCC across three independent readers. We believe this demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. TLX250-CDx was granted breakthrough therapy designation from the FDA in 2020.

We submitted a BLA for TLX250-CDx to the FDA for regulatory approval in December 2023. The BLA was granted on a rolling review process. We completed the BLA submission in May 2024, and in July 2024, the FDA declined to approve the BLA and issued an RTF determination. The denial was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment. The FDA has not indicated any deficiencies in the clinical or nonclinical data relating to the safety or efficacy of TLX250-CDx. While we believe that TLX250-CDx has met all sterility requirements of product release and that we will be able to complete the required remedial actions within 90 days and resubmit the BLA, even if we satisfy the requirements of the RTF determination, there can be no assurance that we will obtain regulatory approval from the FDA. Subject to this regulatory approval, we aim to commercialize TLX250-CDx in 2025. If approved, TLX250-CDx would be the first targeted radiopharmaceutical imaging agent for kidney cancer to be approved in the United States.

The key attributes supporting development of TLX250-CDx include:

- high affinity was observed for CAIX, expressed in up to 94% of ccRCC and many hypoxic solid tumors, low expression in normal tissue;
- positive results in Phase 3 ZIRCON trial including key secondary endpoints that demonstrated detection of ccRCC even in small renal masses (less than 4cm); and
- breakthrough therapy designation from the FDA granted in 2020.

Breakthrough therapy designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX250-CDx will receive marketing approval.

Clinical Programs and Data – TLX250

TLX250 is being evaluated in combination with checkpoint inhibitors for the treatment of patients with ccRCC in two separate investigator-sponsored trials as part of the STARLITE program.

We believe that tumor-targeted radiation stimulates remodeling of the tumor microenvironment and can kill immunosuppressive cells and stimulate T-cell recruitment to attack tumor cells. This immune re-programming may increase the therapeutic response to treatment with checkpoint inhibitors.

STARLITE-1 is a single arm Phase 1/2 investigator-initiated trial of TLX250 in combination with cabozantinib and nivolumab in treatment naïve patients with advanced ccRCC. The trial has a target enrollment of 100 patients. The trial is sponsored by the MD Anderson Cancer Center.

STARLITE-2 is a Phase 2 investigator-initiated open-label trial of nivolumab combined with TLX250 in 29 patients with advanced ccRCC that have progressed on treatment with an immune checkpoint inhibitor. The objective of the trial is to determine the maximum tolerated dose and associated efficacy of the combination. The study is open for recruitment and dosing of the first safety cohort has completed. The trial is sponsored by the Memorial Sloan Kettering Cancer Center.

We are evaluating TLX250 in combination with peposertib in collaboration with Merck KGaA in the Phase 1b STARSTRUCK trial. The trial is evaluating the combination in patients with solid tumors expressing CAIX that are relapsed or refractory to standard-of-care treatment options. The objective of the trial is to assess the safety and tolerability profile of TLX250 with peposertib in up to 85 patients. The first patient was dosed in the third quarter of 2023. We believe that the combination may provide an enhancement in potency through their synergistic action on cancer cells. Targeted radiation effectively induces DNA damage in targeted cancer cells and peposertib may act to prevent the cell from repairing this damage, resulting in higher potency at lower doses. We are conducting the STARSTRUCK trial pursuant to a clinical trial collaboration and supply agreement with Merck KGaA pursuant to which Merck agreed to provide a supply of peposertib for the trial.

Previous clinical trials of TLX250 have demonstrated its potential to stabilize progressive disease in metastatic ccRCC patients as a monotherapy, and that it is generally well tolerated. In a Phase 2 trial evaluating one dose of TLX250 in 14 patients with metastatic ccRCC, eight patients (57%) had stable disease and one patient (7%) experienced a partial response.

In a Phase 1 trial evaluating TLX250 in 23 patients with advanced ccRCC, TLX250 was observed to be well tolerated and to have the potential to stabilize previously progressive disease in metastatic ccRCC. The mean overall survival for all patients was 25.3 months and the mean PFS was 11.1 months.

In the Phase 1 trial, ^{177}Lu-giretuximab injections were well tolerated and no infusion-related or acute allergic reactions were observed. Hematologic toxicity was the most prominent toxicity and was dose limiting. At dose levels of 1,110 and 1480 MBq/m^2 per treatment showed no dose limiting toxicity. The dose level per treatment was increased stepwise from 1,850 to 2,220 2,405MBq/m^2 up to 2,590 MBq/m^2. Moderate dose limited toxicity was observed at these higher dose levels and a final maximum tolerated dose of 2,405MBq/m^2 was determined from this trial.

We are now preparing a Phase 2 trial to explore the combination of TLX250 with existing standards of care in advanced renal cell carcinoma.

Clinical Data – TLX250-CDx

We recently completed the pivotal Phase 3 ZIRCON trial evaluating TLX250-CDx in 300 patients. The trial met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% PPV for ccRCC across three independent readers. We believe this trial demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

The data from the trial demonstrated the ability of TLX250-CDx to characterize renal masses as ccRCC, which could support improved clinical decision making and limiting the need for invasive procedures like biopsies and nephrectomies. A total of 300 patients were dosed with TLX250-CDx in the trial and 284 patients had a central histology reading and evaluable TLX250-CDx PET scan at central review.

The study also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumors ≤4cm (T1a classification), currently a significant clinical challenge in the diagnosis of ccRCC. In very small renal lesions (≤2cm, a secondary endpoint), sensitivity was 84% for all three independent readers, with specificity ranging from 90.0% to 100%.

The table below provides a breakdown of the three independent reader scores, overall score and confidence intervals of the full analysis set.

	Reader 1	Reader 2	Reader 3	Overall % (95% CI)
Sensitivity, %	84.13	85.19	87.30	**85.5**
Lowest bounds, Wilson 95% CI	78.24	79.42	81.80	(79.8; 89.8)
Specificity, %	88.42	88.42	84.21	**87**
Lowest bounds, Wilson 95% CI	80.45	80.45	75.57%	(78.8; 92.3)
Positive predictive value, %	93.53	93.60	91.67	**93** (88; 96)
Negative predictive value, %	73.68	75.00	76.92	**75** (66; 82)
Accuracy, %	85.56	86.27	86.27	**86** (81.5; 89.6)

The majority of adverse events in the trial were post-surgical complications and not treatment related. A total of 261 treatment-emergent adverse events were reported in 122 of 300 patients (40.7%), of which 146 were mild, 50 were moderate and 49 were severe. Four of the treatment-emergent adverse events were life-threatening and one was fatal. 13 treatment-emergent adverse events were considered to be treatment related, of which, nine occurred before surgery and four occurred after surgery. No unexpected safety signals were observed and tolerability data were consistent with experience of girentuximab in previous therapeutic and imaging studies.

In July 2023, we dosed the first patient in the Phase 2 STARBURST trial of TLX250-CDx exploring CAIX expression in patients with a diverse range of solid tumors for potential therapeutic and diagnostic applications. This trial, which aims to enroll 100 patients, may enable us to identify new therapeutic indications for TLX250 through the use of molecular imaging with TLX250-CDx.

In October 2024, we announced that we dosed the first patient in the Phase 2 CA-NINE trial, which is an investigator-initiated Phase 2 trial evaluating TLX250-CDx in patients with ccRCC after surgery. The trial plans to enroll 91 patients with intermediate-to-high risk ccRCC post-surgery and is designed to identify ccRCC where it has recurred, including metastatic disease, and may inform future label expansion for TLX250-CDx.

There are also several investigator-led trials of TLX250-CDx in progress, including the Phase 1 ZiP-UP trial in patients with metastatic urothelial carcinoma or bladder cancer, the Phase 2 OPALESCENCE trial in patients with triple-negative breast cancer, and the Phase 1 PERTINENCE trial in patients with non-muscle invasive bladder cancer. The ZiP-UP is continuing to enroll patients. The OPALESCENCE and PERTINENCE trials reported positive preliminary data during 2022 at the European Association of Nuclear Medicine Annual

Congress, with early results suggesting theranostic potential in these difficult to treat diseases. In December 2023, additional data from the OPALESCENCE was reported from 12 patients with metastatic triple-negative breast cancer that demonstrated the potential for TLX250-CDx to detect lesions that may resist chemotherapy and have a more aggressive profile resulting from hypoxia.

Our Brain Cancer Programs and LAT1/LAT2

Overview

According to the Global Cancer Statistics 2020: GLOBOCAN survey, global incidence of brain and nervous system tumors was 308,102 in 2020. Gliomas make up approximately 30% of all brain and central nervous system tumors and 80% of all malignant brain tumors. In the United States, according to the CBTRUS Statistical Report, the incidence of glioma was 21,950 in 2022.

Glioblastoma is the most aggressive sub-type of glioma, representing 14,190 cases per year in the United States. It has a poor prognosis, primarily due to there being few effective treatment options. Glioblastoma has a median survival from initial diagnosis of 12-15 months.

The mainstay of treatment for glioblastoma is surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients. Our brain cancer program targets membrane transport proteins called LAT1 and LAT2, which are important targets in cancer development as they supply tumors with essential amino acids, promoting cell proliferation, angiogenesis and mediating drug and nutrient delivery across the blood-brain barrier. LAT1 and LAT2 are highly expressed in the blood-brain barrier and in various types of cancer, including glioblastoma.

Market and Opportunity for Brain Cancer Treatment

While surgical resection plus radiation therapy are the mainstays of treatment, the vast majority of patients experience disease recurrence. Thus, there remains an important need for therapies targeted towards glioblastoma in patients in both the front-line treatment setting, as well as for patients experiencing disease recurrence following surgical intervention.

There are several systemic radiotherapies being evaluated in clinical trials for the treatment of glioblastoma. We consider our most direct competitors to be companies developing systemic radiotherapies for brain tumors, including ITM Isotope Technologies Munich SE, Molecular Targeting Technologies, Inc., EvaThera Theranostics, Novartis, RadioPharm Theranostics, Plus Therapeutics and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to treat brain cancer.

Market and Opportunity for Brain Cancer Imaging

We believe there are a number of opportunities to address unmet needs in the market for imaging of glioma. The first is improving the characterization of recurrence. Although MRI is the current standard of care for imaging of glioma patients, the accurate identification of recurrence remains an important unmet medical need. The U.S. market opportunity for imaging in this setting is estimated at 19,600 scans per year. This market is estimated to represent approximately US$95 million to US$140 million per year.

The second is improving adjuvant radiation treatment planning in glioblastoma patients, which is also an important unmet medical need. The U.S. market opportunity imaging in this setting is estimated to be 15,000 scans per year.

The third opportunity is improved identification of recurrence in patients with brain metastases. The incidence of brain metastases in the United States is estimated to be between 98,000 and 170,000 cases per year. The U.S. market opportunity for imaging in this setting is estimated at over 60,000 scans per year. This aggregate market is estimated to represent approximately US$470 million to US$665 million per year.

There are several molecular imaging agents being evaluated in clinical trials for the imaging of glioma and brain metastases. We consider our most direct competitors to be companies developing imaging agents for brain tumors, including Novartis, Blue Earth Diagnostics, RadioPharm Theranostics, Curasight, Molecular Targeting Technologies, Inc., and EvaThera Theranostics. Our competitors could also include companies developing other modalities to image brain cancer.

Therapy – TLX101

TLX101 (^{131}I-IPA) is our therapeutic product candidate for the treatment of patients with brain cancer that targets the LAT1 receptor. TLX101 is a novel approach that is readily able to pass through the blood-brain barrier, the normal protective barrier that prevents many potential drug candidates from entering the brain.

We are currently evaluating TLX101 in front line and recurrent glioblastoma in the IPAX series of trials. TLX101 has been granted orphan drug designation in the United States and Europe for the treatment of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101 will receive marketing approval.

The key attributes supporting development of TLX101 include:

- the IPAX-1 trial demonstrated evidence of tumor responses in recurrent glioblastoma including some patients with prolonged disease stabilization;
- the IPAX-2 Phase 1 trial is designed to extend TLX101 into the front-line setting, building upon experience in recurrent setting;
- evidence of rapid clearance of TLX101 from the brain observed in the IPAX-1 trial; and
- TLX101 has been granted orphan drug designation in the United States and Europe for the treatment of glioma.

Therapy – TLX102

In our TLX102 program, we are also exploring how phenylalanine, the same LAT1 targeting peptide used in TLX101, radiolabeled with an alpha-emitting isotope might deliver a different therapeutic profile. Astatine-211 is an alpha-emitting radioisotope with comparable halogen chemistry to Iodine-131 that can cross the blood-brain barrier. TLX102 has demonstrated pre-clinical proof-of-concept and we believe that TLX102 has the potential to have a favorable efficacy and safety profile in future human clinical trials in patients with glioblastoma and multiple myeloma. Astatine chemistry has been demonstrated, scaled up and automated, ready for clinical production. Due to comparable target binding and molecular structure, we expect that data from our existing LAT1 theranostic programs TLX101-CDx and TLX101 will complement and inform the clinical and regulatory development strategy for TLX102.

In August 2020, TLX102 was granted orphan drug designation from the FDA in the United States for the treatment of multiple myeloma. Orphan drug designation may not lead to a faster development or regulatory review or approval process in multiple myeloma or glioblastoma and does not increase the likelihood that TLX102 will receive marketing approval in either of these disease areas.

Imaging – TLX101-CDx

TLX101-CDx (^{18}F-FET) is a radiolabeled amino acid PET agent for imaging of gliomas that is used in clinical research settings, including in our IPAX series of trials of TLX101, as a complementary diagnostic agent. Clinical data suggest that TLX101-CDx can facilitate the identification of recurrence of brain metastases. ^{18}F-FET is widely used in many jurisdictions and is recommended by the joint guidelines from the European Association of Nuclear Medicine, European Association of Neuro-Oncology, Society of Nuclear Medicine and Molecular Imaging, The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients.

In October 2020, TLX101-CDx was granted orphan drug designation from the FDA in the United States for the imaging of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-CDx will receive marketing approval.

We used TLX101-CDx to select patients and track disease response in our IPAX-1 Phase 1/2 clinical trial and are using TLX101-CDx in the IPAX-2 and IPAX-Linz trials.

In August 2024, we submitted an NDA to the FDA for TLX101-CDx for the characterization of progressive or recurrent glioma in both adult and pediatric patients from treatment related changes through the 505(b)(2) NDA regulatory pathway. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA

goal date, if at all. TLX101-CDx was granted fast track designation by the FDA for this indication in April 2024. Fast track designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX101-CDx will receive marketing approval. We also intend to conduct a label-expanding Phase 3 trial of TLX101-CDx for the imaging of patients with brain metastases from non-brain cancers, including lung and breast cancer.

The key attributes supporting development of TLX101-CDx include:

- potential tool for management of progression and treatment monitoring;
- orphan drug designation, potential to meet major unmet need; and
- widely used in Europe and recommended in the joint guidelines for imaging of gliomas.

Clinical Programs and Data – TLX101

In 2022, we reported the final results from the IPAX-1 Phase 1/2 trial evaluating TLX101 therapy in combination with EBRT in patients with recurrent glioblastoma. The trial met its primary safety and tolerability objective.

We enrolled ten patients in the trial, nine of whom received the full dose of ~2GBq (2000 MBq) of TLX101, either in the form of a single administration or one of two triple-fractionated regimens. All dosing regimens were well tolerated. Dosimetric analysis demonstrates that radiation exposure to key organs is well within acceptable safety limits.

The trial also demonstrated a median overall survival of 23 months from initial diagnosis, or 13 months from the initiation of treatment in the recurring setting. Of the nine patients who received conventional imaging, four (44%) exhibited stable disease at day 135 and two (22%) at day 180, determined by longitudinal imaging.

The most frequent treatment emergent adverse events, or TEAEs, were decreased lymphocyte count, fatigue, headache and hiccups, which occurred in three patients (30%), followed by decreased platelet count, diarrhea, cerebral oedema (swelling), and insomnia, which occurred in two patients (20%). Except for cerebral oedema (swelling), a typical side-effect of radiation to the brain, adverse events were of low grade, did not show any trends or patterns and were clinically manageable, with a significant proportion deemed unrelated to therapy.

In 2023, we initiated a Phase 1 trial, IPAX-2, to further evaluate the safety of TLX101 in 15 patients as a front-line therapy for the treatment of glioblastoma in combination with EBRT and temozolomide in front-line in order to support initiation of a label-indicating Phase 2 trial are continuing to enroll patients in the trial.

TLX101 is being investigated in the recurrent setting in the investigator-initiated IPAX-Linz Phase 2 trial, which is enrolling patients with recurrent glioblastoma. Grand Pharma received approval by the Chinese National Medical Products Administration to initiate the IPAX-China trial of TLX101.

Clinical Programs and Data – TLX101-CDx

In August 2024, we submitted an NDA to the FDA for regulatory approval of TLX101-CDx as a radioactive diagnostic agent indicated for use with PET imaging for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients through the 505(b)(2) NDA regulatory pathway. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all.

The ability of TLX101-CDx trials to differentiate between various tumor subtypes and disease stages has been evaluated in 725 glioma patients across 14 comparative trials. Trial designs were both prospective and retrospective. Using various imaging technique specifications, studies compared TLX101-CDx with magnetic resonance imaging, 2 ^{18}F-fluoro-2-deoxy-D-glucose (FDG-PET), 3’ deoxy 3’ ^{18}F-fluorothymidine, and perfusion weighted MRI. These trials provided evidence that TLX101-CDx tended to result in higher sensitivity and specificity.

TLX101-CDx was also the subject of a published systemic review and meta-analysis covering 26 studies with a total of 1206 patient/lesions, that conclude that TLX101-CDx showed promise as a complementary modality to standard-of-care MRI for the management of brain malignancies.

In addition, we have exclusively licensed prospective, unpublished clinical trial data covering 127 patients, and we aim to confirm the findings of these trials with additional supportive data.

We are also exploring applications of TLX101-CDx imaging in radiation treatment planning through ^{18}F-FET in glioblastoma, or FIG, investigator-initiated trial. This trial aims to show that TLX101-CDx can help improve radiation treatment planning in a prospective, multi-center PET/CT trial.

Our musculoskeletal cancer programs

Soft Tissue Sarcoma and PDGFRα

Soft tissue sarcoma is a rare, complex disease that encompasses a diverse group of relatively rare cancers, with more than 50 histological subtypes. According to the National Cancer Institute, there were an estimated 13,400 new cases and 5,140 deaths were caused by STS in 2023 in the United States. Standard treatment for soft tissue sarcoma includes surgery, radiation therapy and/or chemotherapy. For patients with advanced, unresectable, or metastatic disease, treatment typically involves chemotherapy with single agents (e.g., doxorubicin) or anthracycline-based combination regimens. However, the prognosis for these patients remains poor, with treated patients with metastatic disease having a median overall survival of around 12–18 months.

STS is usually diagnosed using imaging tests (CT, MRI and/or FDG-PET) and/or biopsy, depending on the tumor location. Conventional imaging and biopsy are also used for staging.

There are several programs in clinical development for the treatment of STS, none of which are targeted systemic radiotherapies. We consider our most direct competitors to be companies developing systemic radiotherapies in the soft-tissue sarcoma space, including OncoTherapy Science, RadioPharm Theranostics and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to soft tissue sarcomas cancers.

Therapy – TLX300

In April 2022, we entered into a licensing agreement with Lilly that granted us exclusive worldwide rights to develop and commercialize radiolabeled forms of olaratumab as a targeting agent for radiopharmaceutical imaging and therapy of cancer. Lilly originally developed olaratumab a non-radiolabeled monoclonal antibody targeting PDGFRα, a protein expressed in multiple tumor types that is involved in fibrogenesis. Olaratumab has a well-established clinical and toxicology profile as a non-radiolabeled agent.

Olaratumab was granted accelerated approval in the United States and conditional approval in the European Union based on Phase 2 trial data which showed a 11.8 month survival benefit in patients with STS, when given in combination with standard chemotherapy. Lilly began marketing olaratumab as Lartruvo in 2016.

Sales of Lartruvo peaked at US$304.7 million in 2018. Olaratumab was voluntarily withdrawn from the market by Lilly following the failure of the Phase 3 ANNOUNCE clinical trial, in which olaratumab did not improve survival for patients. We believe that the therapeutic limitations of Lartruvo can be overcome through the re-purposing of olaratumab as a radiopharmaceutical.

Our initial development focus for radiolabeled olaratumab is on STS. We believe that the ability of olaratumab to target PDGFRα makes it a promising candidate for use as a radionuclide targeting agent and that the targeting of activated fibroblasts in the tumor micro-environment is a promising strategy to drive durable treatment responses in certain solid tumors.

Our product candidates, TLX300 and TLX300-CDx employ antibody-directed targeted radiation for both therapeutic and diagnostic applications, respectively, against PDGFRα. We are developing TLX300 for the treatment of patients with advanced or metastatic soft tissue sarcoma, administered in combination with doxorubicin.

We have completed pre-clinical studies evaluating TLX300 and have received ethics approval to initiate a clinical trial in Australia. We expect to initiate a proof-of-concept targeting and biodistribution trial in humans in the fourth quarter of 2024. We intend to develop the therapeutic application of TLX300 for the treatment of STS using an alpha-emitting isotope. We have not yet determined the specific alpha-emitting isotope that we will use in clinical trials of TLX300.

The key attributes supporting development of TLX300 include:

- well-established clinical and toxicology profile of olaratumab as a non-radiolabeled agent;

- submitted ethics application to commence a Phase 1 trial, to be conducted in Australia and New Zealand targeting and biodistribution in humans; and
- potential application in a range of other cancers (e.g., bone, brain, breast, lung, ovarian and prostate cancers).

In a preclinical study of a dose of 10 MBq of TLX300 in mice, we observed a significant increase in survival to tumor endpoint (P=0.0004, Log-Rank test).

Imaging – TLX300-CDx

TLX300-CDx (^{89}Zr-DFOsq-olaratumab, including our proprietary DFO-squaramide chelator) is an investigational imaging agent that we are developing for use with TLX300 as a theranostic pair. DFO-squaramide (DfES) is our proprietary chelator technology, designed to optimize the bioconjugate manufacture, conjugate stability and serum stability for use with this isotope. If approved, TLX300-CDx would be the first diagnostic imaging agent to specifically detect the presence of PDGFRα in patients with STS.

Following the completion of pre-clinical studies, we intend to initiate a Phase 1 imaging clinical trial of TLX300-CDx in Australia and New Zealand. This dose-finding study will assess safety, tolerability, dosimetry, pharmacokinetics and imaging properties of ^{89}Zr-olaratumab in participants with PDGFRα-positive STS. We plan to conduct this trial using a beta-emitting isotope in order to evaluate the safety, pharmacology and dosimetry prior to use of an alpha-emitting isotope in subsequent clinical trials. We have not yet determined the specific isotopes that we will use in these trials.

The pre-clinical studies of radiolabeled-olaratumab have demonstrated that olaratumab can be bioconjugated with chelators and radiolabeled with imaging and therapeutic radionuclides. In a biodistribution study of TLX300-CDx in mice tumor targeting reached 55% of ID/g at 120 hours post-injection, accompanied by accumulation in main clearance organs as predicted based on radiolabeled antibody clearance. We believe results of these pre-clinical studies demonstrate the viability of radiolabeling olaratumab, high uptake of the imaging agent in tumors and subsequent clearance and demonstrated anti-tumor activity with the therapy agent. Animal or pre-clinical results should be interpreted with caution as they may not correlate to results in human clinical trials.

Bone Marrow Conditioning and CD66

Overview

HSCT is an important lifesaving treatment opportunity for various hematological malignancies and a variety of non-malignant conditions such as severe aplastic anemia, inherited bone marrow failure syndromes, sickle cell disease, transfusion-dependent thalassemia, inherited immune deficiency syndromes, and certain metabolic disorders. Experimentally, HSCT has been used in severe refractory autoimmune diseases.

Conditions such as acute myeloid leukemia, multiple myeloma and systemic amyloid light chain amyloidosis may also benefit from more tolerable bone marrow conditioning regimens. The utilization of novel cell and gene therapies may increase by replacing toxic chemotherapy conditioning approaches with bone marrow conditioning.

This program targets distinct members of CD66, a family of receptors expressed on specific types of immune or blood cells that serve as attractive biomarkers for novel experimental conditioning radiopharmaceuticals.

Market and Opportunity for Bone Marrow Conditioning Treatment

According to the World Wide Network of Bone and Marrow Transplantation, there were approximately 90,000 first HSCT performed in 2019, of which 47% were allogeneic. According to the U.S. Health Resources and Services Administration, there were approximately 22,000 HSCT performed in the United States in 2020, 41% of which were allogeneic.

Prior to undergoing HSCT for the treatment of hematologic malignancies patients undergo a bone marrow conditioning treatment. Current standard of care typically requires bone marrow conditioning with multi-drug chemotherapy regimens. However, these regimens are highly toxic, and patients may not tolerate treatment. This creates an important unmet medical need for more tolerable bone marrow conditioning regimens.

There are several systemic radiotherapies being evaluated in clinical trials as conditioning agents for HSCT. We consider our most direct competitors to be companies developing systemic radiotherapies in the hematology

space, including Actinium Pharmaceuticals, Inc., Bayer AG, Sensei Biotherapeutics, Inc., ImaginAb, Inc. Acrotech Biopharma, Inc., Nordic Nanovector ASA, Orano Med, Samus Therapeutics, Inc., Cellectar Biosciences, Inc. and Jasper Therapeutics, Inc.

Market and Opportunity for Imaging of Bone Marrow Infection (Osteomyelitis)

The incidence of osteomyelitis is estimated to be as high as 21.8 cases per 100,000 persons per year. The diagnosis of osteomyelitis is a challenge for diagnostic imaging and timely identification/localization of pathology can be of critical importance for appropriate management of patients.

Imaging modalities used to diagnose osteomyelitis can include X-ray, bone scintigraphy, CT, and MRI. These are typically combined with imaging of white blood cells to distinguish infection, sterile inflammation, and other disorders. White blood cell imaging is typically performed using *in vitro* separation and labelling of white blood cells, which requires preparation time and carries the inherent risk of contamination.

Scintimun has been shown to be more sensitive than white blood cell imaging in certain patients, with faster preparation time and lower production complexity relative to the white blood cell approach. Since CD66 is a neutrophil marker, Scintimun can be used for imaging and pathological characterization A Phase 3 clinical trial demonstrated that Scintimun is accurate and well-tolerated in the diagnosis of peripheral bone infections, providing comparable information to ^{99m}TC-HMPAO-labelled white blood cells. Scintimun was also shown to be more sensitive than ^{99m}TC-HMPAO-labelled white blood cells in patients with microbiologically proven infection of the bone and in patients with chronic osteomyelitis.

Therapy – TLX66

TLX66 (^{90}Y-besilesomab), is a product candidate for bone marrow conditioning for HSCT conditioning, a broad clinical indication.

Our HSCT conditioning agent, TLX66, is being studied in acute myeloid leukemia, multiple myeloma and systemic amyloid light chain amyloidosis through investigator-initiated trials. Clinical data suggest TLX66 could be a well-tolerated (and therefore highly versatile) bone marrow conditioning agent which could be utilized as a single agent or in combination with either reduced or high intensity conditioning agents preceding both autologous or allogeneic HSCT.

We plan to evaluate TLX66 in a Phase 2 clinical trial as a BMC agent in patients with acute myeloid leukemia who are not suitable for conventional BMC regimes. We expect to submit an IND to the FDA for this trial and to commence the trial in 2025.

TLX66 was granted orphan drug designation status in the United States and Europe. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX66 will receive marketing approval.

The key attributes supporting the development of TLX66 include:

- minimal uptake in non-hematopoietic organs such as liver, kidneys and gut;
- approximately 100 patients treated in several Phase 1 and 2 investigator-initiated trials of TLX66 in different hematological diseases requiring autologous or allogeneic stem cell transplantation; and
- orphan drug designation granted in the United States and Europe for TLX66 for bone marrow conditioning.

Manufacturing TLX66 and TLX66-CDx utilizes a small amount of Triton X-100, which is a non-ionic surfactant, in the antibody manufacturing process. Triton X-100 is subject to a regulation in the European Union known as Registration, Evaluation, Authorisation and Restriction of Chemicals, or REACH. Outside of the United States, Curium Pharma is responsible for the manufacturing and commercialization of TLX66-CDx. We are permitted to manufacture TLX66 for research and clinical development in the European Union pursuant to a self-certified exemption applicable to research and development activity. We would need to obtain authorization under REACH in order to use Triton X-100 for the future commercial manufacturing of TLX-66 or re-design the commercial manufacturing process for TLX66 such that Triton X-100 is not used. We are currently planning to re-design the commercial manufacturing process for TLX66 and potentially for TLX66-CDx. We believe that any improvements to the manufacturing process we may make could also result in an increase in productivity and a

potential reduction in manufacturing costs. If we re-design the manufacturing process for TLX66, we may be required to conduct additional clinical trials of TLX66 or meet alternative regulatory standards.

Imaging – TLX66-CDx

TLX66-CDx (^{99m}Tc-besilesomab) is our imaging agent for osteomyelitis.

We out-licensed TLX66-CDx to Curium Pharma who markets it as Scintimun outside the United States. Curium Pharma received marketing authorization for Scintimun in the European Union in 2010 for scintigraphic imaging, in conjunction with other modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. We are entitled to royalties from Curium Pharma. TLX66-CDx has not received marketing approval in the United States. We are evaluating the feasibility of filing for a marketing authorization application in the United States where we retain the rights.

The key attributes supporting the use of TLX66-CDx include:

- EMA approval for imaging of peripheral osteomyelitis in 2010; and
- Phase 3 trial showed that Scintimun imaging is accurate and well-tolerated in diagnosing infection of the peripheral skeleton and provides comparable information.

The approval of Scintimun was based on the results of a multicenter study performed in 22 European centers. This multinational, Phase 3 clinical study was undertaken to compare anti-granulocyte imaging using Scintimun with ^{99m}Tc-labelled white blood cells in patients with peripheral osteomyelitis. The results of this Phase 3 trial showed that Scintimun imaging is accurate and well-tolerated in diagnosing infection of the peripheral skeleton and provides comparable information to ^{99m}Tc-labelled white blood cells in patients with chronic osteomyelitis.

Clinical Data – TLX66

TLX66 has been evaluated in 98 patients in several investigator-initiated-trials as a conditioning agent preceding HSCT in patients with a range of hematological malignancies, including a Phase 1 dose-escalation trial in 55 patients with hematological malignancies, a Phase 1 trial in nine patients with pediatric relapsed/refractory leukemia, a Phase 1/2a trial in nine patients with AL-amyloidosis and a Phase 2 trial in 25 patients with multiple myeloma. In these trials, there have not been significant toxicities and there have not been detectable non-hematological toxicities such as mucositis/colitis. In the pediatric population, TLX66 has been well tolerated with no serious toxicities.

In a Phase 2 trial using TLX66 and HD-melphalan in 24 patients as a conditioning agent for multiple myeloma autologous HSCT, the complete response rate in the combination cohort (12 patients) was 50%, compared to 25% in the HD-melphalan control group (12 patients).

In reported data from 30 patients out of 55 patients treated in a Phase 1 trial of TLX66, patients were given increasing doses of TLX66 followed by reduced intensity conditioning and HSCT. The overall survival rate was 73% ten years after the HSCT procedure with low toxicity for TLX66. There were no severe non-hematological adverse events detected and efficient myeloablation, both in bone marrow and peripheral blood (the anticipated therapeutic effect and prerequisite for both successful autologous and allogeneic HSCT), was observed.

The Phase 1/2a trial evaluating TLX66 in nine patients with AL amyloidosis evaluated the safety and toxicity of TLX66 as a bone marrow conditioning agent prior to HSCT. All nine patients were successfully engrafted following bone marrow conditioning with TLX66 and autologous HSCT without any chemotherapy. TLX66 was well tolerated by all patients and had a very low toxicity profile when compared to chemotherapy-based conditioning regimes.

There were no serious adverse events or transplant-related deaths.

We plan to conduct further development of TLX66 as a bone marrow conditioning agent in high-risk acute myeloid leukemia patients in complete remission with minimal residual disease in combo with reduced intensity conditioning preceding allogenic HSCT.

Bone Metastases and Pain Palliation

TLX090 (^{153}Sm-DOTMP) is a novel kit-based bone-seeking targeted radiopharmaceutical product candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. It is a combination of patented, lower specific activity form of Samarium-153, a beta-emitting radioisotope with a

46-hour half-life, and the chelating agent DOTMP (1,4,7,10-tetraazacyclododecane-1,4,7,10-tetramethylene-phosphonate), which selectively targets sites of high bone mineral turnover, a known characteristic of bone metastases, and minimizes off-target migration. We believe that TLX090 may be administered as a single dose, multiple doses and higher dose regimens for pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090 is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma.

In August 2021, the FDA cleared the IND application to commence Phase 1, open-label, dose escalating study for TLX090 as a treatment for cancer that has metastasized to the bone from the lung, breast, prostate and other areas. Patients received an imaging dose of 0.5 mCi/kg on day 1 and then a therapeutic dose on day 8. A total of five patients were enrolled and treated in the first two cohorts (three patients at 0.5 mCi and two patients at 1 mCi/kg). SPECT/CT scans of these patients showed that TLX090 was highly targeted to bone and had preferential uptake in bone tumors. There was no evidence of soft tissue activity and investigators observed rapid elimination via the kidney and bladder. Complete blood count and comprehensive metabolic panel blood testing data indicated no toxicities or drug-related adverse events; some mild and transient drop in white blood cell counts that recovered after day 38 and no clinically significant changes in liver and kidney function. No transfusions or stem cell recovery procedures were necessary. Visual analogue scale pain scores taken at baseline and then weekly after dosing suggest fast-acting, long-lasting pain relief, improved mobility and improved quality of life. We believe that pain relief is of is evidence that TLX090 may not have similar risks or the potential side effects of opiate pain medications, and may offer a viable alternative treatment option for patients with bone metastases.

We believe that TLX090 has the potential to deliver significant improvements to existing bone-seeking agents in the treatment and management of late-stage metastatic disease. TLX090 may enable the pain management of prostate cancer bone metastases, where there remains a significant unmet medical need particularly after progression from other forms of radionuclide and radiation therapy. We also believe that TLX090 may benefit patients with metastatic lung and breast cancer, where many patients develop brain and bone metastases, and disease management often focuses on quality-of-life palliative care.

TLX090 has also been granted orphan drug and rare pediatric disease designations by the FDA for the treatment of osteosarcoma. The rare pediatric disease designation may enable TLX090 to be brought to market more rapidly through regulatory incentives, including eligibility for a pediatric rare disease priority review voucher that may be applied to this or other programs. The orphan drug designation and the rare pediatric disease designation do not increase the likelihood of marketing approval.

Our Precision-Guided Surgical Programs and AI Technology

We established a MedTech Division to create technologies designed to harness the power of targeted radiation across the entire patient journey from diagnosis to surgical intervention and therapy. We anticipate applying this first in urology, for prostate and kidney cancer, and then across the breadth of indications we are developing.

Radio-Guided Surgery (RGS)

Bringing molecular imaging into the operating theater is a key part of our portfolio strategy for urologic oncology.

In November 2023 we acquired the SENSEI radio-guided surgery business from Lightpoint Medical Ltd, or Lightpoint. SENSEI is a miniature gamma probe device used to detect radiation in patients and guide surgery. The probe is inserted into a surgical port and can then be controlled by the clinician during the procedure. When used with targeted imaging agents, SENSEI may enable the intraoperative detection of cancer in real time, supporting greater precision in the removal of tumors.

The utility of SENSEI has been demonstrated in several studies. These include a prospective multicenter trial assessing the safety and performance of the SENSEI probe for prostate cancer sentinel lymph node biopsy. The primary objective was the sentinel lymph node dissection rate, or SeLND rate, with a 100% detection rate achieved by the drop-in probe and no adverse events linked to the probe. The study concluded that the SENSEI probe meets performance and safety requirements for sentinel lymph node biopsy in prostate cancer, offering

improved maneuverability and sentinel lymph node detection compared to the conventional rigid laparoscopic gamma probe. Another study covering ten patients concluded that using the probe is also safe and feasible for Sentinel Lymph Node detection in early-stage cervical cancer. We are evaluating the regulatory pathway for marketing SENSEI in the United States.

In November 2023, we made a strategic investment of A$9.5 million into Mauna Kea, a leading medical device company pioneering the development of real-time intraoperative visualization of cancer tissue during surgery. This investment is an expansion of our existing IRiS (Imaging and Robotics in Surgery) Alliance with Mauna Kea that we established to develop new hybrid pharmaceutical-device products through the combination of our cancer-targeting agents with Cellvizio, Mauna Kea's confocal surgical laser endomicroscopy *in vivo* cellular imaging platform. Cellvizio is marketed by Mauna Kea pursuant to a 510(k) clearance in the United States and is CE Marked for a range of applications. Cellvizio enables the application of endomicroscopy combined with radiopharmaceutical and fluorescence imaging techniques to build a comprehensive intra-operative imaging toolbox for urology applications.

We believe this technology is complementary to our existing portfolio. When used pre-operatively, our radiopharmaceutical imaging agents, such as Illuccix or TLX250-CDx, potentially enable improved surgical planning to determine the location and extent of disease. SENSEI, a radio-guided surgical probe works in conjunction with suitable cancer-seeking radiotracer agents to enable the intra-operative detection of cancer during a surgical intervention to help accurately answer the question, "where is the cancer?" In a complementary fashion, Cellvizio platform enables localized tissue visualization through endomicroscopic fluorescence detection to potentially define and confirm surgical margins in real-time. We are evaluating the regulatory pathway for marketing the Cellvizio technology with our portfolio of radiopharmaceutical imaging agent product and product candidate in the United States.

Artificial Intelligence (AI)

Radio imaging using targeted radiation relies heavily on digital data processing and input from highly trained technicians and radiologists to correctly interpret the data. We believe that AI technology can recognize complex patterns in large datasets and conduct predictive analysis, with potential to transform imaging analysis and improve the accuracy of decision making for clinicians.

During 2022, we announced a partnership with Invicro LLC to develop an AI platform that we refer to as TelixAI. This platform will initially focus on prostate cancer and we intend to eventually apply it to all of our imaging products. The goal of the platform is to increase the efficiency and reproducibility of imaging assessments by automatically separating healthy versus abnormal tracer uptake and then classifying lesions as either soft tissue or bone lesions.

In 2023, we acquired Dedicaid GmbH and its clinical decision support software, or CDSS, AI platform capable of rapidly generating indication specific CDSS applications from available datasets, for use with PET and other imaging modalities. Each CDSS application is trained to predict outcomes such as the severity of disease, risk to the patient and/or inform treatment decisions. Dedicaid employs an automated machine learning engine. We believe that this platform is differentiated from commercially-available AI solutions currently used in PSMA-PET imaging, which are limited to supporting clinicians in the interpretation and reading of images – without a prediction capability. This platform is designed to reduce the time, cost and level of expertise required to build, test and validate new CDSS applications, facilitating a streamlined development and regulatory pathway for each new application. We are conducting final validation of the Dedicaid platform.

Dedicaid developed the technology with proof of concept on the machine-learning methodology demonstrated for prostate, breast and lung cancer applications published in leading peer-review journals. We expect that our acquisition of this AI platform will provide us with the capability to quickly and easily generate algorithms from clinical data and medical images, add predictive capabilities alongside the imaging analysis module and will be used to accelerate the development of TelixAI applications across the pipeline. The Dedicaid acquisition also included a lead medical device tool that is designed to interpret the risk of prostate cancer advancement from a PSMA-PET scan image by correlating it to a well-known histopathology indicator (the Gleason Grade). A second AI asset supporting Illuccix, being developed in partnership with Invicro LLC, is designed to automate the identification and classification of prostate cancer lesions from PSMA-PET scans to support greater efficiency and standardization in the imaging workflow.

Our focus for our AI platform is to develop AI-powered solutions that support our product candidates and enable them for use by the nuclear medicine community as approved medical devices. We aim to use AI and the Dedicaid platform across our development pipeline by utilizing clinical imaging and outcome data as they become available and to develop and validate medical device applications supporting approved products. The acquisitions of both Dedicaid and Lightpoint's radio-guided surgery business provide a founding MedTech capability that we believe will enable Telix to generate AI and software applications that are complementary to our radiopharmaceutical pipeline.

Global Manufacturing and Supply Chain

We are focused on enhancing our existing global manufacturing and supply chain with a balance of external and in-house capabilities, securing a robust and innovative manufacturing infrastructure and supply chain to serve our patients. Manufacturing and supply chain supporting our portfolio broadly cover the following areas: radioisotopes, radiochemistry, biologics, small molecules, fill/finish, packaging and labeling, and storage and distribution.

Since 2022, we have made significant progress with the buildout of our radioisotope manufacturing facility in Brussels South. We have been granted an updated radiation license by the Belgian Federal Agency for Nuclear Control, enabling site activation subject to the regulatory inspections and approvals.

Our approximately 30,000 square foot radioisotope manufacturing facility is one of Europe's largest radiopharmaceutical production facilities. The site will enable improved access to radiopharmaceuticals for patients across the EMEA region and the world as a primary GMP-capable manufacturing site for our clinical and commercial products. The site also has extensive R&D capabilities, with a focus on alpha-emitting isotopes. We believe the proximity of an alpha radiopharmaceutical laboratory to a production GMP environment is a differentiated capability to our competition. We expect the site to evolve and develop as a hub for strategic collaborations via R&D facilities and manufacturing line designated for university and SME partners.

We aim to have a degree of vertical integration in our three operating regions. In line with this goal, in 2022 we acquired Optimal Tracers, a California-based company that provides radiochemistry process development services and research tracers for use in clinical trials. The acquisition of Optimal Tracers expanded our translational radiochemistry capability and establishes a U.S.-based laboratory and production footprint for clinical trial doses.

Optimal Tracers will also remain available as a strategic collaborative resource to partner organizations and pharma collaborators that need access to specialist radiochemistry knowledge.

Our biologics, small molecule, fill/finish and packaging manufacturing and supply chain are accomplished through relationships with external contract manufacturing organizations, or CMOs, and vendors. We have agreements with late stage/commercial organizations, including ABX-CRO, Grand Rapids Aseptic Manufacturing, PCI, UPS, Patheon Pharma Services, Goodwin Biotechnology Inc, and 3P Biopharmaceuticals. For early-stage manufacturing and supply chain, we are working closely with companies such as GenScrip ProBio to establish platform capabilities in cell line development and antibody production, DiverChim CDMO, Curia Global, and Abzena Holdings (US) LLC. We are also pursuing the addition of in-house capabilities where appropriate through vertical integration.

With respect to producing radiolabeled drug product, we aim to continue to deepen our relationship with key manufacturing networks in the United States: Pharmalogic for ^{18}F and ^{89}Zr products, Cardinal Health for ^{68}Ga and ^{89}Zr products, and BAMF Health for ^{18}F products. We have agreements with Evergreen Theragnostics, AtomVie Global Radiopharma, Eckert & Ziegler Strahlen- und Medizintechnik AG, Seibersdorf Laboratories and South Australian Health and Medical Research Institute for the manufacture of our therapeutic product candidates across multiple regions, and we are working on establishing additional key manufacturers in APAC and the European Union. Our current capabilities encompass ^{177}Lu, ^{131}I, and ^{89}Zr, we aim to build-up our capabilities with respect to producing alpha-emitters such as ^{225}Ac in 2024.

We are dedicated to enhancing our global supply chain capabilities, particularly for the clinical and commercial supply of isotopes used in radiolabeling, as well as for supplying generators. We have established a series of strategic supply agreements with leading industry partners including Eckert & Ziegler Strahlen- und Medizintechnik AG, Trace Sciences International, ITM, SHINE Technologies, the Australian Nuclear Science and Technology Organisation, and Eczacıbaşı-Monrol.

These partnerships are pivotal in ensuring a broad and robust supply network for ^{177}Lu. By diversifying our supply chain through these contracts, we aim to create a resilient system that eliminates dependencies on a single

supply chain. This approach is intended to ensure uninterrupted supply and to enhance our capability to meet growing demand. Each of these agreements includes a firm commitment for the supply of ^{177}Lu.

By these strategic agreements, we aim to maximize the available production process methods and reactor locations. This not only ensures a steady and diverse supply of ^{177}Lu but also allows us to adapt quickly to changing market demands and regulatory environments.

In addition to securing a reliable supply, we are also committed to sustainable practices, particularly in the recycling of the starting material used to produce ^{177}Lu. This recycling process is an integral part of our supply chain, minimizing waste and ensuring the efficient use of resources. By incorporating these sustainable practices, we are not just focusing on meeting current demands but are also paving the way for a more environmentally responsible future in isotope production and supply.

We aim to actively pursue the development and supply of future isotopes. Understanding the critical role these materials play in advancing medical and scientific endeavors, we are dedicated to ensuring a robust and resilient supply chain that can adapt to the evolving needs of the industry.

Our approach is multi-faceted, focusing on strategic partnerships, technological innovation, and sustainable practices. We continuously seek to expand our network of suppliers and collaborators, forming alliances with leading entities in the field. This not only diversifies our supply sources but also fosters innovation through shared expertise and resources.

Moreover, we are investing in cutting-edge technologies and processes that enhance our production capabilities, ensuring efficiency and reliability. Our commitment to sustainability, particularly in the recycling of materials, further strengthens our supply chain, reducing environmental impact while maximizing resource utilization.

We recognize that the future of isotope supply lies in our ability to anticipate and respond to market changes and scientific advancements. Therefore, we are dedicated to ongoing research and development, ensuring that we remain at the forefront of isotope supply. Our goal is not just to meet current demands but to be a driving force in the development of new isotopes, paving the way for groundbreaking applications that can transform industries and improve lives.

Our commitment to a robust and resilient supply chain for future isotopes is unwavering. We understand the significance of our role in this dynamic field and are dedicated to maintaining the highest standards of quality, reliability, and innovation in all our endeavors.

Through these comprehensive efforts, we are seeking to position ourselves as a leader in the supply of isotopes for radiolabeling, backed by a supply chain that is as diverse as it is robust, ensuring the highest standards of quality and reliability for our clients.

Sales and Marketing Operations

Our commercial operations span the Americas, EMEA, and Asia Pacific Regions. Illuccix is approved in the United States, Canada and Australia, and permitted to be sold in New Zealand, and we are commercializing this product in these countries through local sales forces, which currently include over 40 associates, and together with distributor partners. We have secured a number of commercial partnerships covering certain geographies to enable distribution and/or commercialization of its products.

In the United States, we have established a commercial radiopharmacy network of over 220 commercial radiopharmacies to distribute Illuccix, including partnerships with Cardinal Health, Inc., PharmaLogic Holdings, Corp., and Jubilant Radiopharma. We also have a distribution agreement with Isologic Innovative Radiopharmaceuticals Ltd for the Canadian market.

In Asia Pacific, we have secured a strategic collaboration with Grand Pharmaceutical Group Limited, or Grand Pharma, in the Greater China area including Mainland China, Taiwan, Hong Kong and Macau. Grand Pharma has been appointed as our partner for this territory with exclusive development and commercialization rights to our portfolio. We have also secured exclusive distribution agreements in Australia with Global Medical Solutions Australia Pty Ltd and with DuChembio Co., Ltd. In South Korea.

In Europe, we have exclusive distribution agreements for the upcoming launch of Illuccix in a number of geographies, including with Eckert & Ziegler RadioPharma GmbH in Germany, Xiel Ltd in the United Kingdom and Ireland, IRE Elit S.A. in France, Radius S.r.l. in Italy, Nucliber S.A. in Spain, Biokosmos S.A. in Greece and

Cyprus, Sociedade Avanço, Unipessoal, LDA in Portugal, THP Medical Products Vertriebs GmbH in Austrian, Czech Republic and Slovak Republic and WIIK Pharma ApS in Denmark, Finland, Norway and Sweden.

Competition

Our potential competitors include all entities developing and commercializing diagnostics and therapies in the field of oncology, through nuclear medicine and other modalities. This includes companies, academic institutions, government agencies, hospitals, other organizations involved in research, manufacturing, and commercialization of diagnostics and therapies. In addition to the current standard of care for patients, commercial and academic clinical trials are being pursued by a number of parties in the field of radiopharmaceuticals. Early results from these trials have fueled continued interest in radiopharmaceuticals, which is being pursued by several biotechnology companies, as well as by large pharmaceutical companies.

There are several companies with approved beta-based radiopharmaceuticals, including Lantheus Holdings, Novartis, Bayer, Sirtex, Boston Scientific and Q BioMed Inc. and other companies developing beta-based radiopharmaceuticals, including POINT Biopharma Global, ITM Isotope Technologies Munich SE and Y-mAbs Therapeutics, Inc. The beta emitting isotopes used by these companies include Iodine-131, Lutetium-177, Strontium-89 and Yttrium-90.

There are several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Bayer, Novartis, Johnson & Johnson, Abdera Therapeutics, Actinium Pharmaceuticals, Inc, Aktis Oncology, Convergent Therapeutics, Debiopharm, Fusion Pharmaceuticals Inc., ITM Isotope Technologies Munich SE, Lantheus Holdings, Inc., Mariana Oncology, Inc., Perspective Therapeutics, POINT Biopharma Global Inc., RadioMedix, Inc., RayzeBio, Inc., and Y-mAbs Therapeutics, Inc. The only approved alpha particle-based therapy is Bayer's Xofigo (Radium-223) which was approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

We consider our most direct competitors to be companies developing and commercializing diagnostics and therapies in our core therapy areas, including prostate cancer, kidney cancer, brain cancer, sarcoma, and bone marrow conditioning.

In prostate cancer therapy, Pluvicto (^{177}Lu vipivotide tetraxetan), marketed by Novartis, was approved by the FDA for the treatment of patients with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy in March 2022. Pluvicto is the only FDA-approved PSMA-targeted therapy for the treatment of prostate cancer. Several other systemic radiotherapies are being investigated in clinical trials in the mCRPC setting and across other stages of prostate cancer, and potentially could be commercialized in the future.

In mCRPC treatment, there are several companies developing PSMA-targeted therapies in the mCRPC space, including Novartis, Convergent, Point Biopharma, Lilly, Lantheus Holdings, Inc, Curium Pharma, ARTBIO, Inc., Blue Earth Therapeutics, Clarity Pharmaceuticals, Fusion Pharmaceuticals, Bayer, Orano Med SAS, Isotopia Molecular Imaging Ltd, ITM Isotope Technologies Munich SE, Janssen Pharmaceuticals, AdvanCell Isotopes Pty Ltd, Alpha-9 Theranostics, Cancer Targeted Technologies, FutureChem Co Ltd., Sinotau Pharmaceutical Group, RadioPharm Theranostics, Precision Molecular, StarPharma, Ambrx Biopharm, Inc., Amgen Inc., Crescendo Therapeutics, Poseida Therapeutics, Regeneron Pharmaceuticals, BioXcel Therapeutics, Lava Therapeutics, Janux Therapeutics, Bivision Pharmaceuticals and Full-Life Technologies. Our competitors also include companies developing other modalities to treat patients with mCRPC.

In prostate cancer imaging, UCLA and UCSF obtained FDA approval for ^{68}Ga-PSMA-11 in 2020, this was the first PSMA-PET imaging agent to be approved by the FDA. Pylarify (^{18}F-piflufolastat), marketed by Lantheus Holdings, Inc, was approved by the FDA in 2021. Locametz (^{68}Ga-PSMA-11), marketed by Novartis, received FDA approval in 2022 and Posluma (^{18}F-flotufolastat), marketed by Blue Earth Diagnostic, received FDA approval in 2023. Several other PSMA-PET product candidates are being evaluated in clinical trials for prostate cancer imaging and may be commercialized in the future. Companies developing PSMA-PET imaging agents include ABX-CRO, Isotopia Molecular Imaging Ltd, Itelpharma, ITM Isotope Technologies Munich SE, Five Eleven Pharma, Fortis Therapeutics, RadioMedix, Inc., HTA Co. Ltd and Jiangsu Hengrui Pharmaceuticals Co., Ltd.

In kidney cancer therapy, there are several companies developing CAIX-targeted systemic radiotherapies, including Debiopharm SA, Precision Molecular, Inc. Bayer AG and RayzeBio, Inc.

In kidney cancer imaging, there are several companies developing ccRCC or CAIX-targeted imaging agents, including Debiopharm SA, Philogen S.p.A., ImaginAb, Inc., Precision Molecular, Astellas Pharma Inc. and Five Eleven Pharma.

In glioblastoma therapy, there are several companies developing systemic radiotherapies for brain tumors, including ITM Isotope Technologies Munich SE, Molecular Targeting Technologies, Inc., EvaThera Theranostics, Novartis, Radiopharm Theranostics, Plus Therapeutics and Cellectar Biosciences, Inc.

In brain cancer imaging, there are several companies developing imaging agents for primary brain tumors and brain metastases, including Novartis, Blue Earth Diagnostics, RadioPharm Theranostics, Curasight A/S, Molecular Targeting Technologies, Inc. and EvaThera Theranostics.

In sarcoma, there are several companies developing systemic radiotherapies in the soft-tissue sarcoma space, including OncoTherapy Sciences, RadioPharm Theranostics and Cellectar Biosciences, Inc.

In bone marrow conditioning, there are several companies developing systemic radiotherapies in the hematology space, including Actinium Pharmaceuticals, Inc., Bayer AG, Sensei Biotherapeutics, Inc., ImaginAb, Inc. Acrotech Biopharma, Nordic Nanovector ASA, Orano Med SAS, Samus Therapeutics, Cellectar Biosciences, Inc. and Jasper Therapeutics. Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than our product candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be efficacy, safety, convenience, price, availability of the relevant isotope, the effectiveness of imaging diagnostics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Overview

Patent Protection

By their very nature, radiopharmaceuticals must be delivered through a complicated supply chain and go to market model requiring specialized physics, chemistry and biological expertise for successful development and commercialization protected by know-how and trade secrets. This specialization provides a practical barrier to competitor entry without the same specialist expertise, however we aim to build, maintain and continuously improve our exclusivity and patent position to protect our innovation contribution. We aim to integrate regulatory filing strategy designed to maximize regulatory market or data exclusivity (including applicable for biologics, orphan drugs) and through targeted patent protection across the spectrum of compound, dosing, radiolabeling technology, handling, preparation process and manufacturing inventions.

Older radiopharmaceuticals were historically routinely used in the public domain academia for many years under practice of pharmacy or individual named patient prescribing regulatory pathways. This has the benefit of established use and real-life clinical application and experience for such products when made commercially available, but does potentially create the result that patent protection is not available or has only limited remaining exclusivity.

Our original third-party licensed products were in-licensed and were accepted on an “as-is” basis. We have limited opportunity to determine or influence territory and scope of third-party licensor portfolio and the time to make changes to scope or territory has long since passed under applicable patent laws. However even for these earlier products, we have expanded our patent portfolio where possible and seek to obtain related new patents for updates in handling, dosing and manufacturing to maximize patent exclusivity where feasible, in addition to our supply chain know-how and trade secrets.

For our newer programs and next generation radiopharmaceuticals, the patent protection is deeper and wider across the spectrum of compound, method of treatment, dosing, radiolabeling technology, handling, preparation process and manufacturing inventions based on our newer proprietary technologies or due to our innovation in the end-to-end process.

We have in-licensed registered intellectual property associated with our key therapeutic products: TLX591, TLX250, TLX101, TLX102, TLX090, TLX300, TLX66 and related imaging product TLX250-CDx in addition to supplementary intellectual property owned by us. Intellectual property for Illuccix, TLX592, TLX252 and TLX101-CDx is wholly owned by us. We have also filed our own applications for registered patents and trademarks in respect of our key products.

Patents are granted by national and regional intellectual property offices in accordance with the corresponding national laws. Granted patents provide a right to prevent use, sale, importation or other unauthorized exploitation of the invention. Protection is generally limited to actions in or relating to the countries in which protection is obtained, and enforcement is generally by litigation. The scope of protection is defined by the terms of the claims. Patents are (in broad terms) infringed when another party takes all of the elements of one or more of the claims in the patent. Patents generally have a maximum term of 20 years after the filing date, subject to the payment of renewal fees in all the relevant countries.

In the field of pharmaceuticals, patent term extensions or supplementary protection certificates may extend the term of a patent beyond 20 years in certain jurisdictions. Examples of important jurisdictions where these regimes are available are the United States, Europe, Japan and Australia. Many of the patents and patent applications which are in-licensed or owned by us may be able to be extended under the patent term extension or supplementary protection certificate regimes (in jurisdictions where these regimes are available) once the key products have been the subject of regulatory approval as the claims are directed to pharmaceutical products and their uses. The extensions in term are typically up to five years in duration and are often related to the delay between filing the patent and regulatory approval of the pharmaceutical product.

Requirement for Patentability

The requirements for patentability differ in detail from country to country. However, in general terms the main requirements are that the invention relate to patentable subject matter; that the invention is novel and has an inventive step; and that the patent contain an adequate disclosure of performing or making the invention. In order to be new, the invention must not have been disclosed in writing or otherwise in public, or offered for sale, before the priority date. The requirement of inventive step is, in general terms, that the invention must go beyond what the skilled worker in the field would arrive at as a matter of course when attempting to address the same problem as the invention.

Procedure for Obtaining Patent Protection

Patents are granted on a national basis. International patent protection is based upon a system of well-established and widely adopted international conventions. The first application for a patent for an invention is called the priority application, and its filing date is known as the priority date. If patent applications relating to the same subject matter in other countries are filed within a year from the priority date, then (in accordance with the Paris Convention, World Trade Organization (WTO) Treaty and bilateral agreements) they retain the effective filing date of the priority date for the purpose of assessing novelty and inventive step.

There are three different types of patent application of relevance. A provisional application acts as a filing to obtain a priority date. It does not proceed to grant; rather, a later application must be filed within a year of the priority date to claim the benefit of that filing. Provisional applications are not examined by the patent authorities. A national filing is a regular patent application in a particular country or region. It will be examined in most cases by the local or regional patent authorities. Applications can be filed directly in the country or

region, or using another convention called the Patent Cooperation Treaty, or PCT. The PCT allows for a single application to be filed in a single patent office, designating all the member states, obtain a preliminary search and opinion, and delay filing into the national and regional intellectual property offices for a period of 30 months from the priority date. The PCT currently has 148 members, including all OECD member countries. At the end of this period, national filings must be made in the countries of interest. The patent application is examined in each country (or in some cases regional offices) according to its national laws and procedures.

Potential Limitations of Patent Protection

Certain limitations are inherent in the patent system. In all relevant countries it is possible to challenge the validity of a patent even after it has been granted by the intellectual property office. This may be possible by administrative processes at the relevant patent office, court procedures, or both. A successful challenge to validity will result in the patent being narrowed in scope, or completely revoked. Patent offices do not guarantee the validity of patents granted. Because of the limited scope of material searchable by the patent office, compared to the potential to use any document or act before the priority date to attack validity, there is a risk that presently unknown material relevant to patentability will be discovered at a later time, with consequent risks to validity. The scope of a granted patent may be significantly different to a pending application, and so it is not possible to advise with certainty in relation to infringement of a pending application.

Pending patent applications may never proceed to be granted patents. It is not generally possible to commence litigation based on a pending application, it is necessary to obtain a granted patent. However, damages in some instances and in some jurisdictions may be backdated for part of the period of pendency. Our review shows that none of the patents and patent applications in-licensed or owned by us are presently the subject of a challenge by a third party. EP0956506 has previously been challenged in opposition proceedings before the European Patent Office but the opposition was successfully dismissed.

Patent Proprietorship

It is a requirement for validity of patents in Australia and other jurisdictions that there be a clear chain of title from the inventor to the applicant or owner. Challenges to proprietorship can be a basis for revocation of patents.

Trademarks

Registered trademarks protect indications which serve to distinguish the goods or services of one competitor from those of others, and provide the owner with the exclusive right to use or authorize others to use the trademark in relation to the goods and services for which it is registered. Trademarks are granted generally on a national or regional basis. International filings are governed by international treaties, in a similar manner to patents, but with a six-month priority period. The intellectual property offices in each country in most cases conduct searches and examination prior to registration. Applications are typically pending for a period of six months to two years prior to grant. Trademarks are subject to challenge by third parties in each jurisdiction before and after grant, using administrative and/or court-based processes on various grounds.

In total, as of August 23, 2024, we own 13 registered U.S. trademarks, 16 pending U.S. trademark applications, 137 foreign trademarks registered in jurisdictions such as Australia, Europe, China, Brazil and Japan, and 94 pending foreign trademark applications applied for in jurisdictions such as Australia, Europe, China, Brazil and Japan. We currently have trademark registrations in the United States for the Telix Pharmaceuticals name, the Illuccix name and logo, the ANMI name, the SENSEI name, and the RADMAB name and other trademarks are pending in the United States such as the Optimal Tracers name and logo, the Lightpoint logo, the Lightpoint Surgical name, the Dedicaid name, Pixclara and Zircaix. Outside of the United States, Illuccix is registered in Australia, Brazil, Canada, China, the European Union, India, Israel, Japan, Malaysia, New Zealand, Norway, Peru, Philippines, South Korea, Singapore, Switzerland, Taiwan, Turkey, the United Kingdom and is pending in Thailand. We are also selectively filing the following names and logos outside of the United States: Pixclara, Zircaix, Lightpoint, Dedicaid, Optimal Tracers, ANMI, and RADMAB.

Data and Market Exclusivity Provisions

Data and market exclusivity provisions exist in each jurisdiction. Relevantly for us, they relate to the regulatory approval of pharmaceutical products *inter alia*. The provisions provide periods within which a competitor is limited in their ability to obtain regulatory approval for a follow-on product. Data exclusivity relates to the

period in which information relating to the safety and efficacy of a product, provided to a regulatory authority for the purposes of obtaining regulatory approval, remains confidential, or cannot be relied upon by the regulatory authority or a third-party in order to obtain regulatory approval of a follow-on product. Data exclusivity is separate from other forms of exclusivity, such as the monopoly provided by patents. In some instances, the period of data exclusivity may extend beyond the term of any patent which protects the same product. Market exclusivity refers to a period where a party wishing to sell a follow-on product is prohibited from doing so, even if regulatory approval has been obtained.

As our key products are radio pharmaceutical products, they will have the benefit of periods of data and market exclusivity available in each jurisdiction following regulatory approval. These are typically five years or more in duration (and eight years data exclusivity plus two years market exclusivity for European jurisdictions).

Our Patent Portfolio

Our commercial success depends in part on our ability to obtain and maintain regulatory exclusivity, proprietary or intellectual property protection for our products and product candidates, our core technologies, and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary or intellectual property rights. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and in foreign jurisdictions related to our proprietary technology and products and product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We also in-license patent portfolios relating to our product pipeline and to emerging product candidates as well as technologies that are adjacent such as radiolabeling technologies, linker technologies, chelator technologies, bioconjugation techniques, antibody manufacturing and modifications, isotope manufacture, AI techniques and applications, and medical imaging devices,

In total, as of August 23, 2024, we have in-licensed 27 U.S.-issued patents and 313 foreign-issued patents granted in jurisdictions such as Australia, Canada, Germany, Italy, Spain, the United Kingdom, France, Turkey, Russia, Japan, China, Korea, Singapore, India, Israel, Mexico, and Brazil. As of August 23, 2024, we have also in-licensed eight pending non-provisional U.S. patent applications and 49 pending foreign-patent applications applied for in jurisdictions such as in Australia, Canada, Europe, Russia, Japan, China, India, Mexico, and Brazil.

In total, as of August 23, 2024, we own either solely, or jointly with our commercial partners, 12 U.S.-issued patents and 114 foreign patents granted in jurisdictions such as Australia, Canada, Germany, Italy, Spain, the United Kingdom, France, Turkey, Russia, Japan, China, India, Israel, Mexico, and Brazil. As of August 23, 2024, we also have pending, either solely or jointly with our commercial partners, 22 non-provisional U.S. patent applications, 111 foreign patent applications applied for in jurisdictions such as in Australia, Canada, Europe, Japan, China, Korea, Singapore, India, Israel, Mexico, and Brazil, and ten pending international applications filed under the PCT. The PCT is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the member states. Although a PCT application is not itself examined and cannot issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

The intellectual property portfolios for our key products and product candidates as of August 23, 2024 are summarized below.

Illuccix

Our Illuccix patent portfolio covers the pharmaceutical product and the unique arrangement of components of the kit as well as methods of making gozetotide. The patent family directed to the pharmaceutical product and the unique arrangement of components of the kit consists of four U.S.-issued patents; 53 foreign-issued patents granted in Australia, Canada, Belgium, Finland, Switzerland, Lichtenstein, the Czech Republic, Denmark, Austria, Greece, Hungary, Ireland, the Netherlands, Norway, Portugal, Sweden, Germany, Italy, Spain, the United Kingdom, France, Turkey, Russia, Japan, China, India, Israel, Mexico, South Africa, New Zealand and Brazil, 10 pending foreign patent applications applied for in Australia, Europe, India and Hong Kong, and four pending U.S. non-provisional applications. The patent family directed to methods of making gozetotide consists of one pending U.S. non-provisional patent application and ten pending foreign patent applications in Australia, Brazil, Canada, Mexico, China, Europe, Japan, Korea, Hong Kong and Singapore.

There is one U.S. patent registered under the U.S. Orange Book which is directed to methods of imaging using the pharmaceutical product prepared with Illuccix.

Any patents that may issue in the United States as part of our patent portfolio directed to the pharmaceutical product or the kit will expire no earlier than 2035, not including any terminal disclaimer, patent term adjustment due to administrative delays by the U.S. Patent and Trademark Office, or USPTO, or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2035. Any patents that may issue in the United States directed to methods of making gozetotide will expire in 2042, absent any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire in 2042.

TLX250-CDx (^{89}Zr-girentuximab) and TLX250 (^{177}Lu-girentuximab)

We have in-licensed six patent families from Heidelberg Pharma AG (formerly Wilex AG) directed to the CAIX-targeting girentuximab antibody and various therapeutic and imaging applications thereof.

The in-licensed patent portfolio includes four U.S.-issued patents, 22 foreign-issued patents granted in Australia, Canada, Germany, Spain, Italy, France, the United Kingdom, Korea, New Zealand, South Africa, Israel, Russia and Mexico, and four foreign patent applications applied for in Brazil, Hong Kong, China and Japan. Expiry dates vary from 2025 to 2034 across the portfolio, not including any patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, or equivalent provisions in foreign jurisdictions.

We have two patent families directed to aspects of the manufacture of TLX250-CDx. These patent families include two pending U.S. non-provisional patent applications and 16 foreign patent applications applied for in Australia, Brazil, Canada, Europe, Korea, Singapore, China and Japan. Any patents that may issue in the United States based on the non-provisional US patent applications will expire no earlier than 2042, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

We have two patent families directed to the use of TLX250-CDx and TLX250 in imaging and therapy of CAIX-expressing cancers other ccRCC. These patent families consist of two pending PCT applications. Any patents that may issue in the United States based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

We have one patent family directed to combinations of TLX250 with checkpoint inhibitors. This patent family consists of one pending PCT application. Any patents that may issue in the United States based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

We have one patent family directed to the combination of TLX250 with DNA damage repair inhibitors. This patent family include one pending U.S. non-provisional patent application and ten foreign patent applications applied for in Australia, Brazil, Canada, Europe, Israel, Korea, Mexico, Singapore, China and Japan, Any patents that may issue in the United States based on the U.S. non-provisional patent application will expire no earlier than 2042, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

As biological products, TLX250-CDx and TLX250 will be entitled to 12 years data exclusivity from the date of product approval.

TLX252 (^{225}Ac-DOTA-girentuximab)

We have a single patent family patent directed to the composition of matter of TLX252, its radiolabeled forms and uses in imaging and therapy. The patent family includes one pending U.S. non-provisional patent application and 16 pending foreign patent applications in Canada, Chile, China, India, Japan, Korea, Mexico, Australia,

Europe, Eurasia, India, New Zealand, Brazil, Hong Kong, Israel and Singapore. Any patents that may issue in the United States will expire no earlier than 2040, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2040.

TLX101-CDx (^{18}F-FET)

We have orphan drug and fast track designation for TLX101-CDx in the United States, which we expect to yield up to seven years regulatory exclusivity following product approval.

TLX101 (^{131}I-IPA) and TLX102 (^{211}At-IPA)

We have in-licensed a patent portfolio directed to methods of treatment using TLX101 and TLX102 licensed from Dr. Samuel Samnick, a German nuclear medicine researcher. There are two U.S.-issued patents which will expire no earlier than 2028 and 2031 respectively, not including any patent term extension under the Hatch-Waxman Act. There are eight foreign issued patents in Australia, Canada, Germany, the United Kingdom, Spain, France, Japan, and Korea which will expire no earlier than 2026.

We have in-licensed a patent portfolio directed to a method of manufacturing TLX101 and TLX102 from Osaka University. There is one U.S.-issued patent, one pending US non-provisional application, two foreign-issued patents in Australia and Japan and one pending foreign application in Europe. Any patents that may issue in the United States based on the pending PCT application will expire no earlier than 2038, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2038.

We have orphan drug designation for TLX101 in the United States and Europe which will grant us the customary regulatory exclusivity, currently expected to be up to seven years from date of product approval.

TLX591 (^{177}Lu rosopatamab tetraxetan)

We have sub-licensed a Cornell University (and associated entities) patent portfolio from BZL Biologics LLC directed to TLX591 and combination therapies of TLX591 with androgen deprivation therapy.

The sub-licensed patent portfolio includes one U.S.-issued patent, one pending U.S. non-provisional patent application, 14 foreign-issued patents in Belgium, Canada, Japan, Germany, France, Spain, the United Kingdom, Luxembourg and the Netherlands, and a pending foreign application in Europe directed to combinations with androgen deprivation therapy. Any patents that may issue in the United States will expire no earlier than 2028, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2028.

As a biological product, TLX591 will be entitled to 12 years data exclusivity from the date of product approval.

TLX592 (^{225}Ac-RADmAb®)

We have a single patent family patent directed to the composition of matter of TLX592, its radiolabeled forms and uses in imaging and therapy. The patent family includes one pending U.S. non-provisional patent application and 16 pending foreign patent applications in Canada, Chile, China, India, Japan, Korea, Mexico, Australia, Europe, Eurasia, India, New Zealand, Brazil, Hong Kong, Israel and Singapore. Any patents that may issue in the United States will expire no earlier than 2040, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2040.

TLX592 is currently in early development so regulatory pathway to product approval is not yet confirmed or know, however the customary regulatory exclusivity period is expected to apply.

TLX300-CDx (^{89}Zr-girentuximab) and TLX300.

We have four pending international applications filed under the PCT directed to radiolabeled forms of olaratumab and their use in imaging and therapy. Any patents that may issue in the United States will expire no earlier than

2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2043.

TLX66-CDx (^{99m}Tc-besilesomab, Scintimun) and TLX66 (^{90}Y-besilesomab)

We have one patent family directed to the use of TLX66 in the treatment of multiple myeloma. The patent family includes one U.S.-issued patent and foreign-issued patents in Canada, Australia, and Europe (validated in Belgium, Germany, Spain, France, the United Kingdom and Italy). The U.S. patent has a maximum expiry date of 2031, not including any patent term extension under the Hatch-Waxman Act. The other patents will expire no earlier than 2026.

A second patent family is directed to the use of TLX66 for treating AL-amyloidosis and for specific bone-marrow conditioning. We have one pending U.S. non-provisional patent application and pending applications in China, Japan and Canada.

The second family includes a granted patent in Europe which has been validated under the unitary patent system (which covers seventeen European countries and includes coverage of Belgium, Germany, France, and Italy) and has also been validated in Switzerland, Spain, and the United Kingdom. There are also foreign-issued patents in Australia and South Africa.

Any patents in the United States that may issue in the second family will expire no earlier than 2038, not including any terminal disclaimer, patent term adjustment, or patent term extensions under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2038.

We do not have patent families directed to the use of TLX66-CDx (Scintimun).

Lightpoint Medical

In connection with our acquisition of Lightpoint's radio-guided surgery business, we acquired a patent portfolio relating to surgical applications of radiopharmaceuticals including the SENSEI probe. The patent portfolio comprises four U.S.-issued patents, 22 foreign-issued patents in Australia, Belgium, Luxembourg, Switzerland, Germany, Italy, France, the Netherlands, Spain and the United Kingdom, four pending non-provisional U.S. applications, and four pending foreign applications in China and Europe. Any patents issued or that may issue based on the pending applications in the United States will expire no earlier than 2033, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2033.

TLX090 (^{153}Sm-DOTMP)

We have in-licensed three patent families from IGL Pharma, Inc in connection with our acquisition of QSAM Biosciences, Inc., which are directed to methods of manufacturing TLX090, kits comprising TLX090, and its use in treatment. The portfolio includes four U.S.-issued patents, 39 foreign-issued patents in Canada, Germany, France, Great Britain, Hungary, Ireland, Iceland, Italy, Luxembourg, the Netherlands, Norway, Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, Poland, Portugal, Slovakia, Slovenia, Sweden, Switzerland, Turkey and Japan, two pending non-provisional U.S. patent applications and three pending foreign patent applications in Japan and Europe. Any patents issued or that may issue based on the pending applications in the United States will expire no earlier than 2035, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2035.

Collaboration and License Agreements

Advanced Nuclear Medicine Ingredients SA

In December 2018, we acquired Advanced Nuclear Medicine Ingredients, or ANMI, including the pre-cursor kit that was ultimately developed to become Illuccix. We paid A$2.7 million in cash and issued 6,090,805 ordinary shares, based on a share price of A$0.637 per share, in connection with the closing of the acquisition.

We are obligated to make deferred earn-out payments to former shareholders of ANMI on an annual basis equal to a percentage in the low teens of net sales of Illuccix in the United States and equal to a percentage in the low twenties of net sales of Illuccix outside the United States, in each case until April 13, 2027, which is five years following the first commercial sale of Illuccix in the United States. We hold an option to buy out the remaining deferred payments by paying €10 million within 90 days of April 13, 2025.

Heidelberg License Agreement

On January 16, 2017, we entered into a license agreement, or, as amended, the Heidelberg License, with Wilex AG (now Heidelberg Pharma AG, or Heidelberg), pursuant to which Heidelberg granted us an exclusive, royalty-bearing license under certain patents and know-how to develop, manufacture and commercialize the CAIX-targeting girentuximab antibody, or girentuximab, radio-labeled with an isotope in both diagnostic and therapeutic products. We paid Heidelberg US$250,000 in connection with the execution of the Heidelberg License and initial technology transfer. In addition, from 2018 to 2022, we have paid Heidelberg US$1.25 million for achievement of certain manufacturing and regulatory milestones for IND approval and enrollment of the last patient in a Phase 3 clinical trial. Under the agreement, we are obligated to pay milestone payments to Heidelberg of US$2.4 million in the aggregate with payment owed upon FDA approval for a BLA for a diagnostic product and upon first reimbursements for first indication of a diagnostic product. Under the Heidelberg License, Heidelberg retained the right to develop and commercialize products that contain girentuximab that are not radio-labeled. In the event we intend to file a BLA for a therapeutic product that includes girentuximab, we are obligated to notify Heidelberg and may be required to pay up to US$3.0 million to extinguish any of Heidelberg's retained rights that have been granted to a third party for co-promotion of girentuximab in the United States. In the event of commercial launch of a diagnostic product, we are obligated to pay Heidelberg royalties in the low twenties on net sales of such product by us or a sublicensee during the first ten years of such sales and mid single-digit royalties on net sales of such product during the second ten years of such sales. In the event of commercial launch of a therapeutic product, we are obligated to pay Heidelberg low single-digit royalties on net sales of such product during the first ten years of such sales. Our obligation to pay royalties on net sales of diagnostic products expires 20 years after first commercial sale of each diagnostic product and our obligation to pay royalties on therapeutic products expires ten years after first commercial sale of each therapeutic product. We are obligated to use commercially reasonable efforts to develop products for regulatory approval worldwide subject to certain excepted countries for therapeutic products. The Heidelberg License expires when we cease selling products subject to the license granted thereunder, subject to customary termination provisions regarding material breach by or bankruptcy of either party. In addition, we can terminate the agreement upon 180 days' written notice for any reason. In the event of termination of the agreement for Heidelberg's material breach or bankruptcy, we have the option to purchase intellectual property relating to the products for nominal consideration.

On March 1, 2024, Heidelberg assigned its rights and obligations under the Heidelberg License to HDP G250, AG & Co. KG, a wholly owned subsidiary of Heidelberg. In connection with the assignment, the subsidiary agreed to perform all obligations of Heidelberg under the Heidelberg License. On March 4, 2024, Heidelberg announced that it entered into a royalty financing agreement with HealthCare Royalty Partners relating to royalty payments that Heidelberg is entitled to receive from us under the Heidelberg License.

Olaratumab License Agreement

In April 2022, we entered into a license agreement, or the Lilly License, with Eli Lilly Kinsale Limited, or Lilly, pursuant to which Lilly granted us an exclusive, royalty-bearing license under certain patents and know-how directed to its proprietary antibody, olaratumab, to develop, manufacture and commercialize radio-labeled forms of olaratumab for the diagnosis and treatment of human cancers. Under the Lilly License, we are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize radio-labeled forms of olaratumab in several major markets. As consideration for the Lilly License, we paid Lilly an upfront payment of US$5.0 million and are obligated to pay up to a total of US$225.0 million upon satisfaction of specified clinical, regulatory and commercial milestones. In the event of launch of a commercial product, we are also obligated to pay Lilly royalties in the low teens based on net sales of products, with the royalty term being, on a product-by-product and country-by-country basis, the latest of (i) the 12th anniversary of the first commercial sale of such product in such country, (ii) the first day on which there is not at least one of Lilly's patents covering such product in such country, or (iii) the expiration of the last-to-expire data exclusivity period for such product

in such country, which we refer to as the Telix Royalty Term. The royalties may also be subject to reductions during the Telix Royalty Term in the event the product is not covered by a valid claim of a licensed patent or in the event we are required to obtain a license from a third party to commercialize the product. In addition to the foregoing royalties on net sales of products, we are obligated to pay Lilly a percentage of any sublicense revenue received pursuant to any sublicense or similar agreement. The Lilly License defines sublicense revenue to include amounts paid for milestones similar to the milestones specified in the Lilly License, but solely to the extent such amounts are above the amount paid to Lilly under the Lilly License, and further defines sublicense revenue to exclude royalties calculated on the basis of sales of the product for which royalties are already due under the Lilly License, reimbursement for patent costs, certain profit sharing payments and any equity or debt investment at fair market value. The Lilly License further specifies that the royalty owed on such sublicense revenue varies based on the date we enter into such sublicense or similar agreement, ranging from mid-teens if entered into within one (1) year of the effective date of the Lilly License down to mid-single digits if entered into following the third (3rd) anniversary of the effective date of the Lilly License.

Under the Lilly License, we also granted Lilly an option to enter into an exclusive license under certain patents and know-how to develop, commercialize and otherwise exploit a companion diagnostic for use with olaratumab, or the companion diagnostic option. To exercise the companion diagnostic option, Lilly is obligated to pay us an option exercise fee of US$5.0 million and would be obligated to pay up to a total of US$30.0 million upon satisfaction of specified regulatory milestones. In the event of launch of a companion diagnostic, Lilly would pay us low single digit royalties on net sales of its products incorporating olaratumab, or Lilly Products, for the labeled use for the treatment of human cancer and mid-single digit royalties on net sales of companion diagnostics, with the royalty term being, on a product-by-product and country-by-country basis, the latest of (i) the 12th anniversary of the first commercial sale of such Lilly Product or companion diagnostic in such country, (ii) the first day on which there is not at least one of our patents covering such Lilly Product or companion diagnostic in such country, or (iii) the expiration of the last-to-expire data exclusivity period for such Lilly Product or companion diagnostic in such country, or the Lilly Royalty Term. The royalties may also be subject to reductions during the Lilly Royalty Term in the event the Lilly Product or companion diagnostic is not covered by a valid claim of a licensed patent or in the event Lilly is required to obtain a license from a third party to commercialize the product.

The Lilly License continues until the expiration of the last-to-expire Telix Royalty Term or, if Lilly exercises the companion diagnostic option, the Lilly Royalty Term, subject to customary termination provisions regarding material breach by or bankruptcy of either party. Each party, in its capacity as the licensee, may terminate the agreement with respect to the licenses granted to it upon 30 days' written notice to the other party. Lilly may terminate the agreement if a patient has not been enrolled in a Phase 1 or Phase 2 clinical trial using the companion diagnostic by April 8, 2025. If Lilly exercises the companion diagnostic option, we may terminate the agreement if no patient has qualified for enrollment into a registrational study of the Lilly Product for use by patients that have been screened using the companion diagnostic within two years of the date that Lilly exercised the companion diagnostic option.

Lightpoint Medical Share Sale Agreement

In June 2023, we entered into a share sale agreement to acquire the SENSEI business from Lightpoint. We completed the acquisition of Lightpoint on November 1, 2023. The acquisition was implemented through the purchase of Lightpoint Medical Limited's wholly owned subsidiary, Lightpoint Surgical Limited, as the then owner of Lightpoint's business, assets and operation. We paid upfront consideration of US$20.0 million, of which we paid US$19.6 million through the issuance of 3,298,073 ordinary shares at a price of A$9.3659 per share. We are obligated to pay an additional US$15.0 million via an earn-out in the form of performance rights, which may be settled in cash or ordinary shares, at our option, upon achievement of regulatory, commercial and operational milestones relating to the ongoing development and commercialization of SENSEI.

Strategic License and Commercial Partnership with Grand Pharma

In November 2020, we entered into a strategic partnership with Grand Pharma, pursuant to which we appointed Grand Pharma as our partner with exclusive development and commercialization rights to our portfolio of imaging and therapeutic products and product candidates in Mainland China, Taiwan, Hong Kong and Macau, or the Grand Pharma Territory. As part of the strategic partnership, we entered into an Imaging Products Commercialization Agreement and a Therapeutic Products License Agreement with Grand Pharma.

Pursuant to the Imaging Products Commercialization Agreement, we appointed Grand Pharma as our exclusive commercial partner in the Grand Pharma Territory for Illuccix and TLX250-CDx. The Imaging Products Commercialization Agreement includes minimum annual purchase obligations of Grand Pharma following marketing authorization in applicable regions in the Grand Pharma Territory in order to maintain exclusivity in the Grand Pharma Territory. There are currently no approved imaging products in the Grand Pharma Territory under the Imaging Products Commercialization Agreement.

The Imaging Products Commercialization Agreement has a 15-year term for each product beginning on the date of marketing authorization in China and the agreement will automatically renew for five-year renewal terms unless either party gives a written notice of nonrenewal. Either party may terminate the Imaging Products Commercialization Agreement upon material breach or insolvency by the other party.

Pursuant to the Therapeutic Products License Agreement, Grand Pharma is responsible, at its own cost, for conducting any clinical trials of therapeutic products in the Grand Pharma Territory in accordance with the agreed development plan. Pursuant to the Therapeutic Products License Agreement, we are eligible to receive payments of up to US$69.0 million upon achievement of regulatory milestones with respect to therapeutic products by Grand Pharma and up to US$156.0 million upon achievement of commercial milestones with respect to therapeutic products by Grand Pharma. We are also eligible to receive single-digit percentage royalties on net sales of therapeutics products in the Grand Pharma Territory for ten years after marketing authorization is granted in the Grand Pharma Territory. There are currently no approved therapeutic products in the Grand Pharma Territory and we have not received any milestone payments from Grand Pharma under the Therapeutic Products License Agreement.

We received an upfront, non-refundable cash payment of US$25.0 million upon execution of the Therapeutic Products License Agreement. This upfront payment will be credited against any regulatory or commercial milestone payments owed to us by Grand Pharma.

The Therapeutic Products License Agreement has a ten-year term ending after the date that marketing authorization is granted in respect of each product. Either party may terminate the Therapeutic Products License Agreement upon material breach or insolvency by the other party.

Agreement and Plan of Merger with IsoTherapeutics Group, LLC

On February 27, 2024, we entered into an agreement and plan of merger, or the IsoTherapeutics Agreement, to acquire IsoTherapeutics Group, LLC, or IsoTherapeutics, a specialty radiopharmaceutical development and bioconjugation firm, based in Texas. IsoTherapeutics provides radiochemistry and bioconjugation development and contract manufacturing services to many companies in the radiopharmaceutical industry. We completed the acquisition of IsoTherapeutics on April 9, 2024.

We expect that the acquisition will further enhance our internal drug development capabilities. A key driver for the acquisition is to enable us to internalize select aspects of our development programs, with the goal of reducing cost and time to achieve technical milestones. The acquisition expanded our U.S. manufacturing footprint with a site that includes a GMP clean room and production infrastructure suitable for clinical use. The site also has extensive capacity to process a wide variety of therapeutic isotopes used in our development portfolio.

IsoTherapeutics will continue to provide development and manufacturing services to its existing customer base and may continue to provide services to our strategic partners and collaborators. We aim to realize cost savings from internalizing radiochemistry-related R&D activities.

The purchase price for the acquisition consists of (i) US$8.1 million paid at closing in the form of US$2.1 million in cash and US$6.0 million in our ordinary shares, (ii) US$5.0 million in performance-related milestone payments, which are payable in cash and are subject to meeting certain milestone conditions within 12 months of closing, and (iii) a two-year revenue share that is based on actual revenue earned from existing customers of IsoTherapeutics, which we estimate will require total cash payments of approximately US$0.6 million. The upfront cash consideration is subject to customary working capital, debt and transaction expense adjustments. The number of shares issued at closing was determined by converting US$6.0 million to Australian dollars using the Reserve Bank of Australia exchange rate at closing and dividing that amount by the volume weighted average price at which our ordinary shares traded on the ASX over the 10-trading day period prior to closing. The shares issued at closing are subject to voluntary escrow restrictions.

Share Purchase Agreement with ARTMS Inc.

On March 5, 2024, we entered into a share purchase agreement, or the ARTMS Agreement, to acquire ARTMS Inc., or ARTMS, a radioisotope production technology company based in Canada, and its advanced cyclotron-based isotope production platform, manufacturing plant and stockpile of ultra-pure rare metals required for consumable target production. We completed the acquisition of ARTMS on April 11, 2024. ARTMS is a commercial-stage company that specializes in the physics, chemistry and materials science of cyclotron-produced radionuclides and its technology is used by major manufacturing networks to optimize production of a range of medical radioisotopes. We expect that the acquisition will further enhance the vertical integration of our supply chain and manufacturing by providing a greater level of control and security over each of our diagnostic isotopes.

ARTMS' core technology platform is based on the QUANTM Irradiation System, or QIS, a complete cyclotron-based isotope production system that is designed to support high efficiency and cost-effective production of commercially important medical isotopes including Zirconium-89, Gallium-68, Technetium-99m and Copper-64. We also expect that its advanced cyclotron technologies will have immediate application and differentiation in the production of future commercially important alpha-emitting, therapeutic isotopes, including Actinium-225 and Astatine-211.

We believe that QIS may be able to produce Zirconium-89 that is ready for radiopharmaceutical use with TLX250-CDx by irradiating Yttrium-89. ARTMS also holds a stockpile of Zinc-68, which is used to produce Gallium-68 that could be used with Illuccix. Following closing of the acquisition, we intend to work with pharmacy networks and partners to enhance the reliability and routine production of commercially useful cyclotron-produced diagnostic radionuclides such as Copper-64 and Technetium-99. In particular, ARTMS has a stockpile of Nickel-65, an essential raw material for Copper-64 production, and which is in limited global supply. As part of the acquisition, we also acquired ARTMS' production facility and clean rooms, located in Burnaby, British Columbia. We plan to continue to operate and expand ARTMS' R&D and production capabilities at the Burnaby location to support our in-house and customer needs, subject to applicable laws and transaction terms.

The purchase price for the acquisition consists of: (i) US$57.5 million upfront consideration, US$15.0 million of which we paid in cash and the balance of which we paid in the form of 5,674,635 of our ordinary shares issued at closing, (ii) US$24.5 million in contingent future earn out payments, payable in cash following achievement of certain regulatory and commercial milestones, and (iii) cash earnouts representing low teens percentage royalties based on net sales of ARTMS products and related services and representing low single-digit percentage royalties based on net sales of Telix products prepared using ARTMS products for up to three years depending on the product location where the sale occurs. All earn-out royalties which have not otherwise expired will terminate on the 10-year anniversary following closing of the ARTMS acquisition. The cash upfront consideration is subject to customary working capital, debt and transaction expense adjustments. The shares issued at closing are subject to voluntary escrow restrictions.

Agreement and Plan of Merger with QSAM Biosciences, Inc.

On February 7, 2024, we entered into an Agreement and Plan of Merger, or the QSAM Agreement, with QSAM Biosciences, Inc., or QSAM, and we completed the acquisition of QSAM on May 3, 2024.

QSAM is developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer. Its lead product candidate is Samarium-153-DOTMP, or ^{153}Sm-DOTMP, which is a novel kit-based bone-seeking targeted radiopharmaceutical candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. ^{153}Sm-DOTMP, which we have designated as TLX090, has two potential applications – pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090 is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma.

TLX090 has shown evidence of safety, efficacy and future commercial utility in pre-clinical studies and early clinical trials. We believe that it has the potential to deliver significant improvements on prior bone-seeking agents in the treatment and management of late-stage metastatic disease. TLX090 may enable the pain management of prostate cancer bone metastases, where there remains a significant unmet patient need particularly after progression from other forms of radionuclide and radiation therapy. We also believe that TLX090 may benefit patients with metastatic lung and breast cancer, where many patients develop brain and bone metastases, and disease management often focuses on quality-of-life palliative care.

TLX090 has also been granted orphan drug and rare pediatric disease designations by the FDA for the treatment of osteosarcoma. The rare pediatric disease designation may enable TLX090 to be brought to market more rapidly through regulatory incentives, including eligibility for a pediatric rare disease priority review voucher that may be applied to this or other programs. The orphan drug designation and the rare pediatric disease designation do not increase the likelihood of marketing approval.

The total consideration, calculated based on the announced purchase price, for the acquisition consists of: (i) US$33.1 million upfront consideration, US$27.8 million of which was paid in closing consideration through the issuance of 3,671,120 ordinary shares, and the balance of which was paid in certain cash adjustments or through the issuance of approximately 409,026 of our ordinary shares in change of control fees, transaction bonuses and holdback shares reserved for settlement of purchase price adjustments and (ii) up to US$90.0 million in contingent future earn-out payments, in cash and/or ordinary shares, without interest, upon the achievement of certain regulatory and commercial milestones, at the times and subject to the terms and conditions of the contingent value rights agreement. The ordinary shares issued upon closing are subject to voluntary escrow conditions. The ordinary shares issued as part of the upfront purchase price were issued pursuant to an exemption from registration under the Securities Act, in reliance on Section 4(a)(2) and Regulation D thereunder, as a transaction by an issuer not involving a public offering.

Stock Purchase Agreement with RLS (USA) Inc.

On September 20, 2024, we entered into a stock purchase agreement, or the RLS Agreement, to acquire RLS. The purchase price for the acquisition consists of: (i) US$230.0 million upfront consideration, payable in cash at closing of the acquisition, which amount will be adjusted for transaction expenses, cash and cash equivalents (net of restricted cash), debt and debt equivalents and working capital, and (ii) milestone payments of up to US$20.0 million in the aggregate, payable in cash upon the achievement of certain commercial milestones. We expect to fund the purchase price and related transaction costs from existing cash reserves. We expect the acquisition to close in the first quarter of 2025, subject to the satisfaction of closing conditions.

RLS is a U.S.-based radiopharmacy company distributing PET, SPECT and therapeutic radiopharmaceuticals. Its network includes 31 licensed radiopharmacies located in major metropolitan areas in 18 states across the United States. The RLS footprint includes over 100,000 square feet of licensed expansion space that we believe can be utilized to meet rapidly growing production demand. RLS has approximately 1,500 customers and currently is one of the distributors of Illuccix in the United States.

The acquisition, if consummated, will significantly expand our North American manufacturing footprint and establish the basis of a next generation radiometal production network. By augmenting our existing distribution network with RLS' capabilities, we aim to provide additional supply chain back-up and improve capacity to meet future demand, while broadening access for patients across the entire U.S. market, including under-served populations. We believe the acquisition of RLS is highly aligned with our investment strategy to strengthen our vertically integrated supply chain and manufacturing and distribution capabilities. We expect the acquisition to provide a pathway for deploying ARTMS' QIS technology by enabling us to scale up the production of key isotopes and build a stable and consistent supply of PET and SPECT diagnostic tracers, along with therapeutic radiopharmaceuticals across the United States.

Following closing of the acquisition, RLS will continue to service its existing customer base and will operate as part of our Manufacturing Services business, which includes ARTMS, IsoTherapeutics, Optimal Tracers and our manufacturing facility in Brussels South, Belgium. We expect that RLS will become a key node in our network of U.S. manufacturing and distribution partnerships and is geographically complementary to our manufacturing facility in Belgium.

The closing of the acquisition is subject to various conditions set forth in the RLS Agreement, including regulatory approvals, RLS shareholder approval, license transfers and certain-third party consents. The RLS Agreement also provides the parties with customary rights to terminate the RLS Agreement in certain circumstances, including by mutual written consent of us and RLS or by either party if the acquisition has not been consummated by February 17, 2025, in each case on the terms set forth in the RLS Agreement.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, or EU, extensively regulate, among other things, the research,

development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biologics in the United States

In the United States, the FDA approves and regulates drugs under the FDCA and related regulations. Biological products are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations. Pursuant to Section 3621 of the Consolidated Appropriations Act of 2023, which was signed into law on December 29, 2022, contrast agents and radioactive pharmaceuticals are regulated as drugs or biologics.

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the United States must typically secure the following:

- completion of preclinical laboratory tests in compliance with the FDA's good laboratory practice, or GLP, standards and applicable regulations;
- design of a clinical protocol and submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCPs to establish the safety and efficacy of the proposed drug product for each proposed indication or with respect to biologics, the safety, purity and potency of the product candidate for each proposed indication;
- submission to the FDA of an NDA for a drug candidate product and a BLA for a biological product requesting marketing for one or more proposed indications;
- review of the request for approval by an FDA advisory committee, where appropriate or if applicable;
- completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMPs to assure the product's identity, strength, quality and purity;
- completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before a sponsor begins testing a drug or biologic compound with potential diagnostic or therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured substance or active pharmaceutical ingredient and the formulated product, as well as *in vitro* and animal studies to assess the safety and activity of the product candidate for initial testing in humans and to establish a rationale for therapeutic use. These studies are generally referred to as IND-enabling studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP standards and regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is a request for FDA authorization to administer a product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects and patients will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue, if the clinical hold is initiated after the study has begun. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency.

A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical protocol or protocols under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols or parts of the protocols may do so. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise demonstrating to the satisfaction of the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval in the United States. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, or DSMB, or committee. This group provides authorization for whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

The clinical investigation of an investigational drug or biological product is generally divided into four phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The four phases of an investigation are as follows:

- Phase 1. Phase 1 studies include the initial introduction of an investigational new drug or biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug or biological product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug or biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug or biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug or biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug or biological product, and to provide an adequate basis for product approval.
- Phase 4. Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

In March 2022, the FDA released final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

In December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a DAP for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

In June 2023, the FDA issued draft guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical

trials to facilitate the development of medical products. The draft guidance is adopted from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's, or ICH's, recently updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In addition, the FDA issued draft guidance outlining recommendations for the implementation of decentralized clinical trials.

Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to US$10,000 for each day the violation continues. Although the FDA has historically not enforced these reporting requirements due to the long delay by HHS in issuing final implementing regulations, those regulations have now been issued and the FDA has issued several pre-notices for voluntary corrective action and several notices of non-compliance during the past two years. These notices of non-compliance did not result in civil monetary penalties.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the candidate product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Interactions with the FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. With passage of FDORA, Congress clarified FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND (Pre-IND meeting), at the end of Phase 2 clinical trial (EOP2 meeting) and before an NDA is submitted (Pre-NDA meeting). Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-NDA meetings as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A type D meeting is focused on a narrow set of issues (should be limited to no more than 2 focused topics) and should not require input from more than 3 disciplines or Divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such

recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Manufacturing and Other Regulatory Requirements

Concurrently with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate, and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Specifically, the FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Pediatric Studies

Under PREA, an application or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit an initial Pediatric Study Plan, or PSP, prior to the assessment data. The PSP must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has recently taken steps to limit what it considers abuse of this statutory exemption.

The Food and Drug Administration Reauthorization Act of 2017, or FDARA, also established new requirements to govern certain molecularly targeted cancer indications. Any company that submits an application three years after the date of enactment of that statute must submit pediatric assessments with the application if the product is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under

Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) thus authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved as well as for any new indication sought by the Section 505(b)(2) applicant.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation. None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to help the sponsor design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

With passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The agency indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Submission and Review of an NDA or BLA by the FDA

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls, safety updates, patent information, abuse information, and proposed labeling, are submitted to the FDA as part of an application requesting approval to market the product candidate for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of a drug product, and potency, purity and safety of a biologic product, to the satisfaction of the FDA.

The fee required for the submission and review of an application under PDUFA is substantial (for example, for fiscal year 2024, this application fee is US$4,048,695), and the sponsor of an approved application is also subject to an annual program fee, which for fiscal year 2024 is US$416,734 per eligible prescription product. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the sponsor is a small business submitting its first human drug application for review.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, the FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that the FDA determines that an application does not satisfy this standard, it will issue an RTF determination to the applicant. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information, or analyses needed to evaluate safety and efficacy or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an application to extend beyond the PDUFA goal date.

In connection with its review of an application, the FDA may submit information requests to the sponsor and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer an application, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval.

The FDA also may require submission of a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS and the FDA will not approve the application without a REMS.

The FDA's Decision on an NDA or BLA

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either a Complete Response Letter, or CRL, or an approval letter. To reach this determination, the FDA must evaluate

whether the expected benefits of the proposed product outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the body of evidence about the product's safety and efficacy in the NDA or BLA.

If the FDA decides not to license or approve the application, it will issue a CRL. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots (where applicable), and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six month extension to respond. For those seeking to challenge the FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Under the Ensuring Innovation Act, which was signed into law in April 2021, the FDA must publish action packages summarizing its decisions to approve new drug products within 30 days of approval of such products. To date, CRLs are not publicly available documents.

Post-Approval Regulation

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;

- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs, BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act, or PIE Act, in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance, but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products. In October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Generic Drugs and Regulatory Exclusivity

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs and it also enacted Section 505(b)(2). To obtain approval of a generic drug, a sponsor must submit an ANDA to the FDA. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug, and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, the FDA has consistently taken the position that an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been

granted, a generic or follow-on drug application may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, a sponsor submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

As part of the submission of an NDA or certain supplemental applications, NDA sponsors are required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. The FDA's regulations governing patient listings were largely codified into law with enactment of the Orange Book Modernization Act in January 2021. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book. Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the generic drug or follow-on drug applicant does not challenge the innovator's listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new generic product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent and a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

Biosimilars and Regulatory Exclusivity

The ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, the FDA has approved a number of biosimilars and several interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the

biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. In December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the product candidate and its potential use. Orphan drug designation does not shorten the regulatory review and approval process, although it does convey certain advantages such as tax benefits and user fee exemptions.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug or biologic for the same disease or condition for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. If a drug or biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan exclusivity will not bar approval of another product under certain circumstances, including if a company with orphan drug exclusivity is not able to meet market demand and in cases where a subsequent product with the same drug or biologic for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity. For drug products, the six-month exclusivity may be attached to the term of any existing patent or regulatory exclusivity. For biologic products, the six-month period may only be attached to any existing regulatory exclusivities but not to any patent

terms. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of non-patent exclusivity for drugs and biologics, or patent protection that covers a drug product, are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND approval and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

U.S. Regulation of Medical Devices

The FDCA defines a medical device in pertinent part to include any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or to affect the structure or function of the body. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States. In addition to traditional devices, like surgical tools, the FDA regulates certain software, including artificial intelligence and machine learning algorithms, as medical devices depending on their intended use.

Device Classification

The FDA categorizes medical devices into one of three classes—Class I, II, or III—based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device's safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events or certain malfunctions, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

PMA Pathway

Class III devices generally require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of "valid scientific evidence" to the FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Following receipt of a PMA, the FDA determines whether the application is

sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. As part of the FDA's review of a PMA, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose requirements related to design controls, manufacturing controls, documentation and other quality assurance procedures. The user fee costs and the length of FDA review time for obtaining PMA approval are significantly higher than for a 510(k) notification or a *de novo* classification.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

510(k) Notification Pathway

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months, but often takes longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, discussed below.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why

a new 510(k) is not required. However, if the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified under the FDCA into Class III, which generally requires PMA approval. However, the FDA can reclassify or a sponsor can seek *de novo* classification for a novel device that is low to moderate risk and would otherwise meet the FDCA standards for a Class I or Class II device, permitting the device to be marketed without PMA approval.

De Novo Classification

The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could be eligible for *de novo* classification only if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent to a legally marketed predicate device. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low to moderate risk, or that general controls would be inadequate to control the risks and special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

Investigational Device Exemption Process

Clinical trials are almost always required to support a PMA and *de novo* classification and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the

clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements.

Expedited Development and Review Programs for Medical Devices

The FDA has implemented a Breakthrough Devices Program, which is a voluntary program offering manufacturers of certain devices an opportunity to interact with the FDA more frequently and efficiently as they develop their products with the goal of expediting commercialization of such products to help patients have more timely access. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and constitutes a device (i) that represents a breakthrough technology, (ii) for which no approved or cleared alternatives exist, (iii) that offer significant advantages over existing approved or cleared alternatives, or (iv) the availability of which is in the best interest of patients. Devices granted Breakthrough Device designation are eligible to rely on certain features of the Breakthrough Device Program, including interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design and priority review of premarket submissions.

Postmarket Regulation of Medical Devices

After a device is cleared or approved by the FDA for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes subject to FDA oversight are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product

does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Under the Outpatient Prospective Payment System, or OPPS, the costs associated with diagnostic radiopharmaceuticals have been packaged into the payment for the nuclear medicine tests with which they are used. In July 2024, CMS recognized that in certain instances the payment amount for the nuclear medicine tests may not adequately account for the cost of certain specialized diagnostic radiopharmaceuticals, even when those agents may be the most clinically appropriate. Accordingly, CMS proposed to revise its policies so as to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 and removing such costs from the payment amounts for the nuclear medicine tests. Any diagnostic radiopharmaceutical with a per-day cost equal to or below that threshold would continue to be policy-packaged, with costs incorporated into the payment rates for the nuclear medicine tests. The 60-day comment period for this proposal ended on September 9, 2024, and CMS has indicated that the final rule will be issued in early November 2024 and become effective in January 2025.

Healthcare Compliance

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to healthcare providers and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchase, order, or arranging for or recommending the purchase or order of a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers and teaching hospitals to CMS within the HHS for re-disclosure to the public, as well as ownership and investment interests held by physicians (as defined by statute) and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of drug products, limiting coverage and reimbursement for medical products and other changes to the healthcare system in the United States.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for pharmaceutical products under government healthcare programs. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers, which went into effect in April 2013 and will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Pursuant to subsequent legislation, these Medicare sequester reductions were suspended and reduced in 2021 and 2022 but, as of July 1, 2022, the full 2% cut has resumed. Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Act delays the 4% Statutory Pay-As-You-Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into FY 2032 and lowers the payment reduction percentages in FYs 2030 and 2031.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden rescinded those orders and issued a new executive order that directs federal agencies to reconsider rules and other policies that limit access to healthcare, and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance

Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and under the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a SIP to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, several states had submitted Section 804 Importation Program proposals to the FDA. On January 5, 2023, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The order directs the HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (i) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (ii) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (iii) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated US$4,000 a year in 2024 and, thereafter beginning in 2025, at US$2,000 a year. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 and the second cycle will commence in the fall of 2024.

On June 6, 2023, Merck filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, and wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs. These measures could reduce the ultimate demand for our product candidates, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Regulation by the Nuclear Regulatory Commission of Radionuclides Used for Medical Purposes

The Nuclear Regulatory Commission, or NRC, and the FDA share federal responsibility for the regulation of medical devices, drugs and biological products that utilize radionuclides. In August 1993, the two agencies established a Memorandum of Understanding, or MOU, outlining the respective responsibilities of each agency and identifying ways in which FDA and NRC should coordinate their regulatory actions involving such products. Under the MOU, FDA maintains full responsibility for review and approval of radiopharmaceuticals under the FDCA for drugs and the PHSA for biologics. Pursuant to its authority under the Atomic Energy Act, the NRC regulates the medical use of nuclear materials to protect public health and safety and the environment.

In addition to the MOU, the NRC has issued a Medical Use Policy Statement. It provides that the NRC will: (i) continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public; (ii) not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public; (iii) when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of the radionuclides is in accordance with the physician's directions; and (iv) in developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches for achieving radiation safety.

Consistent with the MOU and to implement its Medical Use Policy, the Commission has established policies and regulations to govern the use, handling and disposal of byproduct materials for medical purposes. Specifically, the Commission regulates the medical use of byproduct material through licensing, inspection and investigation of medical, industrial, academic and commercial facilities and authorization of physician users. These regulations

are meant to provide for the radiation safety of workers, the general public, patients, and human research subjects without interfering with treatment protocols established by the physician. To that end, the rules set out procedures and standards to govern the issuance of licenses to facilities seeking to use byproduct material for medical purposes. Medical use licenses are issued by an Agreement State or, in Non-Agreement States, the NRC.

U.S. Data Privacy Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If a sponsor fails to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, it could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

In addition to potential enforcement by HHS, a sponsor is also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. Sponsors will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements.

In November 2020, California voters passed a ballot initiative for the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – the sole responsibility of which is to enforce the CPRA and other California privacy laws, which will further increase compliance risk.

In addition to California, many other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws that will go into effect in 2025 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk.

Other states have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Review and Approval of Medical Products in the European Union

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before we may commence clinical trials or market products in those countries or areas. In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Studies

Clinical trials of medicinal products in the European Union must be conducted in accordance with EU and national regulations and the ICH guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the European Union, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the European Union has been subject to recent changes. On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the European Union and repealed and replaced the prior Clinical Trials Directive 2001/20/EC. Unlike directives, the new Regulation is directly applicable in all EU member states without the need for member states to further implement it into national law. It aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union.

Under the new coordinated procedure, the sponsor of a clinical trial to be conducted in more than one member state will only be required to submit a single application. The Regulation allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU member states and the public.

Beyond streamlining the process, the new Regulation includes a single set of documents to be prepared and submitted for the application and a harmonized procedure for the assessment of applications for clinical trials,

which is divided in two parts. Part I is subject to a coordinated review by competent authorities of all EU member states in which an application for authorization has been submitted (member states concerned). One of the member states concerned (the reporting member state) prepares a draft assessment report which is submitted to other member states concerned for their joint review, allowing for a single assessment report to be issued at the term of the assessment process. Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications, or CTAs. The role of the relevant ethics committees in the assessment procedure will continue to be governed at national levels; however, overall related timelines are set out under the Clinical Trials Regulation. The Regulation also provides for simplified reporting procedures for clinical trial sponsors.

All ongoing clinical trials in the European Union approved under the prior Clinical Trials Directive must be transitioned to the Clinical Trials Information System by January 31, 2025. This date marks the end of a three-year transition period that began when the Clinical Trials Regulation became applicable in the European Union on January 31, 2022. Clinical trials that were started under the Clinical Trials Directive and are subject to transition to the Clinical Trials Regulation will by January 31, 2025 have to comply with the obligations of the Clinical Trials Regulation even if these are not included in the previous study protocol, such as (i) obligations of notification via the Clinical Trials Information System; (ii) safety reporting rules; (iii) archiving requirement; and (iv) transparency requirements. Failure to transition ongoing clinical trials to the Clinical Trials Regulation by January 31, 2025 can result in corrective measures under Article 77 of the Clinical Trials Regulation, including revocation of the authorization of the clinical trial or suspension of the clinical trial, as well as criminal sanctions and fines under national law of EU Member States.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the European Union at the EudraCT website.

Marketing Authorization

In order to market our product candidates in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the European Union, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs: "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and are valid throughout the European Union. The centralized procedure is compulsory for certain types of medicines such as (i) medicinal products developed by specified biotechnological processes, (ii) products designated orphan medicinal products, (iii) advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines), and (iv) products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that represent a significant therapeutic, scientific, or technical innovation, or whose authorization would be in the interest of public health.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

"National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU member state (which acts as the reference member state), in accordance with the national procedures of that member state. Following this, further MAs can be progressively sought from other EU member states in a procedure whereby the member states concerned agree to recognize the validity of the original, national MA produced by the reference member state. Under the decentralized procedure, if the product has not received a national MA in any member state at the time of application, a sponsor may apply for simultaneous authorization in more than one

EU member state. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Conditional Marketing Authorization

In particular circumstances, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. A conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. Conditional MAs are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional MA, but sponsors can also request the EMA to conduct an accelerated assessment, for instance in cases of unmet medical needs.

Marketing Authorization Granted under Exceptional Circumstances

A MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Except conditional MAs, MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, sponsors have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (i) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (ii) the disease or condition occurs only in adult population; or (iii) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products

representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the CHMP or Committee for Advanced Therapies are appointed early in the PRIME scheme, facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance to the sponsor on the overall development and regulatory strategies.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety, and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Regulatory Exclusivity

In the European Union, new products authorized for marketing (*i.e.,* reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic sponsors from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic sponsor from commercializing its product in the European Union until ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Drug Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition, (ii) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment, and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term 'significant benefit' is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the European Economic Area, or the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The sponsor will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: (i) the second sponsor can establish that its product, although similar, is safer, more effective, or otherwise clinically superior; (ii) the sponsor consents to a second orphan medicinal product application; or (iii) the sponsor cannot supply enough orphan medicinal product.

Pediatric Exclusivity

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC, or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder.

Post-Approval Requirements

As in the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, and the competent authorities of EU member states. The MA holder must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. In particular, the MA holder must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The manufacturing process for medicinal products in the European Union is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU GMP standards when manufacturing medicinal products and API.

In the European Union, the advertising and promotion of approved products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising, and unfair commercial practices. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the European Union. Direct-to-consumer advertising of

prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Supplementary Protection Certificate

The European Union also provides for patent term extension through SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of 15 years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months (*see* "Pediatric Development"). Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Reimbursement and Pricing of Prescription Pharmaceuticals

In international markets including the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process, which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states.

The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

In the European Union, similar political, economic, and regulatory developments to those in the United States may affect our ability to profitably commercialize our product candidates, if approved. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of a marketing approval for a product. To obtain reimbursement or pricing approval in some countries, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the European Union, including the

establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the European Union, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing used by various EU member states, and parallel distribution and parallel trade can further reduce prices. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced member states). There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidates, if approved in those countries.

HTA of medicinal products in the European Union is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Regulation of Medical Devices in the European Union

The European Union has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices. Until May 25, 2021, medical devices were regulated by the EU Medical Devices Directive, or MDD, which has been repealed and replaced by the EU Medical Devices Regulation, or MDR. However, as of May 26, 2021, some of the MDR requirements apply in place of the corresponding requirements of the MDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements.

Medical Devices Directive

Under the MDD, all medical devices placed on the market in the European Union must meet the essential requirements laid down in Annex I to the MDD, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by

the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards and the aforementioned EU rules is generally applicable in the EEA.

Medical Devices Regulation

The regulatory landscape related to medical devices in the European Union recently evolved. On April 5, 2017, the MDR was adopted with the aim of ensuring better protection of public health and patient safety. The MDR establishes a uniform, transparent, predictable and sustainable regulatory framework across the European Union for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the MDD, the MDR is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the European Union.

The MDR became effective on May 26, 2021. In accordance with its recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the MDD prior to May 26, 2021 and (ii) legacy devices lawfully placed on the EU market after May 26, 2021 in accordance with the MDR transitional provisions may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the MDR, in particular the obligations described below.

The MDR requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date.

All manufacturers placing medical devices on the market in the European Union must comply with the EU medical device vigilance system which has been reinforced by the MDR. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs, must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the MDD continue to apply. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e.g., inadequacy in the information supplied by the manufacturer, undesirable side-effect), which, directly or indirectly, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat.

An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices are subject to some general principles set forth in EU legislation. According to the MDR, only devices that are CE marked may be marketed and advertised in the European Union in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and

comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the European Union, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The aforementioned EU rules are generally applicable in the EEA.

EU General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. In the United Kingdom, the GDPR is retained in domestic law as the U.K. GDPR and sits alongside an amended version of the U.K. Data Protection Act 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues of the respective group of companies, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

For transfers of personal data from the European Union to the United States, the European Commission has adopted an adequacy decision for the EU-US Data Privacy Framework in in July 2023. It is widely expected that this adequacy decision will be challenged in court, so uncertainties around this issue continue.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's withdrawal from the European Union took place on January 31, 2020. The European Union and the United Kingdom reached an agreement on their new partnership in the Trade and Cooperation Agreement, which was applied provisionally beginning on January 1, 2021, and which entered into force on May 1, 2021. The Trade and Cooperation Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the European Union and the United Kingdom will form two separate markets governed by two distinct regulatory and legal regimes, except that Northern Ireland will continue to broadly follow EU laws as further described below. As such, the Trade and Cooperation Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the United Kingdom is no longer part of the single market. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or

MHRA, became responsible for supervising medicines and medical devices in Great Britain, or GB, comprising England, Scotland, and Wales under domestic law whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol.

On February 27, 2023, the U.K. government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA will be responsible for approving all medicinal products destined for the U.K. market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single U.K.-wide MA will be granted by the MHRA for all medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. The Windsor Framework was approved by the EU-U.K. Joint Committee on March 24, 2023, so the U.K. government and the European Union will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025. The Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or HMR, is the primary legal instrument for the regulation of medicines in the United Kingdom. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

EU laws which have been transposed into U.K. law through secondary legislation continue to be applicable as "retained EU law." However, new legislation such as the (EU) Clinical Trials Regulation will not be applicable in GB. Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, MAs, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of our product candidates in the United Kingdom. For example, the United Kingdom is no longer covered by the centralized procedures for obtaining EU-wide MAs from the EMA, and a separate MA will be required to market our product candidates in the United Kingdom. A new international recognition framework has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA.

The medical device regulatory framework in GB continues to be broadly based on the requirements of the (EU) MDD as implemented into national law. On June 26, 2022, the MHRA published its response to a 10-week consultation on the future regulation of medical devices in the U.K. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the MHRA has confirmed that the core elements of the new framework are now expected to be in place in 2025, while priority measures to enhance post-market surveillance will be put in place first in 2024. Medical devices bearing CE marks issued by EU notified bodies under the (EU) MDR or (EU) MDD are now subject to transitional arrangements. Devices certified under the (EU) MDR may be placed on the market in GB under the CE mark until June 30, 2030. However, devices certified under the (EU) MDD may be placed on the market until June 30, 2028. Following these transitional periods, it is anticipated that all medical devices will require a U.K. Conformity Assessed, or UKCA, mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the mandatory deadlines. However, UKCA marking will not be recognized in the European Union. Following the transitional periods, compliance with the U.K. regulations will be a prerequisite to be able to affix the UKCA mark to medical devices, without which they cannot be sold or marketed in GB.

In addition, new regulations applicable in GB now require that all medical devices must be registered with the MHRA prior to being placed on the market. Additionally, manufacturers based outside the United Kingdom will need to appoint a U.K. Responsible Person to register devices with the MHRA.

Human Capital Resources

As of June 30, 2024, we had 424 full-time employees and 17 part-time employees. Of our 441 full and part-time employees, 20% have Ph.D. or M.D. degrees and 74% have graduate or post-graduate qualifications. 40% of our employees are engaged in research and development activities and 42% are engaged in commercialization activities. 18% are engaged in global services activities including finance, legal, risk, people and culture, information technology.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We support our employees by offering annual performance-based bonus, equity-based incentive program, employee assistance programs, paid wellness days, hybrid work arrangements and support for learning and development.

Legal Proceedings

We are not currently a party to any material legal proceedings or investigations worldwide. From time to time, we may become involved in other litigation or legal proceedings particularly relevant to defending our IP rights or in response to any relating to claims arising from the ordinary course of business.

Seasonality

We do not believe that seasonal influences have had a material effect on our business, financial condition, or results of operations. The target disease indications for Illuccix and our other product candidates are not seasonal diseases. Accordingly, once we have successfully obtained regulatory approvals to commercialize our other product candidates, if ever, we do not anticipate that our business will be materially affected by seasonal influences in the future.

C. Organizational Structure

The following table sets out for each of our subsidiaries, the state or jurisdiction of incorporation or organization, percentage ownership and voting interest held by us (directly or indirectly through subsidiaries):

Name of Entity	State or Jurisdiction of Incorporation or Organization	Percentage Ownership and Voting Interest (%)
Telix Pharmaceuticals Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals International Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals Australia Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals (Innovations) Pty Ltd	Australia	100
Telix Pharmaceuticals (ANZ) Pty Ltd	Australia	100
Telix Pharmaceuticals (Corporate) Pty Ltd	Australia	100
Telix Pharmaceuticals (NZ) Limited	New Zealand	100
Telix Pharma Japan KK	Japan	100
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100
Telix Pharmaceuticals (US) Inc.	Delaware	100
Telix Optimal Tracers LLC	Delaware	100
Telix Pharmaceuticals (Canada) Inc.	Canada	100
Telix Innovations SA	Belgium	100
Telix Pharmaceuticals (Germany) GmbH	Germany	100
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100
Telix Pharmaceuticals (Belgium) SRL	Belgium	100
Dedicaid GmbH	Austria	100
Lightpoint Surgical Ltd	United Kingdom	100
Lightpoint Surgical Spain S.L.	Spain	100
Rhine Pharma GmbH(1)	Germany	100
Therapeia GmbH & Co. KG	Germany	100
Therapeia-Verwaltungs GmbH	Germany	100
Telix Pharmaceuticals (France) SAS	France	100
Telix Pharmaceuticals (UK) Ltd	United Kingdom	100
Telix IsoTherapeutics Group Inc.	Delaware	100
Telix ARTMS Inc.	Canada	100
ARTMS US, Inc.	Delaware	100
Telix QSAM, Inc.	Delaware	100
QSAM Therapeutics Inc.	Texas	100

(1) As of the date of this registration statement on Form 20-F, Rhine Pharma GmbH is our wholly owned subsidiary. Once key milestones are achieved, we plan to restructure Rhine Pharma GmbH as an independent company.

D. Property, Plants and Equipment

Our principal headquarters are located in Melbourne, Australia where we lease office space. We also maintain offices in Sydney and Brisbane Australia, in Brussels, Herstal (near Liège) and in South Brussels, Belgium and in Geneva, Switzerland, in Kyoto, Japan, in Indianapolis, Indiana, Sacramento, California, Angleton, Texas, and Vancouver, Canada. We believe that our current facilities are adequate to meet our ongoing needs and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

For additional information on our property, plant and equipment, see Note 16 to our audited consolidated financial statements included elsewhere in this registration statement.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis are based upon and should be read together with our consolidated financial statements and the accompanying notes and other financial information included elsewhere in this registration statement. This discussion includes both historical information and forward-looking information based upon current expectations that involve risk, uncertainties and assumptions. Our actual results may differ materially from management's expectations as a result of various factors, including, but not limited to, those discussed in "Item 3. Key Information — D. Risk Factors" and elsewhere in this registration statement.

Our audited consolidated financial statements as of December 31, 2022 and 2023 and for the years ended December 31, 2021, 2022 and 2023 have been prepared in accordance with IFRS Accounting Standards as issued by the IASB. All information as of June 30, 2024 and for the six months ended June 30, 2023 and 2024 is derived from our unaudited interim consolidated financial statements included elsewhere in this registration statement. Our unaudited consolidated financial statements as of June 30, 2024 and for the six months ended June 30, 2023 and 2024 have been prepared on a basis consistent with our audited consolidated financial statements.

A. Operating Results

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals. Our mission is to be the global leader in radiopharmaceuticals by combining therapeutic and diagnostic modalities for the benefit of patients, an innovative precision medicine concept generally referred to as "theranostics." We have an extensive pipeline of theranostic radiopharmaceutical product candidates with a focus in urologic oncology (prostate and kidney), neuro-oncology (glioma), musculoskeletal oncology (sarcoma) and bone marrow conditioning. Our theranostic approach is intended to use imaging and therapy together to "see and treat" cancer and rare diseases, to both better inform treatment decisions and deliver personalized therapy for patients.

Our prostate cancer portfolio includes Illuccix, our commercially available ^{68}Ga-labelled PSMA prostate cancer imaging agent. Illuccix was approved by the TGA in November 2021, the FDA in December 2021, and Health Canada in October 2022. We have built a highly effective, specialist commercial team, which we believe has been integral to the commercial success of Illuccix to date. As of June 30, 2024, we have generated A$1.0 billion in revenue from product sales of Illuccix since the commercial launch in April 2022 and 98% of this revenue has been generated from sales in the United States. The revenues generated from sales of Illuccix, the costs associated with such sales and our operating and other expenses resulted in a profit of A$5.2 million and a loss of A$104.1 million for the years ended December 31, 2023 and 2022, respectively, and a profit of A$29.7 million and a loss of A$14.3 million for the six months ended June 30, 2024 and 2023, respectively. In the year ended December 31, 2021, which was prior to commercial launch of Illuccix, we had a loss of A$80.5 million.

We intend to leverage our commercial revenues as a source of funding for the development of additional therapeutic and diagnostic product candidates in our pipeline. These product candidates include TLX591, a therapeutic rADC, being evaluated in a Phase 3 clinical trial for the treatment of patients with prostate cancer and three innovative imaging agents, TLX250-CDx for kidney (renal) cancer, TLX101-CDx for brain (glioma) cancer and TLX007-CDx for prostate cancer.

Beyond these programs, we are developing a pipeline of therapeutic product candidates with an initial focus on large oncology indications, as well as rare diseases, which represent areas of high unmet medical need. This includes two additional therapeutic radiopharmaceutical candidates that are being evaluated in Phase 2 clinical trials, TLX250, a late-stage product candidate for the treatment of kidney cancer, and TLX101 for the treatment of brain cancer, each of which we are developing as an integrated theranostic with the corresponding investigational imaging agent.

Our ordinary shares have been listed on the ASX since 2017. Our corporate headquarters is located in Melbourne, Australia and we have regional operations in Sydney and Brisbane, Australia. We have international operations in Belgium, Japan, Switzerland, and the United States.

Our operations have been financed primarily through cash generated by our commercial operations and the issuance and sale of ordinary shares. As of June 30, 2024, we had cash and cash equivalents of A$118.8 million and accumulated losses of A$233.5 million. We have raised aggregate proceeds of A$272.6 million (before

deducting share issuance costs) between January 1, 2018 and June 30, 2024 from the issuance and sale of new ordinary shares. We have also received an aggregate of A$52.4 million between January 1, 2018 and June 30, 2024 under the Australian government's R&D Tax Incentive Scheme for the funding of the development and clinical trials of new products. In July 2024, we issued and sold A$650.0 million of Convertible Bonds and received net proceeds of A$635.0 million.

Our total comprehensive loss was A$0.5 million, A$103.5 million and A$82.0 million for the years ended December 31, 2023, 2022 and 2021, respectively. Our total comprehensive income was A$41.6 million for the six months ended June 30, 2024 and our total comprehensive loss was A$10.0 million for the six months ended June 30, 2023. We expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company in the United States. In addition, if and when we seek and obtain regulatory approval to commercialize additional product candidates, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our total comprehensive income or loss may fluctuate significantly from period-to-period, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Key Factors Affecting Results of Operations

Our operating and financial performance have been, and will continue to be, affected by a number of important factors, including the following:

Strategic Acquisitions

We have expanded our pipeline of product candidates through strategic acquisitions. Supporting our growth strategy through acquisitions continues to be key to strengthening our global supply chain, enhancing our ability to serve patients in all global markets, developing our production expertise through in-house manufacturing and leveraging our capabilities to identify and develop novel targets, clinical applications and manufacturing technologies for our future pipeline. We have pursued and plan to continue pursuing strategic acquisitions and partnerships to further advance and expand our pipeline, scale our production and leverage the expertise and effort of our team.

Successful Commercialization of Our Product Portfolio

Our financial performance is dependent on our ability to manage and develop our business model and global presence to support the commercialization of existing and future products. Commercial sales of Illuccix have had a significant impact on revenue in the prior and current periods, and the successful continued commercialization of Illuccix continues to determine our ability to generate product revenue. Successful commercialization includes the receipt of regulatory approvals, successful product launches, the ability to supply and sell products to customers and the ability to obtain adequate reimbursement coding coverage and payments for products. Success in each of these areas is essential to our ability to realize and retain value from our product portfolio. The ongoing commercial success of Illuccix and any other products for which we obtain regulatory approval will also depend in part on the impact of new and existing competitive products in the market and our ability to continue to drive market growth.

Development and Funding of Product Pipeline

We have developed a strong research and innovation team and strategy to continuously identify and progress early development on a broad pipeline of pre-clinical and clinical assets. While increased product development activity in a given period results in increases in operating expenses, our long-term sustainable viability is also determined by our ability to continue successfully identifying, developing and funding a pipeline of products capable of commercialization. Our growth in revenue from the commercialization of our assets will affect the amount of funding available for the development of our core pipeline. Our ability to be successful in this area in the context of a dynamic and changing competitive landscape will also be dependent on the protection of our intellectual property position.

Supply Chain Resilience

Nuclear medicine products and technologies have inherently complex manufacturing, supply and logistics chains. We are dependent on third parties for the manufacture and supply of a substantial portion of our commercialized products and our products in development. We have dual supply surety where possible and continue to seek

viable and sustainable opportunities for supply chain integration, including the acquisition and development of in-house manufacturing capability at our Brussels South, IsoTherapeutics, Optimal Tracers and ARTMS facilities. The impact of expenses or losses attributable to supply chain disruptions or key product component unavailability will depend on the efficacy of our integration efforts, supplier diligence, vendor management and vendor audit programs in mitigating these risks.

Components of Our Results of Operations

Revenue from Contracts with Customers

Revenue from our commercial operations consists of sales of Illuccix and sales-based royalties in connection with the out-licensing of TLX66-CDx outside the United States. We expect revenue from these out-licensing arrangements to be nominal in future periods as intellectual property out-licensing is not a core strategy of our business.

Sales are recognized at point-in-time when control of the products has transferred, being when the products are administered to the patient. Revenue from these sales is recognized based on the price specified in the contract, net of the estimated volume discounts, which are estimated and provided for using the expected value method, and revenue is only recognized to the extent it is highly probable that a significant reversal will not occur.

Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes, Medicaid rebate programs for our products and certain distributor related commissions. Revenue recognized upon administration of our products to patients is limited to the price specified under Medicaid, Medicare or other government rebate programs where provided under such program. The calculation of the accrual for these rebates and allowances is based on an estimate of the third party's expected purchases and the resulting applicable contractual rebate to be earned over a contractual period.

Revenue from our product development operations consists of out-licenses of intellectual property and research and development services. The transaction price is allocated to the research and development activities based on a cost-plus margin approach. Revenue from research and development services is recognized over time based on the costs incurred to date as a percentage of total forecast costs.

When licenses of intellectual property are distinct from other goods or services promised in the contract, a portion of the transaction price is allocated to the license. The timing of revenue recognition of the transaction price allocated to the license performance obligation is based on the nature of the license. Where we perform activities that significantly affect the intellectual property to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of our activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur, the nature of the license is a "right to access" license. The transaction price allocable to a right to access license is recognized as revenue over time as activities are performed. Where the license arrangement does not meet the criteria for a right to access license, the license is a "right to use" license and the transaction price allocated to the license is recognized in full upon transfer of control of the license to the customer.

Revenue from our manufacturing services consists of the provision of contract manufacturing services to companies in the radiopharmaceutical industry. The transaction price is allocated to the services based on a cost-plus margin approach. Revenue from contract manufacturing services is recognized over time based on the costs incurred to date as a percentage of total forecast costs.

Cost of Sales

Cost of sales primarily comprises manufacturing costs of Illuccix (including direct materials and direct labor), freight, storage and shipping from contract manufacturers to warehouses and radiopharmacies, fixed and variable overheads and dispensing and administration fees paid to distributors. Overhead expenditure is allocated based on normal operating capacity. Costs are assigned to individual items of inventory using the weighted average cost method. Costs of purchased inventory are determined after deducting rebates and discounts. Other costs in cost of sales expenses include amortization of intangible assets related to commercial products and sales-based royalties paid to licensors.

Research and Development Costs

R&D costs relate primarily to the development of new products to add to our portfolio and costs related to our medical affairs, medical information and quality and regulatory functions. Our direct R&D costs consist of costs of materials, a proportion of overhead, direct labor and external service costs, such as fees paid to CROs, CMOs, research laboratories and outside consultants in connection with our process development, manufacturing and clinical development activities. R&D costs also include:

- expenses incurred in connection with the clinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- the cost of manufacturing and purchasing drug products for use in our clinical trials, including under agreements with third parties, such as consultants and CMOs;
- other research and development related activities, which include pre-clinical expenses and research expenditure on novel targets and technologies;
- costs related to compliance with regulatory requirements and patent expenses;
- intellectual property costs, such as milestone payments and fees to licensors; and
- consulting, pre-launch commercialization activities and travel and conferences related to new products in development.

We expense R&D costs as incurred and have not capitalized any amounts of R&D costs as of December 31, 2023 or June 30, 2024. For the year ended December 31, 2023, we made A$11.3 million in advance payments for goods or services to be received in future periods for use in R&D activities. These payments have been recorded as prepayments within current assets in our consolidated statement of financial position as of December 31, 2023. As of June 30, 2024, we recorded A$0.5 million in advance payments for goods or services to be received in future periods for use in R&D activities.

Our direct R&D costs are tracked by stage of program for our product candidates and consist primarily of external costs, such as fees paid to CROs, CMOs, research laboratories and outside consultants in connection with our process development, manufacturing and clinical development activities. We do not allocate employee costs associated with our research efforts to specific programs. We use internal resources primarily to conduct our research activities as well as for managing our process development, manufacturing and clinical development activities. These employees work across multiple development programs and, therefore, we do not track these costs by program.

R&D costs in fiscal years after December 31, 2023 are expected to comprise costs of a similar nature to that recorded to date. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our R&D costs will increase in connection with our planned clinical development, manufacturing and regulatory approval activities in the near term and in the future, including as we execute our ProstACT GLOBAL clinical trial for the treatment of prostate cancer. We also anticipate that we will incur increased labor expenses allocable to R&D costs as we increase headcount to support these manufacturing and clinical development activities.

Because of the risks inherent in the discovery and development of therapeutic and diagnostic products, we cannot determine with certainty the nature, timing and estimated costs of the efforts necessary to complete the development of our programs or the anticipated completion dates of any of these programs. We may never succeed in achieving regulatory approval for product candidates in our pipeline. The duration, costs and timing of clinical trials and development of our product candidates depend on a variety of factors, including:

- the scope, rate of progress and expense of our planned clinical trials as well as other R&D activities;
- clinical trial results;
- the terms and timing of regulatory approvals;
- the expense of filing, maintaining, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the ability to raise necessary additional funds, whether through commercial operations or investment;

- the ability to commercialize and achieve market acceptance for any products that receive regulatory approval;
- a continued acceptable safety profile following approval in any indication; and
- the ability to establish and maintain agreements with third-party suppliers and manufacturers for clinical supply and commercial manufacturing for any product candidate, if approved.

A change in the outcome of any of these factors could significantly change the duration, costs and timing associated with clinical trials and development of our product candidates. Data obtained from our clinical trials and other R&D activities at any step in the development process may be adverse and lead to discontinuation or redirection of our R&D expenditure and activity with respect to a product candidate. Data obtained from these activities are also susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our product development efforts, as well as our financial position and our business overall. As a result of these risks and uncertainties, we are unable to determine with any significant degree of certainty the duration and completion costs of our R&D programs or when, and to what extent, if at all, we will generate material net cash inflows from each program.

We expect our R&D costs to continue to increase as we expand our clinical trial activity and other R&D activity, as our current product candidates advance through development and as we invest in future product candidates and programs. The capital requirements of our current or future R&D programs and the extent to which we may need to obtain additional funding to finance our R&D program activity will depend on many factors. See the "Funding Requirements" section in "— B. Liquidity and Capital Resources" for more information on these factors.

R&D costs also comprise patent expenses related to the cost of outside patent attorneys to manage and prosecute claims for our patent portfolio, and intellectual property costs to the license and patent assignment costs in respect of our in-license agreements for certain technologies.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of salaries and other related costs for personnel in field sales, marketing and customer service functions. Other costs in selling and marketing expenses include bad debt expense, the development and printing of advertising and promotional material, professional services, market research and sales meetings.

Manufacturing and Distribution Costs

In the second quarter of 2024, we reclassified several operating expenses related to product quality control, supply chain and logistics activities. In the discussion of results of our operations set forth below and in our consolidated financial statements included elsewhere in this registration statement, all prior periods presented have been retrospectively revised to reflect this reclassification of expenses. Manufacturing and distribution costs predominantly consist of personnel costs and are ancillary in nature to support the expansion of supply chain, logistics and quality activities prior to commercial launch.

We expect that our manufacturing and distribution costs will increase as we continue to invest in the vertical integration of our supply chain operations through strategic acquisitions and the buildout of our existing Brussels South, IsoTherapeutics, Optimal Tracers and ARTMS facilities.

General and Administration Costs

General and administration costs consist of salaries, employee benefit expenses (including share-based payment expenses) and other related costs for personnel in executive, finance, legal, information technology, human resource and other corporate functions. Other costs included in general and administration costs are professional fees for information technology services, external legal fees, consulting and accounting services as well as certain facility and insurance costs, including director and officer liability insurance.

We anticipate that our administration expenses will increase in the future as we increase our headcount to support commercial operations and our research and development activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company in the United States.

Other Gains/(Losses) (Net)

Other gains/(losses) (net) primarily consist of the remeasurement of contingent consideration liabilities, reflecting the impact of changes in the underlying assumptions and inputs used in the valuation.

We acquired Advanced Nuclear Medicine Ingredients SA, or ANMI, in December 2018. We are liable for future variable payments which are calculated based on the percentage of net sales of Illuccix through April 13, 2027, which is five years following the first commercial sale of the product. The applicable percentage of net sales is equal to a percentage in the low teens for sales achieved in the United States and equal to a percentage in the low twenties for sales in the rest of the world. We also hold an option to buy out the remaining deferred payments by paying €10 million within 90 days of April 13, 2025. When presenting financial statement information, we estimate the fair value of the contingent consideration liability as of the end of the period presented using a discounted cash flow model based on the risk-adjusted post-tax discount rate, expected sales volumes, net sales price per unit and the exercise of the buy-out option. If it is determined that a remeasurement is needed to adjust the carrying value of the contingent consideration to its fair value, the amount of the remeasurement is recognized in other gains/(losses) (net). The carrying value of this contingent consideration as of June 30, 2024 was A$102.1 million.

Other gains/(losses) (net) also comprise foreign exchange gains and losses, which represent the impact of the variance in exchange rates between the Australian dollar and the U.S. dollar, Euro, British Pound and Canadian dollar on our cash and cash equivalents, financial assets, financial liabilities and foreign currency denominated transactions.

Finance Income

Finance income comprises interest on cash and cash equivalents.

Finance Costs

Finance costs comprise the unwind of discounts applied to the measurement of contingent consideration, contract liabilities, government grant liabilities and decommissioning liabilities. The discount rate applied to present value liabilities is specific to the liability, with reference to our weighted average cost of debt or, where appropriate, the risk-free rate of debt.

Other finance costs include interest expense on lease liabilities and bank fees on cash and cash equivalents held with financial institutions.

Income Tax Benefit/(Expense)

We operate across multiple tax jurisdictions with varying degrees of activities. As a result, we report a blended effective tax rate reflecting these multiple tax jurisdictions.

We expect that we will continue to reflect a blended tax expense or credit from the relevant tax jurisdictions, considering our tax risk profile and our activities in the differing tax jurisdictions.

We are eligible under the Australian government's R&D Tax Incentive Scheme to obtain a cash amount or an R&D tax incentive credit from the Australian Taxation Office. The tax incentive is available to us based on specific criteria with which we must comply. In the event that global revenue exceeds A$20 million in a fiscal year, the cash receipt option is not available and we are only eligible to receive a non-refundable tax credit, which can be carried forward. The tax incentives may only be offset against Australian taxable income. As such, they are recognized as a component of income tax expense or benefit to the extent that the relevant recognition criteria under IFRS Accounting Standards have been satisfied.

Results of Operations for the Six Months Ended June 30, 2024 and 2023

The following table sets forth a summary of our unaudited consolidated statement of comprehensive income or loss for the periods presented.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands, except per share data)			
Revenue from contracts with customers	363,964	220,834	143,130	65%
Cost of sales	(124,938)	(81,791)	43,147	53%
Gross profit	**239,026**	**139,043**	**99,983**	**72%**
Research and development costs	(84,190)	(48,726)	35,464	73%
Selling and marketing expenses	(37,311)	(24,171)	13,140	54%
Manufacturing and distribution costs	(13,327)	(4,302)	9,025	210%
General and administration costs	(59,341)	(30,315)	29,026	96%
Other losses (net)	(2,870)	(38,159)	35,289	92%
Operating profit/(loss)	**41,987**	**(6,630)**	**48,617**	**733%**
Finance income	1,373	453	920	203%
Finance costs	(8,678)	(6,123)	2,555	42%
Profit/(loss) before income tax	**34,682**	**(12,300)**	**46,982**	**382%**
Income tax expense	(5,028)	(2,020)	3,008	149%
Profit/(loss) for the half-year	**29,654**	**(14,320)**	**43,974**	**307%**
Other comprehensive income/(loss):				
Items that will not be reclassified to profit or loss in subsequent periods:				
Changes in fair value of equity investments at fair value through other comprehensive income	(618)	—	(618)	—
Items to be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	12,517	4,302	8,215	191%
Total comprehensive income/(loss) for the half-year	**41,553**	**(10,018)**	**51,571**	**515%**
Total comprehensive income/(loss) for the half-year attributable to:				
Owners of the Company	41,553	(10,018)	51,571	515%
Basic earnings/(loss) per share after income tax attributable to the ordinary equity holders of the Company (in cents)	9.05	(4.51)		
Diluted earnings/(loss) per share after income tax attributable to the ordinary equity holders of the Company (in cents)	8.75	(4.51)		

Revenue from Contracts with Customers

Revenue from contracts with customers was A$364.0 million for the six months ended June 30, 2024, an increase of A$143.1 million, or 65%, compared to A$220.8 million for the six months ended June 30, 2023. This increase was due to an 72% increase in commercial sales volumes of Illuccix in the United States in the first half of 2024 compared to the first half of 2023. Commercial sales volume growth was primarily driven by an expanding PSMA-PET imaging market and increased clinical utilization.

Cost of Sales

Cost of sales increased by A$43.1 million, or 53%, to A$124.9 million for the six months ended June 30, 2024 from A$81.8 million for the six months ended June 30, 2023. The increase was primarily driven by higher dose administration fees to distributors as a result of higher sales volumes.

Gross margin was 66% for the six months ended June 30, 2024, representing an improvement compared to 63% in the six months ended June 30, 2023. This increase reflected stable selling prices, optimization and efficiency gains in manufacturing and lower royalties.

Research and Development Costs

R&D costs were A$84.2 million for the six months ended June 30, 2024, an increase of A$35.5 million, or 73%, compared to A$48.7 million for the six months ended June 30, 2023. This increase was primarily driven by investment in our prostate cancer therapy program, including the Phase 3 ProstACT GLOBAL trial that we commenced in November 2023, and an increase in employment and general and administration costs to support the increased clinical activity in our late-stage product candidates.

Selling and Marketing Expenses

Selling and marketing expenses were A$37.3 million for the six months ended June 30, 2024, an increase of A$13.1 million, or 54%, compared to A$24.2 million for the six months ended June 30, 2023. This increase was primarily driven by increased investment in Illuccix commercialization activities, including costs associated with the expansion of our sales force operations and promotional marketing program costs (including travel costs).

Manufacturing and Distribution Costs

Manufacturing and distribution costs were A$13.3 million for the six months ended June 30, 2024, an increase of A$9.0 million, or 210%, compared to A$4.3 million for the six months ended June 30, 2023. This increase was driven by an increase in personnel and infrastructure costs to support future supply chain integration following the acquisitions of ARTMS and IsoTherapeutics and the continued buildout of our Brussels South facility.

General and Administration Costs

General and administration costs were A$59.3 million for the six months ended June 30, 2024, an increase of A$29.0 million, or 96%, compared to A$30.3 million for the six months ended June 30, 2023. This increase was primarily driven by higher employee-related costs, an increased investment in infrastructure to support the expansion of support services for our commercial operations and corporate transaction fees related to our proposed initial public offering in the first half of 2024, which we withdrew in June 2024, and our strategic acquisitions.

Other Losses (Net)

Other losses (net) were A$2.9 million for the six months ended June 30, 2024, a decrease of A$35.3 million, or 92%, compared to A$38.2 million for the six months ended June 30, 2023. This decrease was due to a lower amount of remeasurement of contingent consideration recognized in the six months ended June 30, 2024.

Finance Income

Finance income was A$1.4 million for the six months ended June 30, 2024, an increase of A$0.9 million, or 203%, compared to A$0.5 million for the six months ended June 30, 2023. This increase reflects higher cash and cash equivalents placed into short term deposits and higher interest rate yields obtained on deposits in the six months ended June 30, 2024.

Finance Costs

Finance costs were A$8.7 million for the six months ended June 30, 2024, an increase of A$2.6 million, or 42%, compared to A$6.1 million for the six months ended June 30, 2023. This increase was due to a higher unwind of discount on contingent consideration liability as a result of the fair value remeasurement of contingent consideration liabilities recognized for 2023.

Income Tax Expense

Income tax expense was A$5.0 million for the six months ended June 30, 2024, an increase of A$3.0 million, or 149%, compared to A$2.0 million for the six months ended June 30, 2023. This increase was due to the generation of a profit before tax for the six months ended June 30, 2024, compared to a loss before tax in the six months ended June 30, 2023.

Results of Operations for the Fiscal Years Ended December 31, 2023, 2022 and 2021

The following table sets forth a summary of our consolidated statement of comprehensive income or loss for the periods presented.

	Year ended December 31			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage and per share data)						
Revenue from contracts with customers	502,547	160,096	7,596	342,451	214%	152,500	2,008%
Cost of sales	(188,157)	(65,170)	(6,371)	122,987	189%	58,799	923%
Gross profit	**314,390**	**94,926**	**1,225**	**219,464**	**231%**	**93,701**	**7,649%**
Research and development costs	(128,537)	(80,687)	(48,114)	47,850	59%	32,573	68%
Selling and marketing expenses	(50,109)	(36,313)	(5,706)	13,796	38%	30,607	536%
Manufacturing and distribution costs	(9,869)	(3,949)	(460)	5,920	150%	3,489	758%
General and administration costs	(74,181)	(47,156)	(28,192)	27,025	57%	18,964	67%
Other (losses)/gains (net)	(35,854)	(18,751)	6,000	(17,103)	(91%)	(24,751)	(413%)
Operating profit/(loss)	**15,840**	**(91,930)**	**(75,247)**	**107,770**	**117%**	**(16,683)**	**(22%)**
Finance income	1,019	1	—	1,018	*	1	—
Finance costs	(13,772)	(6,693)	(5,218)	7,079	106%	1,475	28%
Profit/(loss) before income tax	**3,087**	**(98,622)**	**(80,465)**	**101,709**	**103%**	**(18,157)**	**(23%)**
Income tax benefit/(expense)	2,124	(5,457)	(45)	7,581	139%	(5,412)	*
Profit/(loss) for the year	**5,211**	**(104,079)**	**(80,510)**	**109,290**	**105%**	**(23,569)**	**(29%)**
Other comprehensive income/(loss):							
Items that will not be reclassified to profit or loss in subsequent periods:							
Changes in fair value of equity investments at fair value through other comprehensive income	(895)	—	—	(895)	—	—	—
Items to be reclassified to profit or loss in subsequent periods:							
Exchange differences on translation of foreign operations	(4,852)	591	(1,452)	(5,443)	(921%)	2,043	141%
Total comprehensive loss for the year	**(536)**	**(103,488)**	**(81,962)**	**102,952**	**99%**	**(21,526)**	**(26%)**
Total comprehensive loss for the year attributable to:							
Owners of the Company	(536)	(103,488)	(81,962)	102,952	99%	(21,526)	(26%)
Basic earnings/(loss) per share after income tax attributable to the ordinary equity holders of the Company (in cents)	1.63	(33.50)	(28.50)				
Diluted earnings/(loss) per share after income tax attributable to the ordinary equity holders of the Company (in cents)	1.61	(33.50)	(28.50)				

* Percentage not meaningful.

Comparison of Years Ended December 31, 2023 and 2022

Revenue from Contracts with Customers

Revenue from contracts with customers was A$502.5 million for the year ended December 31, 2023, an increase of A$342.5 million, or 214%, compared to A$160.1 million for the year ended December 31, 2022. This increase was due to a 223% increase in commercial sales volumes of Illuccix in the United States compared to 2022,

which reflected a full year of commercial sales in 2023 and growth in sales during 2023. Average daily demand for doses increased in 2023 while average prices remained relatively consistent compared to 2022.

Cost of Sales

Cost of sales increased by A$123.0 million, or 189%, to A$188.2 million for the fiscal year ended December 31, 2023 from A$65.2 million for the fiscal year ended December 31, 2022. The increase was primarily driven by higher dose administration fees to distributors and kit manufacturing costs and higher royalties driven by higher sales volumes.

Gross margin improved in 2023 relative to 2022, increasing to 63% for 2023 (up from 59% in 2022). This increase reflected stable selling prices and optimization and efficiency gains in manufacturing and distribution costs.

Research and Development Costs

R&D costs were A$128.5 million for the year ended December 31, 2023, an increase of A$47.9 million, or 59%, compared to A$80.7 million for the year ended December 31, 2022. This increase was primarily driven by investment in two new diagnostic assets and developing late-stage diagnostic assets, including the prostate cancer therapy program.

We expect our R&D costs to continue to increase as we expand our clinical trial activity and other R&D activity, as our current product candidates advance through development and as we invest in future product candidates and programs.

Selling and Marketing Expenses

Selling and marketing expenses were A$50.1 million for the year ended December 31, 2023, an increase of A$13.8 million, or 38%, compared to A$36.3 million for the year ended December 31, 2022. This increase was primarily driven by increased investment in Illuccix commercialization activities, including costs associated with the expansion of our sales force operations and promotional marketing program costs (including travel costs).

Selling and marketing expenses decreased as a percentage of revenue, reflecting improvements in operating expenditure control and revenue growth exceeding cost base growth.

Manufacturing and Distribution Costs

Manufacturing and distribution costs were A$9.9 million for the year ended December 31, 2023, an increase of A$5.9 million, or 150%, compared to A$3.9 million for the year ended December 31, 2022. This increase was primarily driven by higher personnel costs associated with the buildout of our supply chain and logistics functions and the continued buildout of our Brussels South facility prior to commercial launch.

General and Administration Costs

General and administration costs were A$74.2 million for the year ended December 31, 2023, an increase of A$27.0 million, or 57%, compared to A$47.2 million for the year ended December 31, 2022. This increase was primarily driven by higher employee-related costs and an increased investment in infrastructure to support the expansion of support services for our commercial operations in each region.

Other (Losses)/Gains (Net)

Other losses (net) were A$35.9 million for the year ended December 31, 2023, a change of A$17.1 million, or 91%, compared to A$18.8 million for the year ended December 31, 2022. This resulted from higher losses recognized on the remeasurement of contingent consideration.

Finance Income

Finance income was A$1.0 million for the year ended December 31, 2023, an increase of A$1.0 million compared to A$0.0 million for the year ended December 31, 2022. This increase reflects an increase in cash and cash equivalents placed into short term deposits and higher interest rate yields obtained on deposits in the year ended December 31, 2023 compared to the prior year.

Finance Costs

Finance costs were A$13.8 million for the year ended December 31, 2023, an increase of A$7.1 million, or 106%, compared to A$6.7 million for the year ended December 31, 2022. This increase was due to a higher unwind of discount on contingent consideration liability for 2023, reflecting the more significant remeasurement recognized for the year compared to 2022.

Income Tax Benefit/(Expense)

Income tax benefit was A$2.1 million for the year ended December 31, 2023, a change of A$7.6 million compared to a A$5.5 million expense for the year ended December 31, 2022. This resulted from the recognition of A$16.5 million in deferred tax benefits attributable to temporary differences and unused tax losses. Current tax expense increased from A$9.4 million in 2022 to A$14.4 million in 2023 as a result of the increase in taxable profits generated in the United States.

Comparison of Years Ended December 31, 2022 and 2021

Revenue from Contracts with Customers

Revenue from contracts with customers was A$160.1 million for the year ended December 31, 2022, an increase of A$152.5 million, or 2,008%, compared to A$7.6 million for the year ended December 31, 2021. This increase was due to the commercial launch of Illuccix in April 2022 and the subsequent receipt of commercial revenues from our first nine months of sales of Illuccix in the United States.

Cost of Sales

Cost of sales increased by A$58.8 million, or 923%, to A$65.2 million for the fiscal year ended December 31, 2022 from A$6.4 million for the fiscal year ended December 31, 2021. The increase was primarily driven by the incurrence of dose administration fees to distributors, kit manufacturing costs and royalties resulting from commercial sales of Illuccix in the year ended December 31, 2022.

Gross margin improved in 2022 relative to 2021, increasing to 59% for 2022 (up from 16% in 2021). This increase reflected efficiency gains in manufacturing and distribution as we transitioned to a commercial-stage company.

Research and Development Costs

R&D costs were A$80.7 million for the year ended December 31, 2022, an increase of A$32.6 million, or 68%, compared to A$48.1 million for the year ended December 31, 2021. This increase was primarily driven by investment in the clinical development of therapeutic assets and supporting the commercialization of late-stage diagnostic assets.

Selling and Marketing Expenses

Selling and marketing expenses were A$36.3 million for the year ended December 31, 2022, an increase of A$30.6 million, or 536%, compared to A$5.7 million for the year ended December 31, 2021. This increase was primarily driven by our investment in the establishment of our distributor network and Illuccix commercialization activities, including costs associated with the expansion of our sales force operations and promotional marketing program costs (including travel costs).

Manufacturing and Distribution Costs

Manufacturing and distribution costs were A$3.9 million for the year ended December 31, 2022, an increase of A$3.5 million, or 758%, compared to A$0.5 million for the year ended December 31, 2021. This increase was primarily driven by higher personnel costs associated with the buildout of our supply chain and logistics functions and the buildout of our Brussels South facility to prepare for commercial launch in future periods.

General and Administration Costs

General and administration costs were A$47.2 million for the year ended December 31, 2022, an increase of A$19.0 million, or 67%, compared to A$28.2 million for the year ended December 31, 2021. This increase was primarily driven by professional fees associated with obtaining regulatory approvals, higher employee-related costs and an increased investment in infrastructure to support the expansion of support services for our commercial operations in each region.

Other (Losses)/Gains (Net)

Other losses (net) were A$18.8 million for the year ended December 31, 2022, a change of A$24.8 million compared to other gains (net) of A$6.0 million for the year ended December 31, 2021. This change was due to higher losses recognized on the remeasurement of contingent consideration and our ineligibility to recognize any amounts in relation to the R&D Tax Incentive Scheme in 2022 due to global revenue exceeding the eligibility threshold of A$20 million.

Finance Income

Finance income was A$0.0 million for the year ended December 31, 2022, compared to A$Nil for the year ended December 31, 2021.

Finance Costs

Finance costs were A$6.7 million for the year ended December 31, 2022, an increase of A$1.5 million, or 28%, compared to A$5.2 million for the year ended December 31, 2021. This increase was due to a higher unwind of discount on provisions and contingent consideration liabilities in the year ended December 31, 2022, reflecting the more significant remeasurement of contingent consideration recognized for the year compared to the year ended December 31, 2021.

Income Tax Expense

Income tax expense was A$5.5 million for the year ended December 31, 2022, an increase of A$5.4 million compared to A$0.0 million for the year ended December 31, 2021. This increase was due to the taxable income in the United States and Belgium from sales of Illuccix.

Segments

Our four reportable segments are Commercial, Product Development, Medical Technologies and Manufacturing Services, which are categorized based on our principal activities. Following our acquisitions of ARTMS and IsoTherapeutics in April 2024, to align with certain changes in how our chief operating decision maker manages and allocates resources to our business, we revised our reportable segment structure to add two new reportable segments: Medical Technologies and Manufacturing Services. In the discussion of results of our operations set forth below and in our consolidated financial statements included elsewhere in this registration statement, our prior period segment information has been retrospectively revised to reflect our current segment presentation. We evaluate the performance of our segments based on Adjusted EBITDA, calculated as earnings before interest, tax, depreciation and amortization, adjusted for the effects of the remeasurement of contingent consideration and government grant liabilities and other income and expense items which may have an impact on the degree to which earnings reflect the results of core operations, such as an impairment where the impairment is the result of an isolated, non-recurring event. Our management uses Adjusted EBITDA to assess the core operating performance of segments and to make decisions about the allocation of resources. We also believe this measure provides useful information to users of our financial statements by allowing for the assessment of underlying trends in our current operational performance by excluding the impacts of non-cash sunk costs.

Commercial

The Commercial segment focuses on the commercial sales of Illuccix and other products that may obtain regulatory approvals. This segment includes royalties and sales of goods (which account for the majority of our revenue from operations), as well as the sales and marketing expenses and costs of sales necessary to support those revenues.

The following table sets forth the unaudited results of operations for our Commercial segment for the six months ended June 30, 2024 and 2023.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Revenue from contracts with customers	358,818	218,516	140,302	64%
Cost of sales	(124,938)	(81,791)	43,147	53%
Gross profit	**233,880**	**136,725**	**97,155**	**71%**
Research and development costs	—	—	—	—
Selling and marketing expenses	(37,188)	(24,171)	13,017	54%
Manufacturing and distribution costs	(5,071)	(3,143)	1,928	61%
General and administration costs	(16,899)	(14,024)	2,875	21%
Other losses (net)	229	(1,248)	1,477	118%
Operating profit	**174,951**	**94,139**	**80,812**	**86%**
Other losses (net)	(229)	1,248	(1,477)	(118%)
Depreciation and amortization	2,726	2,700	26	1%
Adjusted EBITDA	**177,448**	**98,087**	**79,361**	**81%**

For the six months ended June 30, 2024, revenue from contracts with customers for our Commercial segment consisted of A$357.9 million (first half of 2023: A$218.3 million) in sales of goods and A$1.0 million (first half of 2023: A$0.2 million) in royalty revenue. Sales of Illuccix in the United States were the main driver of the 64% increase in revenue from contracts with customers for the Commercial segment compared to the first half of 2023. Adjusted EBITDA increased by A$79.4 million, or 81%, to A$177.4 million for the six months ended June 30, 2024, up from A$98.1 million in the six months ended June 30, 2023.

The following table sets forth the results of operations for our Commercial segment for the fiscal years ended December 31, 2023, 2022 and 2021.

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
Revenue from contracts with customers	497,051	156,369	5,408	340,682	218%	150,961	2,791%
Cost of sales	(188,157)	(65,170)	(6,371)	122,987	189%	58,799	923%
Gross profit/(loss)	**308,894**	**91,199**	**(963)**	**217,695**	**239%**	**92,162**	**9,570%**
Research and development costs	(282)	(704)	—	(422)	(60%)	704	—
Selling and marketing expenses	(49,925)	(36,217)	(5,692)	13,708	38%	30,525	536%
Manufacturing and distribution costs	(7,127)	(2,139)	(170)	4,988	233%	1,969	1,158%
General and administration costs	(30,151)	(17,207)	(9,512)	12,944	75%	7,695	81%
Other (losses)/gains (net)	(863)	(791)	2,064	(72)	(9%)	(2,855)	(138%)
Operating profit/(loss)	**220,546**	**34,141**	**(14,273)**	**186,405**	**546%**	**48,414**	**339%**
Other (losses)/gains (net)	863	791	(2,064)	72	9%	2,855	138%
Depreciation and amortization	5,594	4,694	596	(900)	(19%)	(4,098)	(688%)
Adjusted EBITDA	**227,003**	**39,626**	**(15,741)**	**187,377**	**473%**	**55,367**	**352%**

Comparison of Years Ended December 31, 2023 and 2022

For the fiscal year ended December 31, 2023, revenue from contracts with customers for our Commercial segment consisted of A$496.2 million (2022: A$156.0 million) in sales of goods, A$0.4 million (2022: A$0.4 million) in royalty revenue and A$0.4 million (2022: A$Nil) in services revenue. Sales of Illuccix in the United States were the main driver of the 218% increase in revenue from contracts with customers for the Commercial segment compared to 2022. Adjusted EBITDA increased by A$187.4 million, or 473%, to A$227.0 million for the fiscal year ended December 31, 2023, up from A$39.6 million in 2022.

Comparison of Years Ended December 31, 2022 and 2021

For the fiscal year ended December 31, 2022, revenue from contracts with customers for our Commercial segment consisted of A$156.0 million (2021: A$4.9 million) in sales of goods and A$0.4 million (2021: A$0.5 million) in royalty revenue. The commercial launch of Illuccix and subsequent sales of Illuccix in the United States were the main driver of the 2,791% increase in revenue from contracts with customers for the Commercial segment compared to 2021. Adjusted EBITDA increased by A$55.4 million to A$39.6 million for the fiscal year ended December 31, 2022, up from negative A$15.7 million in 2021.

Product Development

The Product Development segment focuses on the development of radiopharmaceutical product candidates for commercialization. This segment includes revenue received from license agreements prior to commercialization and research and development services.

The following table sets forth the unaudited results of operations for our Product Development segment for the six months ended June 30, 2024 and 2023.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Revenue from contracts with customers	4,278	2,042	2,236	110%
Cost of sales	—	—	—	—
Gross profit	**4,278**	**2,042**	**2,236**	**110%**
Research and development costs	(83,890)	(48,715)	35,175	72%
Selling and marketing expenses	—	—	—	—
Manufacturing and distribution costs	—	—	—	—
General and administration costs	—	—	—	—
Other losses (net)	—	—	—	—
Operating loss	**(79,612)**	**(46,673)**	**(32,939)**	**(71%)**
Other losses (net)	—	—	—	—
Depreciation and amortization	55	123	68	55%
Adjusted EBITDA	**(79,557)**	**(46,550)**	**(33,007)**	**(71%)**

For the six months ended June 30, 2024, revenue from contracts with customers for our Product Development segment consisted of A$4.3 million (first half of 2023: A$2.0 million) in R&D services revenue. The period-over-period change in revenue from contracts with customers for our Product Development segment reflected higher investment in our R&D expenditure toward new product candidates in the six months ended June 30, 2024. Adjusted EBITDA for the product development segment was negative A$79.6 million in the first half of 2024, compared to negative A$46.6 million in the first half of 2023.

The following table sets forth the results of operations for our Product Development segment for the fiscal years ended December 31, 2023, 2022 and 2021.

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
Revenue from contracts with customers	5,496	3,727	2,188	1,769	47%	1,539	70%
Cost of sales	—	—	—	—	—	—	—
Gross profit	**5,496**	**3,727**	**2,188**	**1,769**	**47%**	**1,539**	**70%**
Research and development costs	(128,212)	(80,000)	(48,114)	48,212	60%	31,886	66%
Selling and marketing expenses	—	—	—	—	—	—	—
Manufacturing and distribution costs	—	—	—	—	—	—	—
General and administration costs	—	—	—	—	—	—	—

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
Other gains (net)	—	11	18,574	(11)	(100%)	(18,563)	(100%)
Operating loss	**(122,716)**	**(76,262)**	**(27,352)**	**(46,454)**	**(61%)**	**(48,910)**	**(179%)**
Other gains (net)	—	(11)	(18,574)	11	100%	18,563	100%
Depreciation and amortization	237	172	—	(65)	(38%)	(172)	—
Adjusted EBITDA	**(122,479)**	**(76,101)**	**(45,926)**	**(46,378)**	**(61%)**	**(30,175)**	**(66%)**

Comparison of Years Ended December 31, 2023 and 2022

For the fiscal year ended December 31, 2023, revenue from contracts with customers for our Product Development segment consisted of A$0.1 million (2022: A$0.4 million) in intellectual property license revenue and A$5.4 million (2022: A$3.4 million) in R&D services revenue. The year-over-year change in revenue from contracts with customers for our Product Development segment reflected higher investment in our R&D expenditure toward new product candidates in the year ended December 31, 2023, paired with relatively low revenue generation attributable to intellectual property licensing and R&D services contracts in the year ended December 31, 2023. Adjusted EBITDA for the Product Development segment was negative A$122.5 million in 2023, compared to negative A$76.1 million in 2022.

Comparison of Years Ended December 31, 2022 and 2021

For the fiscal year ended December 31, 2022, revenue from contracts with customers for our Product Development segment consisted of A$0.4 million (2021: A$Nil) in intellectual property license revenue and A$3.4 million (2021: A$2.2 million) in R&D services revenue. The year-over-year change in revenue from contracts with customers for our Product Development segment reflected higher investment in our R&D expenditure toward new product candidates, as a result of the receipt of commercial revenues in our Commercial segment as a source of funding for our product pipeline, paired with relatively low revenue generation attributable to intellectual property licensing and R&D services contracts in the year ended December 31, 2022. Adjusted EBITDA for the Product Development segment was negative A$76.1 million in 2022, compared to negative A$45.9 million in 2021.

Product Development - Research and Development Costs

We track direct R&D costs by stage of program. Direct R&D costs consist primarily of external costs, such as fees paid to CROs, CMOs, research laboratories and outside consultants in connection with our process development, manufacturing and clinical development activities. We began tracking these costs in this manner for the fiscal year ended December 31, 2020. Our employment costs and general and administration costs recognized as R&D costs are deployed across multiple programs and, as such, are not tracked by product candidate, program, or indication. Allocating employment costs to specific product candidates, programs or indications can limit our ability to allocate resources flexibly across various projects based on evolving priorities and opportunities. In many cases, personnel are in ‘global roles’ or ‘global functions’ and contribute to various R&D programs simultaneously, making it challenging to accurately attribute their time and expenses to specific products. Further, tracking employment costs at such granular levels would involve significant administrative overhead and complexity as our R&D teams are spread across multiple countries, and could potentially introduce inaccuracies due to the dynamic nature of project assignments.

We manage R&D costs based on the development stage of each project. Our management allocates resources and funding and determines our strategic priorities based on the specific stage of development, including early-stage (pre-clinical and Phase 1), clinical trials (Phase 2 and Phase 3) or pre-commercialization. This approach is designed to allow management to strategically align funding allocations with the progress and potential of each project. As such, we have aggregated and presented projects based on their development stage.

The following table sets forth the components of R&D costs for our Product Development segment for the six months ended June 30, 2024 and 2023.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Direct research and development costs by program:				
Therapeutic programs				
Phase 3 – TLX591	15,751	6,373	9,378	147%
Phase 2 – TLX250, TLX101	3,439	3,009	430	14%
Phase 1 – TLX66, TLX300	1,179	—	1,179	—
Diagnostic imaging programs				
Commercial – Illuccix, TLX591-CDx	8,658	1,398	7,260	519%
Pre-commercial – TLX101-CDx (Pixclara), TLX250-CDx (Zircaix), TLX007-CDx	25,667	16,990	8,677	51%
Other research and development programs	3,581	2,576	1,005	39%
Unallocated expenses:				
Employment costs	19,319	14,676	4,643	32%
General and administration costs	6,296	3,693	2,603	70%
Total research and development costs	**83,890**	**48,715**	**35,175**	**72%**

R&D costs were A$83.9 million for the six months ended June 30, 2024, compared to A$48.7 million for the six months ended June 30, 2023. The increase in costs related to our preparation for commercial launch of TLX250-CDx (Zircaix), TLX101-CDx (Pixclara) and TLX007-CDx, including commercial manufacturing process qualification and validation, preparation of FDA filings, commercial launch plans and early access programs. R&D investment was also directed toward clinical manufacturing for the Phase 3 ProstACT GLOBAL trial. The portion of R&D costs that was attributable to employment expenses increased from A$14.7 million in the six months ended June 30, 2023 to A$19.3 million in the six months ended June 30, 2024, reflecting an increase in headcount in our R&D function and increased clinical activity in our late-stage product candidates.

The following table sets forth the components of R&D costs for our Product Development segment for the years ended December 31, 2023, 2022 and 2021 and the total R&D costs incurred from the year ended December 31, 2020 through the year ended December 31, 2023:

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021		Total Incurred in Years ended December 31
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %	2020 through 2023 A$
	(in thousands, except percentage data)							
Direct research and development costs by program:								
Therapeutic programs								
Phase 3 – TLX591	17,326	11,383	6,075	5,943	52%	5,308	87%	37,065
Phase 2 – TLX250, TLX101	5,537	5,528	1,530	9	—	3,998	261%	22,552
Phase 1 – TLX66, TLX300	631	3,358	18	(2,727)	(81%)	3,340	*	4,007
Diagnostic imaging programs								
Commercial – Illuccix, TLX591-CDx	6,637	2,240	7,867	4,397	196%	(5,627)	(72%)	19,527
Pre-commercial – TLX101-CDx (Pixclara), TLX250-CDx (Zircaix), TLX007-CDx	49,592	25,314	15,048	24,278	96%	10,266	68%	94,497
Other research and development programs	6,569	9,116	3,596	(2,547)	(28%)	5,520	154%	22,803

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021		Total Incurred in Years ended December 31
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %	2020 through 2023 A$
	(in thousands, except percentage data)							
Unallocated expenses:								
Employment costs	32,077	19,166	13,723	12,911	67%	5,443	40%	72,125
General and administration costs	9,843	3,895	257	5,948	153%	3,638	1,416%	26,835
Total research and development costs	**128,212**	**80,000**	**48,114**	**48,212**	**60%**	**31,886**	**66%**	**299,411**

* Percentage not meaningful.

Comparison of Years Ended December 31, 2023 and 2022

R&D costs were A$128.2 million for the year ended December 31, 2023, compared to A$80.0 million for the year ended December 31, 2022. The increase in costs related to our preparation for commercial launch of TLX250-CDx (Zircaix) and TLX101-CDx (Pixclara), including commercial manufacturing process qualification and validation, preparation of FDA filings, commercial launch plans and early access programs. R&D was also directed toward clinical manufacturing to progress the ProstACT GLOBAL trial. Direct R&D costs included A$34.8 million relating to pre-launch inventory manufactured prior to regulatory approval of TLX250-CDx and the associated manufacturing process qualification and validation. The portion of R&D costs that was attributable to employment expenses increased from A$19.2 million in the fiscal year ended December 31, 2022 to A$32.1 million in the fiscal year ended December 31, 2023, reflecting an increase in headcount in our R&D function and increased clinical activity in our late-stage product candidates.

Comparison of Years Ended December 31, 2022 and 2021

R&D costs were A$80.0 million for the year ended December 31, 2022, compared to A$48.1 million for the year ended December 31, 2021. The increase in costs related to our investment in preparing and progressing preclinical studies and early-stage clinical trials of TLX300, TLX591 and TLX592. R&D investment was also directed toward progressing two Phase 2 clinical trials, STARLITE-1 and STARLITE-2, and preparing for the launch of a Phase 1b trial, STARSTRUCK, of TLX250. The portion of R&D costs that was attributable to employment expenses increased from A$13.7 million in the fiscal year ended December 31, 2021 to A$19.2 million in the fiscal year ended December 31, 2022, reflecting an increase in headcount in our R&D function to support our transition to a commercial-stage business and increased clinical activity in our late-stage product candidates.

Medical Technologies

The Medical Technologies segment focuses on the development of AI and robotic technologies and includes Dedicaid, the SENSEI radio-guided surgery business and the QDOSE dosimetry software platform. This segment comprises operating expenses associated with the development of AI molecular imaging and guided robotic surgical technologies.

The following table sets forth the unaudited results of operations for our Medical Technologies segment for the six months ended June 30, 2024 and 2023.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Revenue from contracts with customers	—	—	—	—
Cost of sales	—	—	—	—

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Gross profit	—	—	—	—
Research and development costs	(284)	—	284	—
Selling and marketing expenses	—	—	—	—
Manufacturing and distribution costs	(182)	—	182	—
General and administration costs	(890)	—	890	—
Other losses (net)	—	—	—	—
Operating loss	**(1,356)**	**—**	**(1,356)**	**—**
Other losses (net)	—	—	—	—
Depreciation and amortization	5	—	(5)	—
Adjusted EBITDA	**(1,351)**	**—**	**(1,351)**	**—**

R&D costs were A$0.3 million and general and administration costs were A$0.9 million for our Medical Technologies segment for the six months ended June 30, 2024 (compared to A$Nil and A$Nil for the six months ended June 30, 2023, respectively). For the six months ended June 30, 2024, Adjusted EBITDA for the Medical Technologies segment was negative A$1.4 million, compared to A$Nil in the first half of 2023. The period-over-period change in Adjusted EBITDA reflects our investment in the development of complementary AI and robotic technologies, our commercial partnership with the QDOSE dosimetry software platform and the expansion of our infrastructure and operations at Dedicaid and the SENSEI radio-guided surgery business.

We expect R&D costs and other operating expenses associated with our Medical Technologies segment to increase as we continue to develop AI and robotic technologies and as we expand and invest in the ongoing development and commercialization of SENSEI, our operations at Dedicaid and our QDOSE platform partnership with ABX-CRO.

The following table sets forth the results of operations for our Medical Technologies segment for the fiscal years ended December 31, 2023, 2022 and 2021.

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
Revenue from contracts with customers	—	—	—	—	—	—	—
Cost of sales	—	—	—	—	—	—	—
Gross profit	—	—	—	—	—	—	—
Research and development costs	—	—	—	—	—	—	—
Selling and marketing expenses	—	—	—	—	—	—	—
Manufacturing and distribution costs	(3)	—	—	3	—	—	—
General and administration costs	(394)	—	—	394	—	—	—
Other (losses)/gains (net)	—	—	—	—	—	—	—
Operating loss	**(397)**	**—**	**—**	**(397)**	**—**	**—**	**—**
Other (losses)/gains (net)	—	—	—	—	—	—	—
Depreciation and amortization	1	—	—	(1)	—	—	—
Adjusted EBITDA	**(396)**	**—**	**—**	**(396)**	**—**	**—**	**—**

General and administration costs were A$0.4 million for our Medical Technologies segment for the year ended December 31, 2023 (compared to A$Nil for the year ended December 31, 2022). For the fiscal year ended December 31, 2023, Adjusted EBITDA for the Medical Technologies segment was negative A$0.4 million,

compared to A$Nil in the fiscal year ended December 31, 2022. The year-over-year change in Adjusted EBITDA reflects our investment in the development of complementary AI and robotic technologies and the expansion of our infrastructure and operations at Dedicaid and the SENSEI radio-guided surgery business.

Our Medical Technologies business was not in operation prior to the fiscal year ended December 31, 2023.

Manufacturing Services

The Manufacturing Services segment focuses on the operations of our vertically integrated supply chain and manufacturing business and includes our production facilities at Brussels South, IsoTherapeutics, Optimal Tracers and ARTMS. This segment comprises revenue generated from the provision of contract manufacturing services to companies in the radiopharmaceutical industry, as well as the operating expenses associated with our manufacturing solutions business.

The following table sets forth the unaudited results of operations for our Manufacturing Services segment for the six months ended June 30, 2024 and 2023.

	Six Months ended June 30,		2024 vs. 2023	
	2024 A$	2023 A$	Change A$	Change %
	(in thousands)			
Revenue from contracts with customers	868	276	592	214%
Cost of sales	—	—	—	—
Gross profit	**868**	**276**	**592**	**214%**
Research and development costs	(16)	(11)	5	45%
Selling and marketing expenses	(123)	—	123	—
Manufacturing and distribution costs	(8,074)	(1,159)	6,915	597%
General and administration costs	(2,149)	(1,626)	523	32%
Other losses (net)	65	—	65	—
Operating loss	**(9,429)**	**(2,520)**	**(6,909)**	**(274%)**
Other losses (net)	(65)	—	(65)	—
Depreciation and amortization	541	183	(358)	(196%)
Adjusted EBITDA	**(8,953)**	**(2,337)**	**(6,616)**	**(283%)**

Manufacturing and distribution costs were A$8.1 million and general and administration costs were A$2.1 million for our Manufacturing Services segment for the six months ended June 30, 2024 (compared to A$1.2 million and A$1.6 million for the six months ended June 30, 2023, respectively). These increases were predominantly driven by increased personnel and occupancy costs. For the six months ended June 30, 2024, Adjusted EBITDA for the Manufacturing Services segment was negative A$9.0 million, compared to negative A$2.3 million in the first half of 2023. The period-over-period change in Adjusted EBITDA was driven by increased investment in personnel and infrastructure to support future in-house supply chain integration and facilities following the acquisitions of ARTMS and IsoTherapeutics and the continued buildout of our Brussels South facility.

The following table sets forth the results of operations for our Manufacturing Services segment for the fiscal years ended December 31, 2023, 2022 and 2021.

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
Revenue from contracts with customers	—	—	—	—	—	—	—
Cost of sales	—	—	—	—	—	—	—
Gross profit	—	—	—	—	—	—	—
Research and development costs	—	—	—	—	—	—	—
Selling and marketing expenses	—	—	—	—	—	—	—
Manufacturing and distribution costs	(586)	(322)	(290)	264	82%	32	11%

	Year ended December 31,			2023 vs. 2022		2022 vs. 2021	
	2023 A$	2022 A$	2021 A$	Change A$	Change %	Change A$	Change %
	(in thousands, except percentage data)						
General and administration costs	(2,646)	—	—	2,646	—	—	—
Other (losses)/gains (net)	—	—	—	—	—	—	—
Operating loss	**(3,232)**	**(322)**	**(290)**	**(2,910)**	**(904%)**	**(32)**	**(11%)**
Other (losses)/gains (net)	—	—	—	—	—	—	—
Depreciation and amortization	370	322	—	(48)	(15%)	(322)	—
Adjusted EBITDA	**(2,862)**	—	**(290)**	**(2,862)**	—	**290**	**100%**

Manufacturing and distribution costs were A$0.6 million and general and administration costs were A$2.6 million for our Manufacturing Services segment for the year ended December 31, 2023 (compared to A$0.3 million and A$Nil for the year ended December 31, 2022, respectively). These increases were predominantly driven by increased personnel and occupancy costs. For the fiscal year ended December 31, 2023, Adjusted EBITDA for the Manufacturing Services segment was negative A$2.9 million, compared to A$Nil in the fiscal year ended December 31, 2022. The year-over-year change in Adjusted EBITDA was driven by increased investment in our manufacturing, supply chain and logistics functions and the continued buildout of our Brussels South facility.

For more information on our segment reporting, see Note 3 to our audited consolidated financial statements and Note 3 to our unaudited interim consolidated financial statements appearing elsewhere in this registration statement.

Recently Adopted Accounting Pronouncements

We have adopted all relevant new and amended Accounting Standards and Interpretations issued by the IASB that are effective for annual reporting periods beginning on January 1, 2023. The adoption of these Accounting Standards and Interpretations did not have any significant impact on amounts reported in our consolidated financial statements.

Certain new or amended accounting standards and interpretations have been published that are not yet mandatory for the December 31, 2023 reporting period and have not been early adopted. These standards or interpretations are not expected to have a material impact on our financial performance or position in the current or future reporting periods or on foreseeable future transactions.

Internal Control over Financial Reporting

In preparation of our financial statements for the fiscal years ended December 31, 2021, 2022 and 2023 to meet the requirements applicable to this registration statement, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We identified a material weakness related to a lack of appropriately designed, implemented and documented procedures and controls at both the entity-level and process-level to allow us to achieve complete, accurate and timely financial reporting. These controls are necessary to ensure the accuracy and reliability of our financial reporting and compliance with applicable regulations. The material weakness has a pervasive impact on the financial statements, and if left unaddressed, could in the future impact our ability to safeguard assets, prevent and detect errors or fraud, and ensure the integrity of financial information.

We also identified a material weakness related to segregation of duties, which have not been sufficiently established across the key business and financial processes to maintain appropriate segregation of duties over certain manual and IT business controls. Segregation of duties is an internal control principle that helps prevent errors and fraud by dividing tasks and responsibilities among different individuals. In our current control environment, due to the size of our finance team, this segregation has not been adequately maintained. A consequence of the lack of segregation of duties is a heightened risk of fraud or material misstatement where no appropriate mitigating controls are in place. In particular, our IT business processes lack the necessary controls to ensure proper segregation of duties.

We have taken steps designed to mitigate the impact of the identified material weaknesses, including hiring additional accounting and financial reporting personnel, investing in technology to enhance our financial systems and processes, introducing a formalized governance framework across the organization and establishing a compliance register to support accurate financial reporting and compliance with regulatory bodies.

We are in the process of developing a remediation plan designed to improve our internal control over financial reporting to remediate these material weaknesses. These remediation measures are ongoing and include (i) efforts to enhance risk and control documentation practices related to internal control over financial reporting, (ii) strengthening, monitoring and management testing of controls and oversight mechanisms to ensure ongoing compliance with internal control policies and procedures, (iii) investing in training programs, (iv) conducting a comprehensive review of our existing roles and responsibilities to identify areas where segregation of duties is lacking or inadequate, (v) updating and enhancing process documentation to define roles, responsibilities, and segregation of duties requirements and (vi) exploring technology solutions and automation tools that can assist in achieving segregation of duties within our IT systems.

We cannot assure you that the measures we have taken to date, and measures we plan to implement, will be sufficient to remediate the control deficiencies that led to the identified material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our ADSs may decline as a result. See “Risk Factors—We have identified material weaknesses in our internal control over financial reporting.”

Emerging Growth Company Status

As a company with less than US$1.235 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal control over financial reporting; and
- to the extent that we no longer qualify as a foreign private issuer, (i) certain reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information that we provide shareholders and holders of the ADSs may be different than you might obtain from other public companies. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than US$1.235 billion in annual revenue; (ii) the last day of the fiscal year in which we qualify as a “large accelerated filer”; (iii) the date on which we have, during the previous three-year period, issued more than US$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year in which the fifth anniversary of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act occurs.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised

accounting standards. Given that we currently report and expect to continue to report under IFRS Accounting Standards, as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

Foreign Private Issuer Status

We will report under the Exchange Act as a "foreign private issuer" under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain laws and regulations of the SEC and certain regulations of Nasdaq. Consequently, we are not subject to all of the disclosure requirements applicable to U.S. domestic public companies. For example, we are exempt from certain rules under the Exchange Act, as amended, that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our executive officers, the members of our board of directors and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that 50% or more of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of our board of directors or our global management team are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this registration statement. Accordingly, the information contained herein may be different from the information you receive from other public companies.

B. Liquidity and Capital Resources

Prior to the fiscal year ended December 31, 2023, we incurred operating losses in each year since our founding. We anticipate that as we expand through strategic acquisitions, increase our sales and marketing efforts, expand our investment in R&D and incur additional costs associated with being a public company, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, strategic collaborations and other third-party funding arrangements. Our future liquidity and capital resources will depend on product revenue from the successful continued commercialization of Illuccix, revenue from any future products for which we obtain regulatory approval and the R&D costs and other expenditure necessary to support these initiatives and future products. Our total comprehensive loss was A$0.5 million, A$103.5 million and A$82.0 million for the years ended December 31, 2023, 2022 and 2021, respectively. Our total comprehensive income was A$41.6 million for the six months ended June 30, 2024 and our total comprehensive loss was A$10.0 million for the six months ended June 30, 2023. As of June 30, 2024, we had cash and cash equivalents of A$118.8 million and accumulated losses of A$233.5 million. As of June 30, 2024, we held 6.1% of our cash in Australian dollars, 83.2% in U.S. dollars, 9.8% in Euros, 0.1% in Japanese Yen, 0.1% in Canadian dollars and 0.7% in Swiss Francs.

Sources and Uses of Liquidity

Our operations have been financed primarily through cash generated by our commercial operations and the issuance and sale of new ordinary shares. We have raised aggregate proceeds of A$272.6 million (before deducting share issuance costs) between January 1, 2018 and June 30, 2024 from the issuance and sale of new ordinary shares. In January 2022, we completed an institutional placement of 22,727,273 ordinary shares at a price per share of A$7.70 per share for aggregate gross proceeds of A$175.0 million. Additionally, in July 2024, we issued A$650.0 million of Convertible Bonds and received net proceeds of A$635.0 million. We have also received an aggregate of A$52.4 million between January 1, 2018 and June 30, 2024 under the Australian government's R&D Tax Incentive Scheme for the funding of the development and clinical trials of new products. We did not recognize any amounts in relation to the R&D Tax Incentive Scheme in 2022 or 2023, due to global revenue exceeding the threshold of A$20 million.

We intend to leverage our commercial revenues and a portion of the proceeds raised from the issuance of the Convertible Bonds as a source of funding for the development of additional therapeutic and diagnostic product candidates in our pipeline, including conducting label-expanding trials across our portfolio of diagnostic imaging agents and advancing clinical trials for our therapeutic product candidates. In addition, the net proceeds from the issuance of the Convertible Bonds will provide financial flexibility for us to explore opportunities and potentially pursue strategic acquisitions and continued investment in our global supply chain and manufacturing capabilities. In the six months ended June 30, 2024 and 2023 and the years ended December 31, 2023, 2022 and 2021, we received A$343.3 million, A$195.3 million, A$463.7 million, A$124.1 million and A$4.2 million respectively, in receipts from customers, which predominantly consisted of collections from sales of Illuccix.

In the first quarter of 2022, we entered two loan agreements whereby BNP Paribas agreed to lend us A$9.8 million and IMBC Group agreed to lend us A$6.5 million. Each loan is denominated in Euros, in the amounts of €6.1 million and €4.0 million, respectively, and have been translated to Australian dollars based on the applicable exchange rate as of June 30, 2024. Each loan has a 10-year term and an interest rate of 1.85% per annum, payable monthly, and each is repayable in 96 monthly installments beginning at the end of a two-year grace period. As of June 30, 2024, the outstanding balance of these facilities was A$11.9 million (translated based on the applicable exchange rate as of June 30, 2024). In connection with the loan agreement with BNP Paribas, we also entered a roll-over loan agreement whereby BNP Paribas agreed to lend us an additional A$3.2 million (€2.0 million, translated based on the applicable exchange rate as of June 30, 2024). The loan has a two-year extendable term and a per annum interest rate calculated by adding the eurozone interbank interest rate as of the determination date to a 1.5% margin, payable based on our choice of interest period ranging from 1 month to 12 months for each advance (with a default interest period of three months if no alternative is chosen), and it is repayable in full upon its expiration date. As of June 30, 2024, we have drawn down A$Nil from this facility. We have used the borrowings from these loans in order to fund the renovation and redevelopment of our Brussels South production facility.

Funding Requirements

We believe that our existing cash resources and cash that we expect to generate from sales of Illuccix will be sufficient to meet our projected operating expenses and capital expenditure requirements for at least the next 12 months, as well as funding the purchase price and transaction expenses associated with our planned acquisition of RLS and our anticipated longer-term cash requirements and obligations. Our expectations regarding our short-term and long-term funding requirements are based on assumptions that may prove to be wrong, and we may need additional capital resources to fund our operating plans and capital expenditure requirements.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the commercialization of Illuccix and any other product for which we receive regulatory approval and continue clinical development of our therapeutic product candidates. Further, following the listing of the ADSs on Nasdaq, we expect to incur additional costs associated with operating as a public company in the United States. Accordingly, we will need to obtain substantial funding in connection with our continuing operations. Until we can generate a sufficient amount of revenue from the sale of approved products, if ever, we expect to finance our operating activities through cash generated from commercial sales, existing cash and cash equivalents and financing activities, which may include equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise capital through the sale of equity or convertible debt securities, the ownership interest of our investors will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our present and future funding requirements will depend on many factors, including, among other things:

- the amount of revenue received from commercial sales of Illuccix and any of our product candidates for which we may receive marketing approval;
- the initiation, progress, timing, costs and results of our clinical trials for our product candidates;

- the costs associated with in-licensing or acquiring assets to expand our pipeline, acquiring businesses or assets to vertically integrate our supply chain and manufacturing and acquiring complementary business;
- the amount of milestones and royalties that we may be required to pay under existing acquisition and licensing agreements;
- costs associated with expanding our organization;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates; and
- the costs of operating as a public listed company in both Australia and the United States.

For more information as to the risks associated with our future funding needs, see "Item 3. Key Information — D. Risk Factors."

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Year ended December 31,			Six Months ended June 30,	
	2023 A$	2022 A$	2021 A$	2024 A$	2023 A$
	(in thousands)				
Net cash generated from/(used in) operating activities	23,884	(63,970)	(59,328)	39,081	13,259
Net cash used in investing activities	(25,489)	(16,997)	(2,726)	(45,841)	(2,886)
Net cash provided by financing activities	10,186	174,960	2,846	2,153	4,701
Net increase/(decrease) in cash and cash equivalents	**8,581**	**93,993**	**(59,208)**	**(4,607)**	**15,074**

Operating Activities

Net cash generated from operating activities was A$39.1 million during the six months ended June 30, 2024. The primary source of cash from operating activities was A$343.3 million in receipts from customers, which predominantly consisted of collections from sales of Illuccix. The primary uses of cash in operating activities were payments to suppliers and employees, including A$100.8 million spent on dose administration fees, royalties and manufacturing costs, A$80.2 million spent on R&D expenditures, and A$36.1 million spent on selling and marketing efforts. Other operating cash outflows included A$6.8 million in income tax payments.

Net cash generated from operating activities was A$13.3 million during the six months ended June 30, 2023. The primary source of cash from operating activities was A$195.3 million in receipts from customers, which predominantly consisted of collections from sales of Illuccix. The primary uses of cash in operating activities were payments to suppliers and employees, including A$73.4 million spent on dose administration fees, royalties and manufacturing costs, A$48.2 million spent on R&D expenditures, and A$10.5 million spent on selling and marketing efforts. Other operating cash outflows included A$5.9 million in income tax payments.

Net cash generated from operating activities was A$23.9 million during the year ended December 31, 2023. The primary source of cash from operating activities was A$463.7 million in receipts from customers, which predominantly consisted of collections from sales of Illuccix. The primary uses of cash in operating activities were payments to suppliers and employees, including A$183.1 million spent on dose administration fees, royalties and manufacturing costs, A$118.9 million spent on R&D expenditures, and A$42.5 million spent on selling and marketing efforts. Other operating cash outflows included A$16.3 million in contingent consideration payments to former ANMI shareholders and A$10.3 million in income tax payments.

Net cash used in operating activities was A$64.0 million during the year ended December 31, 2022. The primary sources of cash from operating activities were A$124.1 million in receipts from customers, which predominantly

consisted of collections from sales of Illuccix, and A$18.9 million received in R&D tax incentives. The primary uses of cash in operating activities were payments to suppliers and employees, including A$50.6 million spent on manufacturing costs, A$73.2 million spent on R&D expenditures and A$15.2 million spent on selling and marketing efforts.

Net cash used in operating activities was A$59.3 million during the year ended December 31, 2021. The primary sources of cash from operating activities were A$4.2 million received in collections from sales of TLX591-CDx in the EMEA region and A$12.1 million received in R&D tax incentives. The primary uses of cash in operating activities were payments to suppliers and employees, including A$5.4 million spent on manufacturing costs, A$39.2 million spent on R&D expenditures and A$2.8 million spent on selling and marketing efforts.

Investing Activities

Net cash used in investing activities was A$45.8 million during the six months ended June 30, 2024. The primary uses of cash in investing activities were A$23.2 million in payments toward our acquisitions of IsoTherapeutics and ARTMS, A$11.7 million in payments related to the acquisition of intellectual property associated with QSAM, A$4.2 million in payments toward the purchase of Ytterbium-176 isotopes and A$4.7 million in property, plant and equipment purchases for the buildout of our manufacturing facility in Belgium.

Net cash used in investing activities was A$2.9 million during the six months ended June 30, 2023. The primary use of cash in investing activities was A$3.0 million in property, plant and equipment purchases for the buildout of our manufacturing facility in Belgium.

Net cash used in investing activities was A$25.5 million during the year ended December 31, 2023. The primary uses of cash in investing activities were A$13.2 million in payments toward our acquisition of QSAM and strategic investment in Mauna Kea and A$9.7 million in property, plant and equipment purchases for the buildout of our manufacturing facility in Belgium.

Net cash used in investing activities totaling A$17.0 million during the year ended December 31, 2022 was primarily comprised of A$6.8 million paid for the in-license to the worldwide rights to develop and commercialize radiolabeled forms of olaratumab for the diagnosis and treatment of human cancers, A$7.0 million paid for the construction of our manufacturing facilities in Belgium and A$2.2 million paid for the decommissioning and removal of two cyclotrons at our manufacturing facilities in Belgium.

Net cash used in investing activities totaling A$2.7 million during the year ended December 31, 2021 was primarily comprised of A$1.3 million paid for the construction of our manufacturing facilities in Belgium and A$1.4 million paid for the decommissioning and removal of two cyclotrons at our manufacturing facilities in Belgium.

Financing Activities

Net cash provided by financing activities was A$2.2 million during the six months ended June 30, 2024. The primary use of cash in financing activities was A$0.7 million paid toward lease liabilities and A$0.4 million in repayment of our borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium. The primary sources of cash from financing activities were A$2.7 million received from borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium and A$0.6 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees.

Net cash provided by financing activities was A$4.7 million during the six months ended June 30, 2023. The primary use of cash in financing activities was A$0.7 million paid toward lease liabilities. The primary sources of cash from financing activities were A$2.5 million received from borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium and A$2.9 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees.

For the year ended December 31, 2023, net cash provided by financing activities totaled A$10.2 million. Financing activity cash flows included A$6.7 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees, proceeds of A$5.8 million received from borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium and A$2.2 million paid toward lease liabilities.

For the year ended December 31, 2022, net cash provided by financing activities totaling A$175.0 million was primarily comprised of A$173.2 million (net of transaction costs) received from the issuance of new ordinary shares in connection with the exercise of options previously granted to employees and a private placement to institutional investors. Other financing activities comprised A$3.0 million received from borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium and A$1.3 million paid toward lease liabilities.

For the year ended December 31, 2021, net cash provided by financing activities totaled A$2.8 million. Financing activity cash flows included A$3.8 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees, A$0.6 million paid toward lease liabilities and A$0.3 million in repayment of our borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium.

Contractual Obligations

We have commitments against existing development activities and capital commitments relating to the purchase of Ytterbium-176 isotopes from a vendor over a three year period. R&D commitments are estimated based on the contractual obligations included within agreements entered into by us, to the extent that a work order has been executed with the vendor.

Certain of our supply agreements contain minimum purchase commitments in certain situations, the amount and timing of which are not known. Additionally, we enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and clinical trials, research supplies and other services and drugs for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts.

We have entered into collaboration arrangements, including in-licensing arrangements with various companies. Such collaboration agreements may require us to make payments on achievement of stages of development, launch or revenue milestones and may include variable payments that are based on unit sales or profit (e.g., royalty and profit share payments). The amount of variable payments under the arrangements are inherently uncertain and difficult to predict, given the direct link to future sales, profit levels and the range of outcomes. These payments are not included in this table of contractual obligations. For additional details regarding these agreements, see “Item 4. Information on the Company — B. Business Overview.”

The following table summarizes our contractual obligations as of June 30, 2024, grouped as payments due by period:

	Total A$	< 1 year A$	1-3 years A$	3-5 years A$	> 5 years A$
			(in thousands)		
Capital commitments	57,598	22,407	34,941	250	—
R&D commitments	47,705	24,446	23,259	—	—

Contingent Consideration Liabilities

Several of the definitive agreements governing our strategic acquisitions provide for payments that are contingent upon future performance metrics. The table above does not include any amounts related to these obligations. These obligations are recorded within current and non-current liabilities on our consolidated statement of financial position. The following table summarizes our contingent consideration liabilities associated with business combinations, measured at fair value as of June 30, 2024:

	ANMI A$	TheraPharm A$	Optimal Tracers A$	IsoTherapeutics A$	ARTMS A$	Total A$
			(in thousands)			
Current	102,114	—	38	7,518	—	109,670
Non-current	—	2,480	—	—	38,027	40,507
Total contingent consideration	**102,114**	**2,480**	**38**	**7,518**	**38,027**	**150,177**

These contingent consideration arrangements include payouts based on percentage of revenue or net sales metrics and payouts of fixed amounts based on the achievement of certain milestones. The valuation of any future payments under these arrangements utilizes multiple assumptions in calculating a number of unobservable quantitative inputs. A change in the most significant input, such as sales volumes, by an increase/(decrease) of 10% while holding all other variables constant would increase/(decrease) our profit before tax for the fiscal year ended December 31, 2023 by A$5.1 million. See Note 25 to our audited consolidated financial statements appearing elsewhere in this registration statement for more information on the impact of sensitivities from reasonably possible changes in these assumptions where applicable and Note 30.6.2 to our audited consolidated financial statements appearing elsewhere in this registration statement for more information on our valuation processes. A summary of the assumptions we use in the valuation of contingent consideration liabilities is as follows:

- the post-tax discount rate, as determined by an independent third party based on required rates of returns of listed companies in the biotechnology industry (taking into account their stage of development, size and risk adjustments);
- regulatory/marketing authorization approval dates and approval for marketing authorization probability success factors, as determined through benchmarking of historic approval rates and derived in consultation with our regulatory team; and
- expected sales volumes and net sales price per unit, estimated based on market information on annual incidence rates and information for similar products and expected market penetration.

See Note 10.3 to our unaudited consolidated financial statements appearing elsewhere in this registration statement for more information on contingent consideration in relation to the acquisition of QSAM, for which the components acquired were treated as an asset acquisition.

Agreement and Plan of Merger with QSAM Biosciences, Inc.

On February 7, 2024, we entered into the QSAM Agreement, and we completed the acquisition on May 3, 2024. Pursuant to the QSAM Agreement, we paid an upfront purchase price of US$33.1 million, of which we paid US$27.8 million in closing consideration through the issuance of 3,671,120 ordinary shares. We also granted contingent value rights, which represent the right to receive contingent payments of up to US$90.0 million in the aggregate, in cash and/or ordinary shares, without interest, upon the achievement of certain regulatory and commercial milestones, at the times and subject to the terms and conditions of the contingent value rights agreement.

Agreement and Plan of Merger with IsoTherapeutics Group, LLC

On February 27, 2024, we entered into the IsoTherapeutics Agreement. We completed the acquisition of IsoTherapeutics on April 9, 2024. We are obligated to pay an additional US$5.0 million in performance-related milestone payments, which are payable in cash, subject to meeting certain milestone conditions within 12 months of closing. We also agreed to a two-year revenue share that is based on actual revenue earned from existing customers of IsoTherapeutics, which we estimate will require total cash payments of approximately US$0.6 million.

Share Purchase Agreement with ARTMS Inc.

On March 5, 2024, we entered into the ARTMS Agreement. We completed the acquisition of ARTMS on April 11, 2024. We are obligated to pay an additional US$24.5 million in future earn out payments, payable in cash, following achievement of certain regulatory and commercial milestones. We also agreed to pay cash earnouts representing low teens percentage royalties based on net sales of ARTMS products and related services and representing low single-digit percentage royalties based on net sales of Telix products prepared using ARTMS products for up to three years depending on the product location where the sale occurs. All earn-out royalties which have not otherwise expired will terminate on the 10-year anniversary following closing of the ARTMS acquisition.

Stock Purchase Agreement with RLS (USA) Inc.

On September 20, 2024, we entered into the RLS Agreement to acquire RLS. The purchase price for the acquisition consists of: (i) US$230.0 million upfront consideration, payable in cash at closing of the acquisition, which amount will be adjusted for transaction expenses, cash and cash equivalents (net of restricted cash), debt

and debt equivalents and working capital, and (ii) milestone payments of up to US$20.0 million in the aggregate, payable in cash upon the achievement of certain commercial milestones. We expect to fund the purchase price and related transaction costs from existing cash reserves. We expect the acquisition to close in the first quarter of 2025, subject to the satisfaction of closing conditions.

The closing of the acquisition is subject to various conditions set forth in the RLS Agreement, including regulatory approvals, RLS shareholder approval, license transfers and certain-third party consents. The RLS Agreement also provides the parties with customary rights to terminate the RLS Agreement in certain circumstances, including by mutual written consent of us and RLS or by either party if the acquisition has not been consummated by February 17, 2025, in each case on the terms set forth in the RLS Agreement.

Lightpoint Medical Share Sale Agreement

On June 21, 2023, we entered into a share sale agreement with Lightpoint to acquire Lightpoint's SENSEI radio-guided surgery business. The acquisition is intended to support and expand our late-stage urologic cancer pipeline. We completed the acquisition of Lightpoint's SENSEI radio-guided surgery business on November 1, 2023. The acquisition was implemented through the purchase of Lightpoint Medical Limited's wholly owned subsidiary, Lightpoint Surgical Limited, as the then owner of Lightpoint's business, assets and operation. We paid upfront consideration of US$20.0 million, of which we paid US$19.6 million through the issuance of 3,298,073 ordinary shares at a price of A$9.3659 per share. We are obligated to pay an additional US$15.0 million via an earn-out in the form of performance rights, which may be settled in cash or ordinary shares, at our option, upon achievement of specified milestones relating to the ongoing development and commercialization of SENSEI.

Convertible Bonds

On July 30, 2024, we issued the Convertible Bonds in aggregate principal amount of A$650.0 million. The Convertible Bonds were constituted by a trust deed, dated as of July 30, 2024, between us and The Hongkong and Shanghai Banking Corporation Limited, as trustee.

The Convertible Bonds bear interest at a rate of 2.375% per annum, payable quarterly in arrear in equal installments on January 30, April 30, July 30 and October 30 of each year, beginning on October 30, 2024. The maturity date of the Convertible Bonds is July 30, 2029. The Convertible Bonds are convertible at the option of the bondholders, at any time on or after September 9, 2024, into ordinary shares at an initial conversion price of A$24.7775 per ordinary share, subject to certain adjustments. The number of ordinary shares issuable upon conversion is determined by dividing the principal amount of the Convertible Bonds to be converted by the conversion price.

At any time on or after August 13, 2027, we have the right to redeem all of the Convertible Bonds at their principal amount, together with any accrued but unpaid interest, if (i) the closing price of our ordinary shares on the ASX exceeds 130% of the then-applicable conversion price for at least 20 trading days, whether consecutive or not, during any consecutive 30 trading day period or (ii) conversion rights have been exercised in respect of 85% or more in principal amount of the Convertible Bonds.

We may be required to redeem the Convertible Bonds prior to the maturity date in certain circumstances. Following the occurrence of the delisting of our ordinary shares on the ASX or a change of control, each bondholder will have the right to require us to redeem all or some of such bondholder's Convertible Bonds at their principal amount, together with any accrued but unpaid interest. We are also required under the trust deed to redeem the Convertible Bonds on July 30, 2027 at the option of each holder, at their principal amount together with accrued but unpaid interest.

Off-Balance Sheet Arrangements

During the periods presented, we did not, and we do not currently, engage in off-balance sheet financing arrangements as defined under SEC rules, such as relationships with other entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our consolidated statement of financial position. In addition, we do not engage in trading activities involving non-exchange traded contracts.

C. Research and Development, Patents and Licenses, etc.

For a discussion of our research and development activities, see "— A. Operating Results" and "Item 4. Information on the Company — B. Business Overview."

D. Trend Information

Our growth strategy and trends affecting our performance are detailed in "— A. Operating Results" and "Item 4. Information on the Company — B. Business Overview." For a discussion of uncertainties and certain factors that could materially affect our business, see "Item 3. Key Information — D. Risk Factors."

E. Critical Accounting Estimates

We believe that the following accounting policies involve a high degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of our operations. See Note 2 to our audited consolidated financial statements appearing elsewhere in this registration statement for a description of our other significant accounting policies and Note 2.28 to our audited consolidated financial statements appearing elsewhere in this registration statement for additional information on our key judgments and estimates. The preparation of our consolidated financial statements in conformity with IFRS Accounting Standards requires us to make estimates and judgments that affect the amounts reported in those financial statements and accompanying notes. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making those estimates, actual results reported in future periods could differ from those estimates.

Research and Development Costs

As part of the process of preparing our financial statements, we are required to estimate our accrued R&D expenses. This process involves reviewing open contracts and purchase orders, communicating with program directors and managers to identify services that have already been performed for us, estimating the level of services performed with associated costs incurred for the service for which we have not yet been invoiced or otherwise notified of the actual cost. The majority of service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We estimate accrued expenses as of each reporting date based on facts and circumstances known at that time. We periodically confirm the accuracy of estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include fees paid to CROs in connection with clinical studies investigative sites in connection with clinical studies, vendors in connection with preclinical development activities, and vendors related to product manufacturing, process development and distribution of clinical supplies.

Intangible Assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment trigger assessment is performed annually.

We have identified the estimate of the recoverable amount of intangible assets as a significant judgment for the year ended December 31, 2023. In determining the recoverable amount of intangible assets, we have used discounted cash flow forecasts and key assumptions on risk adjusted post-tax discount rates, regulatory/marketing authorization approval dates, expected sales volumes, sales price per unit, and the probability of approval for marketing authorization. We have considered reasonable possible changes in the key assumptions and have not identified any instances that could cause the carrying amounts of the intangible assets as of December 31, 2022 and 2023 to exceed their recoverable amounts. As of June 30, 2024, we have not identified any instances that could cause the carrying amounts of intangibles to exceed their recoverable amounts.

Contingent Consideration

The contingent consideration liabilities associated with business combinations are measured at fair value which has been calculated with reference to our judgment of the expected probability and timing of the potential future milestone payments or with reference to percentage of net sales achieved, based upon level 3 inputs under the fair value hierarchy, which is then discounted to a present value using appropriate discount rates with reference to our weighted average cost of capital.

Contingent consideration in connection with the purchase of individual assets outside of business combinations is recognized as a financial liability only when a non-contingent obligation arises (i.e., when the milestone is met).

The valuation of the contingent consideration has been performed using a discounted cash flow model that uses certain unobservable assumptions. Significant changes in any of the assumptions would result in a significantly lower or higher fair value measurement. A change in the most significant input, such as sales volumes, by an increase/(decrease) of 10% while holding all other variables constant would increase/(decrease) our profit before tax for the fiscal year ended December 31, 2023 by A$5.1 million. See Note 25 to our audited consolidated financial statements appearing elsewhere in this registration statement for more information on the impact of sensitivities from reasonably possible changes in these assumptions where applicable and Note 30.6.2 to our audited consolidated financial statements appearing elsewhere in this registration statement for more information on our valuation processes. A summary of the assumptions we use in the valuation of contingent consideration liabilities is as follows:

- the post-tax discount rate, as determined by an independent third party based on required rates of returns of listed companies in the biotechnology industry (taking into account their stage of development, size and risk adjustments);
- regulatory/marketing authorization approval dates and approval for marketing authorization probability success factors, as determined through benchmarking of historic approval rates and derived in consultation with our regulatory team; and
- expected sales volumes and net sales price per unit, estimated based on market information on annual incidence rates and information for similar products and expected market penetration.

Decommissioning Liabilities

We purchased a radiopharmaceutical production facility in Belgium on April 27, 2020. At the time of purchase, the facility had two cyclotrons installed in concrete shielded vaults which also contained some nuclear contamination associated with past manufacturing activities. As part of this purchase, we assumed an obligation to remove the cyclotrons and restore the site. We removed the cyclotrons from the site during 2022. Other decommissioning activities not required to upgrade the production facility have been deferred to the end of the operating life of the facility in 2041.

We have recognized a provision for our obligation to decommission the radiopharmaceutical production facility at the end of its operating life. At the end of the operating life of a facility, we incur costs to remove certain assets involved in the production of radioactive isotopes. For each period presented, the decommissioning costs that we expect to incur have been discounted using the Belgium risk-free rate and translated to Australian dollars at the exchange rate as of the date of the consolidated statement of financial position. The provisions recognized in the periods presented represent the best estimates of the expenditures required to settle the present obligation as of December 31, 2022 and 2023 and June 30, 2024.

While we believe that we have made our best estimate in establishing the decommissioning liability, because of potential changes in technology as well as safety and environmental requirements, plus the actual timescale to complete decommissioning, the ultimate provision requirements could vary from our current estimates. Any subsequent changes in estimate which alter the level of the provision required are also reflected in adjustments to the plant and equipment asset. Each year, the provision is increased to reflect the unwind of discount and to accrue an estimate for the effects of inflation, with the charges being presented in the consolidated statement of comprehensive income or loss. Actual payments for commencement of decommissioning activity are disclosed as provision utilized.

Revenue from Sales of Goods

Sales are recognized at a point-in-time when control of the products has transferred, being when the products are administered to the patient. Revenue from sales is recognized based on the price specified in the contract, net of the estimated volume discounts and government rebates.

Accumulated experience is used to estimate and provide for discounts, using the expected value method, and revenue is recognized to the extent that it is highly probable that a significant reversal will not occur. No element of financing is deemed present as the sales are made with credit terms ranging from 30 to 45 days, which is consistent with market practice.

Where distributors are used to facilitate the supply of a product, a distribution fee is charged. This fee represents a cost of satisfying the performance obligation to the customer and expensed within “Cost of sales” in the consolidated statement of comprehensive income or loss.

Share-based Payment Transactions

We provide benefits to our directors and employees (including key management personnel) in the form of share-based payments, whereby employees render services in exchange for ordinary shares, options or performance rights over ordinary shares (equity-settled transactions). The cost of these equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The Black-Scholes option pricing model is used to determine fair value, with key assumptions being the listed price per ordinary share on the grant date, the option exercise price, the term of the option, the impact of dilution, expected volatility of the underlying ordinary shares based on the historical share price volatility, the expected dividend yield and the risk-free interest rate.

The cost of the equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date). The charge to profit or loss for the period is the cumulative amount less the amounts already charged in previous periods. There is a corresponding credit to equity. Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so. If an award is cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognized immediately.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

For information about our directors and senior management, see "Item 1. Identity of Directors, Senior Management and Advisers — A. Directors and Senior Management."

Family Relationships

There are no family relationships among any of our executive officers and our directors.

Arrangements for Election of Directors and Members of Management

There are no contracts or other arrangements pursuant to which Directors have been or must be selected.

B. Compensation

Overview and Governance

Our remuneration principles are designed to:

- attract, motivate and retain talent in our operating markets;
- reward corporate performance and execution of our strategy;
- align the interests of employees with shareholders; and
- be simple and transparent.

Executive officers are responsible for making and executing decisions that build our value. In setting the remuneration philosophy and design, our board of directors aims to balance reward for short-term results with long-term business performance and value creation. Our board of directors' aim is to provide clarity so that shareholders, executives, and all other stakeholders understand how our remuneration philosophy helps drive the business strategy, shareholder alignment and reward outcomes. Our remuneration philosophy is:

- providing fixed and variable (or "at risk") remuneration to attract and retain the talent required to build and execute our strategy;
- ensuring variable remuneration is contingent on outcomes that grow and/or protect shareholder value; and
- ensuring a suitable proportion of remuneration is received as an equity-based award so performance is aligned with long-term shareholder interests and aids retention.

The governance of our remuneration framework ensures that:

- our board of directors delegates specific responsibilities to the People, Culture, Nomination and Remuneration Committee, which provides recommendations to the board of directors;
- our strategic objectives, corporate governance principles, market practice and stakeholder interests are considered; and
- achievement of pre-determined financial results and strategic objectives is rewarded through sustainable means for executive officers and the board of directors.

Our board of directors has overall accountability for the oversight of our remuneration approach for executive officers (including the CEO) and non-executive directors, with input and guidance from the People, Culture, Nomination and Remuneration Committee. The People, Culture, Nomination and Remuneration Committee assists and advises our board of directors with recommendations related to remuneration for non-executive directors and executive officers, remuneration policy, short-term and long-term variable remuneration plans, including equity-based plans, and associated Equity Incentive Plan rules, and remuneration-related reporting and disclosures.

Executive Officer Remuneration

The remuneration framework for executive officers is as follows:

	Total Fixed Remuneration (TFR)	Short Term Variable Remuneration (STVR)	Long Term Variable Remuneration (LTVR)
Purpose	Attract and retain global talent capable of leading and delivering our strategy.	Reward achievement of our annual corporate objectives aligned to the delivery of our strategy.	Reward long-term performance aligned with delivery of our strategic objectives.
Remuneration setting	TFR is set considering the elements mentioned under 'Rationale' below	Target STVR remuneration for executive officers is set as a percent of base salary. The maximum outcome is 100% of target.	Target LTVR remuneration for executive officers is set as a percent of base salary.
Composition and delivery	Base salary and statutory pension/ superannuation contributions paid in equal monthly cash installments over the year, and packaged benefits.(1)	Annual performance incentive delivered in cash following completion of the performance period and assessment of performance (approximately February the following year).(2)	Award of Performance Share Appreciation Rights (PSARs)(3) subject to achievement of 3-year performance and vesting conditions.
Rationale	TFR is set with consideration of: • competence and capability; • relativity to market benchmark; and • motivational and retention impact of TFR adjustments.	STVR rewards performance against annual financial and non-financial corporate objectives – maintaining a focus on underlying value creation within the business operations.	LTVR aligns the interests of executive officers with shareholders and rewards the achievement of long-term, sustainable performance and shareholder value creation.

(1) Australian executive officers can choose to cap their superannuation at the statutory superannuation maximum and receive the additional 11% (applicable superannuation rate for 2023) over the maximum as base salary.

(2) From January 1, 2024, equity deferral for executive officer STVR participation applies.

(3) PSARs and other equity incentives are granted in accordance with the Equity Incentive Plan rules.

The sum of the above elements constitutes the Target Total Remuneration Package, or TTRP.

Other Remuneration Elements

To attract and retain a strong and cohesive team of executive officers, additional remuneration awards may be made including sign-on incentives, retention incentives and other one-off incentives, aligned to our remuneration principles and philosophy.

As part of the Group Chief Commercial Officer's appointment in December 2022, our board of directors approved a grant of 35,000 sign-on Performance Share Rights, or PSRs, granted in 2023, and an additional tranche of 35,000 PSRs granted in 2024.

During 2023, two executive officers (the Group Chief Financial Officer and Group Chief Commercial Officer) were identified to receive Performance Share Incentive Rights, or PSIRs, in 2024 (after the 2023 full year results announcement). This one-off grant is intended to retain and motivate these business-critical individuals in the execution of our strategy and the creation of long-term sustainable value for shareholders.

Total Fixed Remuneration (TFR)

TFR is benchmarked against similar executive officer roles within ASX listed companies based on both market capitalization and industry. Our board of directors is committed to increasing TFR over time to align base salary to the market median (50th percentile of the market). It is reviewed annually and adjusted based upon individual performance and competitive benchmarks that may be reviewed from time to time to ensure competitiveness.

Short-term Variable Remuneration (STVR)

STVR is an annual performance incentive delivered in cash following completion of the performance period and assessment of performance (approximately February the following year). From January 1, 2024, 25% of executive officer STVR outcomes will be granted as deferred share rights restricted for 12 months to approximately February 2026, with the remaining 75% of the STVR outcome paid in cash in February 2025. Executive officers are measured against the STVR scorecard, which comprises 100% of their STVR opportunity. The maximum STVR executive officers may achieve is equal to target (there is no additional over-earn potential).

For the year ended December 31, 2023, STVR eligibility was 32% of fixed pay for the CEO and between 26-27% for other executive officers. For the year ending December 31, 2024, STVR eligibility is 65% of fixed pay for the CEO and 35% for other executive officers.

Long-term Variable Remuneration (LTVR)

LTVR is issued in the form of PSARs subject to the achievement of 3-year performance and vesting conditions. The key terms of PSARs are set each February by our board of directors for all PSARs issued in the year, with a measurement period of three calendar years.

PSARs are the right to acquire shares equal in value to the gain above the notional 'exercise' price, subject to the satisfaction of specific performance conditions set by the Board, plus terms and conditions over the performance period.

During the year ended December 31, 2023, the 2023 LTVR was awarded in PSARs based on the following:

- the number of PSARs granted was determined on the concluded value of A$2.9662, which was calculated by adjusting the fair value price of A$3.7866 (the independently determined Black Scholes valuation) for the probability of achievement of the non-market vesting conditions;
- at stretch target for the CEO on May 24, 2023 following shareholder approval;
- at target for all other executive officers on May 2, 2023;
- a notional ‘exercise’ price of A$6.90, being the volume weighted average price (VWAP) of shares over the 20 trading days following the announcement of the 2022 full year annual results (February 28 to March 28, 2023); and
- performance conditions related to:
    - adjusted earnings before interest, taxes, depreciation and amortization and research and development expenses (50%);
    - product milestone 1: ProstACT GLOBAL interim read-out completed (25%); and
    - product milestone 2: Pre-pivotal trial (pre-investigative new drug (IND)) meeting completed with a major regulator for one of our rare disease therapy programs (25%).

During the year ending December 31, 2024, the 2024 LTVR was awarded in PSARs based on the following:

- the number of PSARs granted was determined on the concluded value of A$5.9441, which was calculated by adjusting the fair value price of A$7.5882 (the independently determined Black Scholes valuation) for the probability of achievement of the non-market vesting conditions;
- at stretch target for the CEO on June 26, 2024 following shareholder approval;
- at target for all other executive officers on May 15, 2024;

- a notional 'exercise' price of A$11.94, being the volume weighted average price (VWAP) of shares over the 20 trading days following the announcement of the 2023 full year annual results (February 23 to March 21, 2024); and
- performance conditions related to:
  - adjusted earnings before interest, taxes, depreciation and amortization and research and development expenses (50%);
  - product milestone 1: Marketing authorization submitted in a commercially relevant jurisdiction for prostate cancer therapy (25%); and
  - product milestone 2: Interim data readout from global Phase 3 trial in renal cancer therapy (25%).

Vesting of PSARs granted in the financial year ended December 31, 2022 is subject to achievement of both commercial and product development performance targets on a three-year cumulative basis, reflecting our current emerging status as a generator of sustainable revenue.

In 2023, our executive officers were eligible to receive PSARs under the LTVR plan in amounts ranging between 35 – 50% of their fixed pay, depending on TTRP parity. From January 1, 2024, LTVR participation is 100% of base salary for the CEO and 60% of base salary for other executive officers.

Participants who depart the company prior to vesting are generally treated as follows, although our board of directors retains discretion to determine a different treatment:

- Termination for cause: all unvested PSARs are forfeited.
- Other reasons (death, disability, resignation and redundancy):
  - a pro rata portion of the unvested PSARs based on the portion of the first year of the measurement period served will remain eligible to vest on the usual testing and vesting date; and/or
  - our board of directors will automatically exercise vested unrestricted PSARs into shares for departed executive officers who retain their PSARs after exit within 90 days of the PSARs becoming unrestricted.

2023 Executive Officer Remuneration at Target

The remuneration elements (at target) for 2023 for executive officers are as follows:

Executive Officer	Base Salary	Short Term		Long Term	
		Variable Remuneration (STVR)		Variable Remuneration (LTVR)	
		% of base salary	Annual Target(1)	% of base salary	Annual Target(2)
Christian Behrenbruch	A$475,650	32%	A$152,208	50%	A$237,825
Darren Smith	A$420,000	27%	A$113,400	50%	A$210,000
Colin Hayward	US$449,604	26%	US$116,897	35%(3)	US$157,361
Richard Valeix(4)	CHF295,000	26%	CHF76,700	50%	CHF147,500

(1) STVR maximum opportunity is 100% of target (there is no over-earn potential).
(2) LTVR maximum opportunity is 150% of target (subject to achievement of a stretch financial performance condition).
(3) Dr Hayward's LTVR opportunity was 35% of base salary at target to maintain total remuneration parity.
(4) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024.

2023 Executive Officer Remuneration Review

During 2023, the People, Culture, Nomination and Remuneration Committee, through the Chair, engaged Mercer Consulting (Australia) Pty Ltd (Mercer) to conduct a market analysis and review of our executive remuneration structure and quantum compared to selected peers based on market capitalization and industry.

Mercer provided a remuneration recommendation as defined in section 9B of the Australian Corporations Act in 2023 as part of their review of our CEO, and other executive officer remuneration. Our board of directors is

satisfied that the remuneration recommendation and other advice provided by Mercer during 2023 was provided free from undue influence from the executive officers to whom the recommendation relates.

Remuneration Framework for 2024

In line with the commitment to increase fixed remuneration over time to align to the median (50th percentile) of the market, in 2024 our board of directors implemented year one of the recommended changes to executive officer remuneration made by Mercer, including TFR increases.

In addition, Mercer found that our executive officers' remuneration is heavily weighted to TFR compared to the market benchmark. The implementation of the first year of recommended changes will address the first step of progressive change and alter our remuneration mix to increase the weighting of variable pay components (STVR and LTVR). This change will also better align with shareholder interests by increasing the proportion of variable performance-based remuneration and level of shareholding held by executive officers.

As shown in the below table, the remuneration mix for 2024 has changed from 2023 such that the fixed pay component of total remuneration at target for the CEO will reduce from 57% to 40%, and other executive officers will reduce from 58-63% to 53-54%:

	% of Base Salary			% of Total Remuneration Mix		
Executive Officer	**Base salary**	**STVR**	**LTVR**	**TFR**	**STVR**	**LTVR**
Christian Behrenbruch	100%	65%	100%	40%	24%	36%
Darren Smith	100%	35%	60%	54%	17%	29%
David Cade	100%	35%	60%	53%	17%	30%
Darren Patti	100%	35%	60%	53%	17%	30%
Richard Valeix(1)	100%	35%	60%	54%	17%	29%

(1) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024

Non-Executive Director Remuneration

The total remuneration available for all non-executive directors in the year ended December 31, 2023 was A$700,000 per annum and was approved by shareholders at an annual general meeting of shareholders held on May 12, 2021 (inclusive of superannuation, where applicable). With our growth in the last three years, this limit was reviewed during 2023 and the total non-executive director remuneration available was increased from A$700,000 to A$1,350,000 via shareholder resolution at the annual general meeting of shareholders held on May 22, 2024. In connection with the fee pool increase by shareholders, our board of directors also increased non-executive director fees to align with market benchmarking data provided by Mercer in 2023. These remuneration changes were effective from January 1, 2024.

Total remuneration paid to non-executive directors was A$584,541 and A$625,998 during the years ended December 31, 2023 and 2022, respectively. This included superannuation (where applicable), fees paid to overseas based non-executive directors who attended two meetings or other board-related matters in Australia during the year, and fees paid to:

- the Chairman for his role as Chairman of our board of directors (A$170,000 per annum); and
- non-executive directors (A$86,000 per annum), and additionally for:
  - chairing a committee of our board of directors (A$15,000 per annum, excluding superannuation, if applicable); and
  - membership of a committee of our board of directors (A$7,500 per annum, excluding superannuation, if applicable).

The Chairman of our board of directors is not to be compensated for committee membership but is compensated for his role as chair of the People, Culture, Nomination and Remuneration Committee. In 2022 and 2023, the Chairman of the board of directors waived his entitlement to fees as chair of the People, Culture, Nomination and Remuneration Committee.

Our board of directors determined that there would be no increase in fees payable to non-executive directors for the financial year ended December 31, 2023, other than as a result of legislative requirements and payment of

A$10,000 allowance (in addition to reimbursement of travel costs) to overseas-based non-executive directors (not residing in Australia) to attend two meetings or other board-related matters in Australia per year. Directors are also entitled to be reimbursed for reasonable expenses, including travel costs (which do not contribute to the A$700,000 cap previously set by shareholders).

As part of the 2023 remuneration review completed by Mercer for non-executive directors, our board of directors was advised that the then-current board and committee fees (and aggregate fee pool) were well below market benchmark based on market capitalization and industry. Mercer's benchmarking review confirmed that our non-executive director remuneration was below or at the 25th percentile and significantly below the market median of the market benchmark. To attract and retain suitably qualified talent and deliver on our strategy, the board of directors adopted the approach (not a recommendation) provided by Mercer to achieve non-executive director remuneration aligned with the market median over time (aligned with our approach for executive officers).

At our annual general meeting of shareholders held on May 22, 2024, shareholders approved the increase in the aggregate fee pool payable to non-executive directors to A$1,350,000. In connection with this approval, our board increased fees effective January 1, 2024 to A$230,000 for the Chairman, and A$115,000 for other members of the board. Committee fees were increased for Chairs to A$30,000 for the Audit and Risk Committee and A$20,000 for the People, Culture, Nomination and Remuneration Committee, respectively. Committee fees for membership on the committee were increased to A$10,000 for each. The current non-executive director fees are inclusive of any required superannuation from January 1, 2024, and the travel allowance for overseas based directors no longer applies.

Details of Remuneration for Fiscal Year 2023

Details of the nature and amount of each element of the emoluments of our non-executive directors and executive officers are as follows for the year ended December 31, 2023:

	Salary & Fees A$	Leave Accruals A$	Post-Employment / Superannuation Benefits A$	Short-term Variable Remuneration A$(1)	Long-term Variable Remuneration A$(2)	Termination Benefits A$	Total A$
Non-Executive Directors							
H Kevin McCann	170,000	—	18,275	—	—	—	188,275
Andreas Kluge(3)	43,000	—	—	—	—	—	43,000
Mark Nelson	93,273	—	10,027	—	—	—	103,300
Tiffany Olson	104,300	—	—	—	34,111	—	138,411
Jann Skinner	100,727	—	10,828	—	—	—	111,555
Executive Officers							
Christian Behrenbruch	499,282	13,081	36,632	120,244	349,222	—	1,018,461
Darren Smith	437,650	10,194	33,745	89,586	142,727	—	713,902
Colin Hayward(4)	680,739	(25,145)	11,717	—	377,177	155,252	1,199,740
Richard Valeix(5)	496,571	(1,694)	37,793	105,821	264,413	—	902,904
David Cade(4)	—	—	—	—	—	—	—
Darren Patti(6)	—	—	—	—	—	—	—
Total	**2,625,542**	**(3,564)**	**159,017**	**315,651**	**1,167,650**	**155,252**	**4,419,548**

(1) In 2023, Dr. Behrenbruch was eligible to receive an annual STVR of up to 32% of base salary. Mr. Smith was eligible to receive an annual STVR of up to 27% of base salary, and Dr. Hayward and Mr. Valeix were each eligible to receive an annual STVR of up to 26% of base salary. Non-executive directors were not eligible to receive an STVR amount. In the year ended December 31, 2023, based on actual achievement against corporate objectives, 79% of STVR entitlement due to each eligible executive officer for the year was awarded. The remaining 21% of STVR entitlement due to each eligible executive officer for the year was forfeited.

(2) Long-term variable remuneration is paid in the form of PSARs.

(3) Dr. Kluge's remuneration for 2023 excluded his leave of absence for the period of March 29, 2023 to September 29, 2023, which was unpaid. Dr. Kluge retired from his role as a Non-Executive Director on October 17, 2024.

(4) Dr. Hayward resigned as Group Chief Medical Officer of the company on December 31, 2023. The termination benefit payable to Dr. Hayward is in lieu of notice and in consideration of the agreed non-compete and non-solicit for three months from departure. Dr. Cade was appointed Group Chief Medical Officer effective January 1, 2024.

(5) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024.

(6) Dr. Patti was appointed Group Chief Operating Officer effective March 11, 2024.

Equity Awards

Equity awards for our executive officers and employees are provided through the Equity Incentive Plan, or EIP. Participation in these plans is at the discretion of our board of directors and no individual has an ongoing contractual right to participate in a plan or to receive any guaranteed benefits. For key appointments, an initial allocation of equity may be offered as a component of their initial employment agreement for future vesting in accordance with EIP terms. The structure of equity awards is reviewed by the People, Culture, Nomination and Remuneration Committee and our board of directors to ensure it meets good corporate practice for a company of our size, nature and company lifecycle.

The following describes the material terms of the EIP. "Listing rules" as used in the plan description refers to the official listing rules of the ASX and any other exchange on which we are listed.

Equity Incentive Plan

The purpose of the EIP is to align employees' and directors' interests with shareholders' interests by providing them with equity as part of their remuneration arrangements. This is designed to enable us to attract and retain top-level employees and directors.

The EIP enables our board of directors to award different types of equity instruments tailored to specific application. These can include rights to acquire shares contingent on meeting specified performance metrics, options to acquire shares on payment of an exercise price and rights and/or options that are contingent on remaining in employment, among others. We offer three types of securities under the EIP, including share options, share rights (including share appreciation rights) and restricted shares, which we refer to as Incentive Securities.

Eligibility	The Board determines which of our full-time or part-time employees (including a director employed in an executive capacity), non-executive directors, a casual employee or contractors and any other eligible persons (determined at the board's discretion) may participate in the EIP, collectively referred to as Eligible Employees.
Administration of the EIP	The EIP is managed by our board of directors, which has the power to determine the appropriate procedures for the administration of the EIP.
Invitation	The Board may make an invitation to an Eligible Employee to apply for Incentive Securities on such terms and conditions as our board of directors determines from time to time, including (i) the type and number of Incentive Securities, or the method by which the number will be calculated; (ii) the amount (if any) payable for the grant of Incentive Securities; (iii) any vesting conditions or other conditions in relation to the Incentive Securities; (iv) the procedure for exercising an option or right following vesting; (v) the determination the board of directors has made at its discretion that vesting of share rights and/or exercise of options (as applicable) will be satisfied through an allocation of shares or by cash payment; (vi) the circumstances in which rights and/or options will lapse, shares allocated under the EIP may be forfeited or an EIP participant's entitlement to Incentive Securities may be reduced/extinguished; (vii) how Incentive Securities may be treated in the event that an Eligible Employee ceases employment with us; (viii) any restrictions on dealing shares; and (ix) any other terms and conditions that, in the opinion of our board of directors, are fair and reasonable and not inconsistent with the EIP, and any other information that is required by applicable law.
Grant price	Unless the Board determines otherwise, no payment is required for the grant of Incentive Securities under the EIP.

Cap on number of ordinary shares to be issued under the EIP		The number of equity securities offered to participants under the EIP must not, when aggregated with the number of equity securities issued over the prior three years under (i) the EIP; (ii) any other employee share scheme covered by the ASIC Instrument 2022/1021; or (iii) an ASIC-exempt arrangement of a similar kind to an employee incentive scheme, exceed 32,405,821 equity securities, as approved by shareholders at an annual general meeting of shareholders on May 22, 2024. Our board of directors retains the discretion to adjust the cap on the number of the shares to be issued under the EIP, so long as the adjustment complies with applicable law.
Rights attaching to shares (including restricted shares)		*Ranking*. Shares issued under the EIP rank equally with all our other fully paid ordinary shares at the time of issue, except in relation to any rights attaching to such shares by reference to a record date prior to the date of their issue. *Dividends*. Holders of shares granted under the EIP are entitled to participate in all dividends and other distributions or benefits payable to participants in respect of the shares. *Voting rights*. Holders of shares granted under the EIP are entitled to exercise all voting rights attached to the shares, either generally or in a particular case, in accordance with our Constitution.
Options	Exercise price	When the Board makes an invitation to Eligible Employees to participate in the grant of share options, the Board shall advise each Eligible Employee included in the offer of the procedure for exercising the share options, including any exercise price that will become payable with respect to the share options exercised. Subject to ASX listing rules, prior to the exercise of share options, the Board will retain the power to adjust the relevant exercise price in order to minimize or eliminate any material advantage or disadvantage to a participant resulting from a corporate action by, or capital reconstruction in relation to, our Company.
	Exercise period	Share options will vest and become exercisable when all vesting conditions and any other conditions advised to the participant by the Board have been satisfied (or otherwise waived by the Board). If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the Board may determine that the vesting of the options held by the affected participant will be delayed until such dealings are permitted.
	Lapse of share options	The share options will lapse upon the earliest to occur of: (i) ten years after the date on which the options were allocated to the participant, or any other date nominated as the expiry date of the offer; (ii) the option lapsing in accordance with a provision of the EIP; (iii) failure to meet a vesting condition or any other applicable condition within the vesting period; or (iv) our receipt of a written notice from the participant that the participant has elected to surrender the option.

	Shares issued	Upon the exercise of a share option, we will issue the number of fully paid ordinary shares allocatable to the share options that have been exercised, ranking equally with, and having the same rights and entitlements as, our other ordinary shares on issue at the date of allotment of the share (other than rights and entitlements accrued prior to the date of allotment of the share). Notwithstanding, the Board may determine that the exercise of an option will be satisfied in part or in whole by a cash payment made by us in lieu of an allocation of shares. In the case of options held by/on behalf of a participant who is a director, vested options must be satisfied by shares that have been purchased on market, unless (i) no shareholder approval is required under the listing rules in respect of the director's participation in the EIP; or (ii) shareholder approval has been obtained for the director's participation in the EIP to the extent required under the listing rules.
	Restrictions on transfer of share options	Unless the Board determines otherwise, share options may not be registered in any name other than that of the participant and may not be transferred, assigned, or otherwise dealt with by the participant.
Share Rights	Exercise price	No amount will become payable with respect to share rights upon vesting and exercise.
	Exercise period	Share rights will vest and become exercisable (or will automatically be exercised, if specified by the Board in the terms provided at the time of grant) when all vesting conditions and any other conditions advised to the participant by the Board have been satisfied (or otherwise waived by the Board). If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the Board may determine that the vesting of the rights held by the affected participant will be delayed until such dealings are permitted.
	Lapse of share rights	The share rights will lapse upon the earliest to occur of: (i) ten years after the date on which the rights were allocated to the participant, or any other date nominated as the expiry date in the offer; (ii) the right lapsing in accordance with a provision of the EIP; (iii) failure to meet a vesting condition or any other applicable condition within the vesting period; or (iv) our receipt of a written notice from the participant that the participant has elected to surrender the right.
	Shares issued	Upon vesting, the Board will issue the number of fully paid ordinary shares allocatable to the share rights that have vested, ranking equally with, and having the same rights and entitlements as, our other ordinary shares on issue at the date of allotment of the share (other than rights and entitlements accrued prior to the date of allotment of the share). Notwithstanding, the Board may determine that the exercise of a share right will be satisfied in part or in whole by a cash payment made by us in lieu of an allocation of shares. In the case of share rights held by or on behalf of a participant who is a director, vested rights must be satisfied by shares that have been purchased on market, unless (i) no shareholder approval is required under the listing rules in respect of the director's participation in the

		EIP; or (ii) shareholder approval has been obtained for the director's participation in the EIP to the extent required under the listing rules.
	Share appreciation rights	At its discretion, the Board may determine that share appreciation rights will be granted to Eligible Employees. Share appreciation rights are share rights which only produce value if, at the time of vesting and exercise, the current market price exceeds a notional price specified by the Board at the time of the offer of such share appreciation rights. In the event that the calculation of current market price less notional price results in a zero or negative value at the time of exercise, the participant will not be entitled to any issuance of shares or cash payment. In the event that such calculation returns a positive value, the participant will be entitled to shares (or cash payment, as determined by the Board under the applicable rules of the EIP) with a value equal to the excess of the current market value over the notional price. Notwithstanding, the remainder of the terms of the EIP applicable to share rights (including exercise period, lapse, and restrictions on transfer) apply equally to share appreciation rights.
	Restrictions on transfer of share rights	Unless the Board determines otherwise, share rights may not be registered in any name other than that of the participant and may not be transferred, assigned, or otherwise dealt with by the participant.
Restricted Shares	Cessation of restrictions	A restricted share ceases to be restricted (i.e., vests) where the vesting period and all other relevant conditions have been satisfied or waived by the Board and we notify the participant that the restrictions have ceased or no longer apply. If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the Board may determine that the vesting of the restricted shares held by the affected participant will be delayed until such dealings are permitted.
	Forfeiture of restricted shares	A restricted share will be forfeited upon the earliest to occur of: (i) the restricted share being forfeited in accordance with a provision of the EIP; (ii) the failure to meet a vesting condition or other applicable condition within the vesting period; or (iii) our receipt of a written notice from the participant that the participant has elected to surrender the restricted share.
Vesting conditions		Incentive Securities may be subject to any vesting condition as the Board determines. Incentive Securities will vest in the participant upon all the vesting conditions and any other applicable conditions that apply to such Incentive Securities being satisfied. The Board has discretion to attach individual vesting conditions to the Incentive Securities at the time they are issued. Eligible Employees will be advised of such vesting conditions in connection with their invitation to participate in a grant. The Board may in its absolute discretion waive, amend, or replace any or all of the vesting conditions, provided that the interests of the affected participant are not, in the opinion of the Board, materially prejudiced or advantaged relative to the position reasonably anticipated at the time of grant.

Amendments, suspensions or termination to/of the EIP	Subject to the exceptions listed below, our board of directors may at any time by resolution amend, suspend or terminate any provision of the EIP without the consent of the participant. However, no amendment, suspension or termination may be made if the amendment, suspension or termination materially prejudices the rights of any participant as they existed before the date of the relevant amendment, suspension or termination. The exceptions are amendments introduced: (i) for complying or conforming with present or future laws or regulations; (ii) to correct any manifest error or mistake; or (iii) to take into consideration possible adverse taxation implications in relation to the EIP. Moreover, the Board may waive, amend or replace any vesting condition attaching to an Incentive Security if the Board determines that the original vesting condition is no longer appropriate or applicable.

Outstanding Equity-Based Awards as of December 31, 2023

Equity-based awards granted to our non-executive directors and executive officers consist of options (no longer issued) and PSARs that provide the holder with the right to convert each option or PSAR to a fully paid ordinary share if vesting conditions are met. The following table discloses particulars of all awards outstanding for non-executive directors and executive officers as of December 31, 2023, including awards (as options) granted before fiscal year 2023.

	Equity Based Awards			
	Number of Options Granted	Class of Securities	Expiry Date	Exercise Price A$
Non-Executive Directors				
Tiffany Olson	52,070	PSAR	05/18/2027	4.95
Executive Officers				
Christian Behrenbruch	200,000	Option	01/12/2024(1)	2.23
	100,708	Option	01/26/2026	4.38
	139,672	PSAR	04/04/2027	4.95
	120,268	PSAR	05/24/2028	6.90
Darren Smith	45,449	PSAR	10/24/2027	6.15
	32,463	PSAR	10/24/2027	6.15
	70,798	PSAR	03/27/2028	6.90
Richard Valeix(2)	75,000	Option	07/20/2026	5.37
	89,300	PSAR	04/04/2027	4.95
	81,214	PSAR	03/27/2028	6.90
	35,000	Right	06/15/2028	—
Colin Hayward(3)	85,185	PSAR	04/04/2027	4.95
	79,336	PSAR	03/27/2028	6.90
David Cade(3)	100,000	Right	07/20/2026	—
	78,189	PSAR	04/04/2027	4.95
	67,435	PSAR	03/27/2028	6.90

(1) This award was exercised in full on January 8, 2024, and Dr. Behrenbruch received 153,298 resultant shares.

(2) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024.

(3) Dr. Hayward resigned as Group Chief Medical Officer of the company on December 31, 2023. Dr. Hayward's outstanding awards outlined above remain on-foot. Dr. Cade was appointed Group Chief Medical Officer effective January 1, 2024.

Outstanding Equity-Based Awards as of June 30, 2024

Equity-based awards granted to our non-executive directors and executive officers consist of options (no longer issued) and PSARs that provide the holder with the right to convert each option or PSAR to a fully paid ordinary share if vesting conditions are met. The following table discloses particulars of all awards outstanding for non-executive directors and executive officers as of June 30, 2024, including awards (as options) granted before fiscal year 2024.

	Equity Based Awards			
	Number of Options Granted	Class of Securities	Expiry Date	Exercise Price A$
Non-Executive Directors				
Tiffany Olson	52,070	PSAR	05/18/2027	4.95
Executive Officers				
Christian Behrenbruch	200,000	Option	01/12/2024(1)	2.23
	100,708	Option	01/26/2026	4.38
	139,672	PSAR	04/04/2027	4.95
	120,268	PSAR	05/24/2028	6.90

	Equity Based Awards			
	Number of Options Granted	Class of Securities	Expiry Date	Exercise Price A$
	144,037	PSAR	03/31/2029	11.94
Darren Smith	45,449	PSAR	10/24/2027	6.15
	32,463	PSAR	10/24/2027	6.15
	70,798	PSAR	03/27/2028	6.90
	35,000	PSIR	02/28/2029	—
	50,874	PSAR	03/31/2029	11.94
	35,000	PSIR	02/28/2030	—
Richard Valeix(2)	75,000	Option	07/20/2026	5.37
	89,300	PSAR	04/04/2027	4.95
	81,214	PSAR	03/27/2028	6.90
	35,000	Right	06/15/2028	—
	35,000	PSIR	02/28/2029	—
	60,358	PSAR	03/31/2029	11.94
	35,000	PSIR	02/28/2030	—
	35,000	Right	03/31/2029	—
Colin Hayward(3)	85,185	PSAR	04/04/2027	4.95
	79,336	PSAR	03/27/2028	6.90
David Cade(3)	100,000	Right	07/20/2026	—
	78,189	PSAR	04/04/2027	4.95
	67,435	PSAR	03/27/2028	6.90
	49,461	PSAR	03/31/2029	11.94
Darren Patti(4)	15,000	Right	04/01/2025	—
	15,000	Right	04/01/2025	—
	15,826	PSAR	04/04/2027	4.95
	21,959	PSAR	12/31/2027	6.90
	15,000	Right	11/01/2028	—
	11,450	PSAR	03/31/2029	11.94
	55,388	PSAR	03/31/2029	11.94
	15,000	Right	11/01/2029	—

(1) This award was exercised in full on January 8, 2024, and Dr. Behrenbruch received 153,298 resultant shares.

(2) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024.

(3) Dr. Hayward resigned as Group Chief Medical Officer of the company on December 31, 2023. Dr. Hayward's outstanding awards outlined above remain on-foot. Dr. Cade was appointed Group Chief Medical Officer effective January 1, 2024.

(4) Dr. Patti was appointed Group Chief Operating Officer effective March 11, 2024.

Employment Agreements

All executive officers are employed on ongoing, permanent contracts and have notice period and cascading non-compete and non-solicit clauses in their employment agreements as summarized below:

Role	Notice Period	Non-Compete and Non-Solicit
Christian Behrenbruch	3 months	Non-compete and non-solicit: 6, 3 months Restricted area: Australia/United Kingdom/European Union/United States; Victoria; Melbourne
Darren Smith	4 months	Non-compete and non-solicit: 6, 3, 1 month(s) Restricted area: Australia; Victoria; Melbourne

Role	Notice Period	Non-Compete and Non-Solicit
Colin Hayward(1)	3 months	Non-compete and non-solicit: 6 months Restricted area: Australia/United Kingdom/European Union/United States
David Cade(1)	4 months	Non-compete and non-solicit: 6, 3, 1 month(s) Restricted area: Australia; Victoria; Melbourne
Richard Valeix(2)	3 months	Non-compete and non-solicit: 12 months Restricted area: Switzerland/European Union/United Kingdom/Australia/United States/Canada/Japan/China
Darren Patti(3)	4 weeks	Non-compete and non-solicit: 6 months Restricted area: United States of America; Australia/United Kingdom/European Union; states, provinces or territories within the United States of America

(1) Dr. Hayward resigned as the Group Chief Medical Officer of the company on December 31, 2023 and Dr. Cade was appointed Group Chief Medical Officer effective January 1, 2024.

(2) Mr. Valeix transitioned to the non-Executive Officer role of CEO - Therapeutics effective August 19, 2024.

(3) Dr. Patti was appointed Group Chief Operating Officer effective March 11, 2024.

Employment may be terminated by either the executive officer or the Company on the provision of notice in the minimum period stated above. In the event of termination for cause, the Company may terminate an executive officer's employment immediately without notice.

C. Board Practices

Director Terms

In accordance with the ASX Listing Rules, a director (other than the CEO) must not hold office, without re-election, past the third annual general meeting following the director's appointment or three years, whichever is longer. In addition, under our Constitution, a director appointed by our board of directors who is not a CEO holds office until the next annual general meeting of the Company following his or her appointment and no director who is not the CEO may hold office without re-election beyond the third annual general meeting of the Company following the meeting at which such director was last elected (or re-elected). Under our Constitution, to the extent that the ASX Listing Rules require an election of directors to be held and no director would otherwise be required to submit for election or re-election, the director to retire is any director who wishes to retire (whether or not he or she intends to stand for re-election), otherwise it is the director who has been longest in office since their last election or appointment (excluding the CEO). As between directors who were last elected or appointed on the same day, the director to retire must be decided by lot (unless they can agree among themselves).

Service Contracts

Other than as disclosed in this section, we do not have any service contracts with directors which provide for benefits upon termination of employment.

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our Audit and Risk Committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account the board's Charter independence requirements, H. Kevin McCann, Mark Nelson, Tiffany Olson and Jann Skinner are

"independent directors." In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The independence criteria under the applicable Nasdaq Stock Market rules differ from the independence criteria set forth in by the ASX in the Corporate Governance Principles and Recommendations, 4th edition. Under the Corporate Governance Principles and Recommendations, 4th edition, H. Kevin McCann, Mark Nelson, Tiffany Olson and Jann Skinner are "independent directors."

Role of the Board of Directors in Risk Oversight

The Audit and Risk Committee of our board of directors is primarily responsible for overseeing our risk management processes on behalf of our board of directors. Our Audit and Risk Committee receives reports from management at least quarterly regarding our assessment of risks. In addition, the Audit and Risk Committee reports regularly to our board of directors, which also considers our risk profile. The Audit and Risk Committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Audit and Risk Committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

Board Committees

To assist with the effective discharge of its duties, our board of directors has established an Audit and Risk Committee, a People, Culture, Nomination and Remuneration Committee and a Disclosure Committee. Each committee (other than the Disclosure Committee which reviews and approves all material announcements to the market, where not approved by the full board of directors as specified by our continuous disclosure policy) operates under a charter approved by our board of directors, which sets forth the purposes and responsibilities of the committee as well as qualifications for committee membership, committee structure and operations and committee reporting to our board of directors.

Audit and Risk Committee

We have an Audit and Risk Committee established in accordance with our Constitution that operates under a Charter approved by our board of directors. The Audit and Risk Committee's role outlined in the Charter is to review and make recommendations (as appropriate) to our board of directors in relation to its accounting, auditing, financial reporting, internal control, risk management, legal and regulatory compliance, sustainability responsibilities, and internal and external audit functions.

The current membership of the Audit and Risk Committee is:

- Jann Skinner (Chair);
- H Kevin McCann;
- Mark Nelson; and
- Tiffany Olson.

People, Culture, Nomination and Remuneration Committee

We have a People, Culture, Nomination and Remuneration Committee established in accordance with our Constitution that operates under a Charter approved by our board of directors. The People, Culture, Nomination and Remuneration Committee's nomination roles outlined in the Charter include assisting our board of directors in fulfilling its responsibilities relating to our key people and organizational culture strategies and their alignment with our purpose and strategy, responsibilities relating to the size and composition of our board of directors and reviewing board performance, oversight responsibilities to shareholders with respect to our remuneration policies and practices, non-executive director and senior executive management appointment, succession planning and diversity initiatives.

The current membership of the People, Culture, Nomination and Remuneration Committee is:

- H Kevin McCann (Chair);
- Mark Nelson;
- Jann Skinner; and
- Tiffany Olson.

Foreign Private Issuer Exemption

We qualify as a "foreign private issuer" as defined in Rule 3b-4 of the Exchange Act of 1934, as amended. As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our executive officers and directors are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules, to the extent applicable.

The foreign private issuer exemption will also permit us to follow home country corporate governance practices or requirements instead of certain Nasdaq listing requirements, including the following:

- We expect to rely on an exemption from the requirement that our independent directors meet regularly in executive sessions. The ASX Listing Rules and the Australian Corporations Act do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we expect to rely on this exemption.
- We expect to rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq rules. Our Constitution provides that two shareholders present and entitled to vote on a resolution at the meeting shall constitute a quorum for a general meeting. Nasdaq requires that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares, which quorum may not be less than 33 1/3% of the outstanding shares of an issuer's voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from Nasdaq's quorum requirements, we expect to rely on this exemption.
- We expect to rely on an exemption from the requirement prescribed by Nasdaq that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, changes of controls or private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for the ability to seek prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12 month period (but, in determining the available issue limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties, certain substantial shareholders and their respective associates (as defined in the ASX Listing Rules) and (iii) directors or their associates acquiring securities under an employee incentive plan. Due to differences between Australian law and rules and the Nasdaq shareholder approval requirements, we expect to rely on this exemption.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and the listing rules of Nasdaq.

Code of Conduct

We have adopted a Code of Conduct applicable to all of our directors, officers, employees, consultants and contractors to the Telix Group. Our Code of Conduct is publicly available on our website at www.telixpharma.com. We post on our website all disclosures that are required by law, the ASX Listing Rules or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the Code of Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this registration statement.

D. Employees

As of June 30, 2024, we had 441 employees based in 11 countries, as shown in the chart below.

	Employees
United States	233
Australia	84
Belgium	48
Canada	36
Switzerland	13
United Kingdom	13
Japan	6
France	3
Spain	2
The Netherlands	2
Sweden	1
Total	441

None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders.”

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The below table sets forth information with respect to the beneficial ownership of our ordinary shares as of September 30, 2024, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our ordinary shares;
- each of our executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own.

Applicable percentage ownership is based on 334,683,357 ordinary shares outstanding as of September 30, 2024. As of September 30, 2024, we had 70 holders of record of our ordinary shares in the United States, holding, in the aggregate 6,221,262 ordinary shares, or 1.86% of our outstanding ordinary shares. In computing the number of shares beneficially owned by a person or entity and the percentage ownership of such person or entity, we deemed to be outstanding all shares subject to options held by the person or entity that are currently exercisable, or exercisable within 60 days of September 30, 2024. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person or entity. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares. Each of our shareholders is entitled to one vote per ordinary share. None of the holders of our ordinary shares currently, or will upon the listing of the ADSs on Nasdaq, have different voting rights from other holders of our ordinary shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. For further information regarding options to purchase ordinary shares held by our directors and executive officers, see “Item 6. Directors, Senior Management and Employees — B. Compensation.”

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Telix Pharmaceuticals Limited, 55 Flemington Road, North Melbourne, Victoria, 3051, Australia.

Name of Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percentage
5% or greater shareholders		
State Street Corporation(1)	17,516,215	5.23%
Directors and Executive officers		
H Kevin McCann(2)	1,150,000	*
Christian Behrenbruch(3)	23,329,006	6.97%
Andreas Kluge(4)	22,675,000	6.78%
Mark Nelson(5)	3,628,750	1.08%
Tiffany Olson(6)	95,235	*
Jann Skinner(7)	595,000	*
Darren Smith(8)	6,500	*
Darren Patti(9)	100,000	*
David Cade(10)	373,133	*
All directors and executive officers as a group (ten persons)	51,952,624	15.52%

* Less than one percent.

(1) Based on information filed with the ASX by State Street Corporation and subsidiaries on August 30, 2024. The address for State Street Corporation is State Street Financial Center, 1 Lincoln Street, Boston, MA 02111.

(2) Consists of (i) 1,150,000 ordinary shares beneficially owned or with right to control and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(3) Consists of (i) 23,228,298 ordinary shares beneficially owned and (ii) 100,708 ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(4) Consists of (i) 22,675,000 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024. Dr. Kluge retired from his role as a Non-Executive Director on October 17, 2024.

(5) Consists of (i) 3,628,750 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(6) Consists of (i) 95,235 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(7) Consists of (i) 595,000 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(8) Consists of (i) 6,500 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

(9) Consists of (i) no ordinary shares beneficially owned and (ii) 100,000 ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024. Dr. Patti was appointed Group Chief Operating Officer effective March 11, 2024.

(10) Consists of (i) 373,133 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of September 30, 2024.

B. Related Party Transactions

Since January 1, 2021, we have engaged in the following transactions in which the amounts involved exceeded US$120,000 and any of our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Director and Executive Officer Compensation

See “Item 6. Directors, Senior Management and Employees — B. Compensation” for information regarding compensation of our executive officers and directors.

Master Services Agreement with ABX-CRO

ABX-CRO is a clinical research organization that specializes in radiopharmaceutical product development. We have entered into a master services agreement with ABX-CRO for the provision of clinical and analytical services for its programs. Dr. Andreas Kluge, a non-executive director on our board of directors until October 17, 2024, is the principal owner and Managing Director of ABX-CRO. In the year ended December 31, 2021, the total amount paid or payable to ABX-CRO was A$1,997,836. During the year ended December 31, 2022, the ZIRCON trial was extended to increase patients from 248 to 300 and ABX-CRO resumed key site monitoring activities when COVID restrictions were lifted at hospitals. During the year ended December 31, 2022, the total amount paid, including the ZIRCON trial support, was A$3,685,543. In the year ended December 31, 2023, ABX-CRO was engaged to perform close-out activities relating to the ZIRCON trial, and the total amount paid to ABX-CRO was A$1,256,490. The transactions with ABX-CRO are reviewed on an ongoing basis by the Audit and Risk Committee in accordance with Australian law.

QDOSE Platform Partnership with ABX-CRO

In March 2024, we entered into an agreement to commercially partner the QDOSE dosimetry software platform with ABX-CRO and its development partner, Quantinm AB. QDOSE is a software platform designed to enable reliable estimation of patient-specific dosimetry for both therapeutic and diagnostic radiopharmaceuticals. We agreed to pay ABX-CRO upfront cash consideration of €1.2 million, a share of profits generated from QDOSE sales and a referral fee on deals referred from or initiated by ABX-CRO for two years.

Indemnification Agreements

Our Constitution provides that, except to the extent prohibited by law including under the Australian Corporations Act, we must indemnify every person who is or has been a director, alternate director or executive officer of the Company and such other officers or former officers of the Company or of its related bodies corporate as the board of directors in each case determines against all losses, liabilities, costs, charges and expenses incurred by that person as a director or officer.

We have entered into Deeds of Indemnity, Insurance and Access, or Indemnity Deeds, with H Kevin McCann, Mark Nelson, Tiffany Olson, Jann Skinner and Christian Behrenbruch, and Deeds of Indemnity and Insurance with Darren Smith, David Cade and Darren Patti. Under the Indemnity Deeds, we have agreed to indemnify (to the maximum extent permitted under Australian law and our Constitution, subject to certain specified exceptions) each director and executive officer against all liabilities incurred in their capacity as our or our subsidiaries' director or officer and any and all costs and expenses relating to such a claim or to any notified event incurred by such director or executive officer, including costs and expenses reasonably and necessarily incurred to mitigate any liability for such a claim or any claim which may arise from such a notified event. The Indemnity Deeds provide that the indemnities are unlimited as to amount, continuous and irrevocable.

Separately, we have obtained insurance for our directors and executive officers, as required by the Indemnity Deeds. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related Party Transaction Policy

We comply with Australian law and the ASX Listing Rules regarding approval of transactions with related parties. Our Audit and Risk Committee is responsible for reviewing and monitoring the propriety of related party transactions, as set out in the Audit and Risk Committee Charter.

We intend to amend our related party transaction policy to set forth our procedures for the identification, review, consideration and approval or ratification of related party transactions to comply with SEC Listing Rules. For purposes of our policy, a related party transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related party are, were or will be participants and the amount involved in the transaction exceeds US$120,000, with the exception of usual transactions concluded under normal conditions. A related party is any member of our board of directors, our executive officers or any beneficial owner of more than 5% of any class of our ordinary shares, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our executive officers must present information regarding the related party transaction to the chief financial officer and the transaction will be subject to review, consideration and approval by the Audit and Risk Committee or, if required, the Board. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related party, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our board of directors and executive officers to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

All of the transactions described above were entered into prior to the effective date of the amended written policy, but our board of directors evaluated and approved all transactions that were considered to be related party transactions under Australian law and the ASX Listing Rules at the time at which they were consummated.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements" for our consolidated financial statements filed as part of this registration statement.

Legal Proceedings

We are not currently a party to any material legal proceedings or investigations. From time to time, we may become involved in other litigation or legal proceedings, particularly relevant to defending our IP rights or in response to or relating to claims arising from the ordinary course of business.

Dividends

Due to the stage of our company and the corporate objective of building and investing in our pipeline for the future, we have not declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our operations and pipeline development activities and build the capabilities of our business to drive growth and value accretion. Future dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to applicable Australian law.

While we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, any dividend that we may declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of the ADSs, subject to the terms of the deposit agreement. See "Item 12. Description of Securities Other Than Equity Securities — D. American Depositary Shares."

B. Significant Changes

Except as otherwise disclosed in this registration statement, no significant change has occurred since the date of the most recent financial statements included in this registration statement.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

The principal trading market for our ordinary shares is the ASX in Australia, where our ordinary shares have been listed since 2017. Our ordinary shares trade under the symbol "TLX." On October 28, 2024, the closing price of our ordinary shares as traded on the ASX was A$21.46 per ordinary share (or US$14.14, based on an assumed exchange rate of A$1.00 to US$0.6591, which was the official exchange rate published by the Reserve Bank of Australia on October 28, 2024).

We have applied to have the ADSs listed on Nasdaq under the symbol "TLX." For a description of the rights of the ADSs, see "Item 12. Description of Securities Other Than Equity Securities — D. American Depositary Shares."

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are publicly traded on the ASX under the symbol "TLX." We are filing this registration statement on Form 20-F in anticipation of the listing of the ADSs, each representing one of our ordinary shares, on Nasdaq under the symbol "TLX." We make no representation that such application will be approved or that the ADSs will be listed or remain listed on Nasdaq or be considered readily tradable on an established securities market in the United States now or in the future. JPMorgan Chase Bank, N.A., acting as depositary, will register and deliver the ADSs.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issuer

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

General

The following description of our ordinary shares is only a summary. We encourage you to read our Constitution, which is included as an exhibit to this registration statement on Form 20-F.

We are a public company limited by shares registered under the Australian Corporations Act by the Australian Securities and Investments Commission, or ASIC. Our corporate affairs are principally governed by our Constitution, the Australian Corporations Act and the ASX Listing Rules. Our ordinary shares trade on the ASX, and we have applied to list our ADSs on Nasdaq.

The Australian law applicable to our Constitution is not significantly different from Delaware laws applicable to a Delaware corporation's Charter except we do not have a limit on our authorized share capital and the concept of par value is not recognized under Australian law.

Subject to restrictions on the issue of securities in our Constitution, the Australian Corporations Act and the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with the rights and restrictions and for the consideration as determined by our board of directors.

The rights and restrictions attaching to ordinary shares are derived through a combination of our Constitution, the common law applicable in Australia, the ASX Listing Rules, the Australian Corporations Act and other applicable law. A general summary of some of the rights and restrictions attaching to our ordinary shares is provided below. Each ordinary shareholder is entitled to receive notice of, and to be present, vote and speak at, general meetings.

As of December 31, 2023, we had 323,726,683 ordinary shares outstanding. As of June 30, 2024, we had 334,231,398 ordinary shares outstanding.

Share Options

Option holders are issued with one ordinary share upon the due exercise of each option in accordance with its terms and the receipt by us of the designated exercise price payable in respect of the share prior to the time of expiry on the designated expiry date. Alternatively, option holders may exercise options on a cashless basis in exchange for forfeiting a portion of their vested options.

As of June 30, 2024, we had 1,165,502 outstanding share options at a weighted-average exercise price of approximately A$0.41 per share, with 275,708 held by executive officers and employees, none by directors and 889,794 by others.

Performance Share Appreciation Rights

PSARs are treated similarly to options and enable the holder to acquire our ordinary shares for no cash consideration at a notional exercise price, conditional on the achievement of performance-based vesting conditions at the end of the applicable measurement period.

As of June 30, 2024, we had outstanding 10,776,459 PSARs, which will convert into 8,821,991 fully paid ordinary shares (based on the closing price of our ordinary shares on the ASX on June 30, 2024) upon the satisfaction of performance-based vesting conditions at the end of the applicable measurement period. 1,134,141 of the PSARs are held by executive officers and employees and 52,070 are held by a director.

Share Rights

Share rights are issued from time to time to high performing/high potential employees. Holders of share rights may exercise their rights to acquire one ordinary share per share right in accordance with their offer terms, subject to achievement of continued service and/or performance conditions.

As of June 30, 2024, we had outstanding 1,325,000 share rights, which convert into 1,325,000 fully paid ordinary shares upon the satisfaction of service based vesting condition at the end of the applicable measurement period. 160,000 of the rights are held by an executive officer, 100,000 of which are subject to an additional performance condition.

As of June 30, 2024, we had outstanding 70,000 share rights, which have the ability to convert into 105,000 fully paid ordinary shares upon the satisfaction of service-based and performance-based vesting conditions at the end of the applicable measurement period.

Performance Share Incentive Rights

PSIRs are issued from time to time to executive officers and high performing employees. Upon exercise, each PSIR will convert into one ordinary share upon the satisfaction of continued service and performance conditions.

As of June 30, 2024, we had outstanding 440,000 PSIRs, which have the ability to convert into 440,000 fully paid ordinary shares upon the satisfaction of service-based and performance-based vesting conditions at the end of the applicable measurement period. 140,000 of these PSIRs are held by executive officers.

Acquisition Performance Rights

As of June 30, 2024, we had outstanding 2,523,720 performance rights which will convert into fully paid ordinary shares (or be paid in cash, at our election) upon achievement of specified milestone events associated with the acquisition of Lightpoint's radio-guided surgery business. The number of any ordinary shares issued will be calculated by converting the U.S. dollar amount of performance rights being satisfied into Australian dollars on the relevant date and dividing that amount by the 20-trading day volume weighted average price.

As of June 30, 2024, we had outstanding 4,284,000 performance rights which will convert into fully paid ordinary shares (or be paid in cash, at our election) upon achievement of specified milestone events associated with the acquisition of QSAM. The number of any ordinary shares issued will be calculated by converting the U.S. dollar amount of performance rights being satisfied into Australian dollars on the relevant date and dividing that amount by the 20-trading day volume weighted average price.

Convertible Bonds

On July 30, 2024, we issued the Convertible Bonds in aggregate principal amount of A$650.0 million. The Convertible Bonds were constituted by a trust deed, dated as of July 30, 2024, between us and The Hongkong and Shanghai Banking Corporation Limited, as trustee. The Convertible Bonds were issued in denominations of A$200,000 and integral multiples of A$100,000 in excess thereof.

The Convertible Bonds bear interest at a rate of 2.375% per annum, payable quarterly in arrear in equal installments on January 30, April 30, July 30 and October 30 of each year, beginning on October 30, 2024. The maturity date of the Convertible Bonds is July 30, 2029. The Convertible Bonds are convertible at the option of the bondholders, at any time on or after September 9, 2024, into ordinary shares at an initial conversion price of A$24.7775 per ordinary share, subject to certain adjustments. The number of ordinary shares issuable upon conversion is determined by dividing the principal amount of the Convertible Bonds to be converted by the conversion price.

At any time on or after August 13, 2027, we have the right to redeem all of the Convertible Bonds at their principal amount, together with any accrued but unpaid interest, if (i) the closing price of our ordinary shares on the ASX exceeds 130% of the then-applicable conversion price for at least 20 trading days, whether consecutive or not, during any consecutive 30 trading day period or (ii) conversion rights have been exercised in respect of 85% or more in principal amount of the Convertible Bonds.

We may be required to redeem the Convertible Bonds prior to the maturity date in certain circumstances. Following the occurrence of the delisting of our ordinary shares on the ASX or a change of control, each bondholder will have the right to require us to redeem all or some of such bondholder's Convertible Bonds at their principal amount, together with any accrued but unpaid interest. We are also required under the trust deed to redeem the Convertible Bonds on July 30, 2027 at the option of each holder, at their principal amount together with accrued but unpaid interest.

We may also redeem all of the Convertible Bonds in the event that we have or will become obliged to pay additional amounts in respect of payments on the Convertible Bonds as a result of any change in, or amendment to, the laws or regulations of Australia or any political subdivision or any authority thereof or therein having power to tax, or any change in the general application or official interpretation of such laws or regulations, which change or amendment becomes effective on or after July 23, 2024, and such obligation cannot be avoided by us after taking reasonable measures available to us, subject to a bondholder's right to elect that such bondholder's Convertible Bonds shall not be redeemed.

Subject to certain exceptions, for so long as any of the Convertible Bonds are outstanding, the trust deed restricts us and certain of our subsidiaries from creating or permitting to subsist any mortgage, charge, lien, pledge or other form of encumbrance or security interest to secure certain indebtedness unless certain conditions are met. The Convertible Bonds are subject to customary events of default.

We are permitted under the trust deed to list ordinary shares, depositary shares or depositary receipts on Nasdaq. The Convertible Bonds may be convertible, at the option of each bondholder, into depositary shares or receipts to be listed on Nasdaq when such underlying equity interests are fungible with our ordinary shares, subject to approval of such alternative listing and consequential amendments to the terms and conditions of the Convertible Bonds.

The Convertible Bonds and the trust deed are governed by, and construed in accordance with, English law.

The Convertible Bonds are listed for trading on the Singapore Exchange Securities Trading Limited. We have not applied to have the Convertible Bonds listed on the ASX or Nasdaq. Upon conversion of the Convertible Bonds into our ordinary shares, an application for the quotation of the ordinary shares on the ASX will be completed. The Convertible Bonds and the ordinary shares to be issued upon conversion of the Convertible Bonds have not been, and will not be, registered under the Securities Act.

Changes to Our Share Capital

Below is information regarding securities issued by us since January 1, 2021. None of the securities issued by us since such date were registered under the Securities Act, and, we have made no public offerings in the United States. Except as noted below, all offers and sales of securities by us were made either (i) in offshore transactions pursuant to the exclusion from registration provided by Regulation S under the Securities Act or (ii) within the United States in compliance with available exemptions from the registration requirements of the Securities Act.

- On January 27, 2022, we completed an institutional placement of 22,727,273 ordinary shares at a price per share of A$7.70 per share for aggregate gross proceeds of A$175.0 million.
- From time to time since January 1, 2021 through June 30, 2024, we have granted options to directors, employees, and consultants covering an aggregate of 3,519,848 options over ordinary shares, with exercise prices ranging from A$1.83 to A$5.37 per share. As of June 30, 2024, 1,396,771 of these options have been exercised, and 957,575 of these options have lapsed or been forfeited without being exercised.
- From time to time since January 1, 2021 through June 30, 2024, we have granted performance share appreciation rights to directors, employees, and consultants covering an aggregate of 12,952,977 performance share appreciation rights over ordinary shares, with notional exercise prices ranging from A$4.95 to A$11.94 that convert into a number of ordinary shares based on a vesting formula upon the satisfaction of various performance conditions. As of June 30, 2024, none of these performance share appreciation rights have been exercised, and 2,176,518 of these performance share appreciation rights have lapsed or been forfeited without being exercised.
- From time to time since January 1, 2021 through June 30, 2024, we have granted rights to directors and high performing employees covering an aggregate of 1,602,000 rights over ordinary shares, with nil exercise price that each convert into one ordinary share upon the satisfaction of continued service conditions. In addition, we have granted 70,000 rights which have the ability to convert into 105,000 ordinary shares (150%) upon achievement of performance and continued service conditions. As of June 30, 2024, 125,000 of these rights have been exercised, and 152,000 of these rights have lapsed or been forfeited without being exercised.
- From time to time since January 1, 2021 through June 30, 2024, we have granted performance share incentive rights to executive officers and high performing employees covering an aggregate of 440,000 rights over ordinary shares, with nil exercise price that each convert into one ordinary share upon the satisfaction of continued service and performance conditions. As of June 30, 2024, none of these rights have been exercised, and none of these rights have lapsed or been forfeited without being exercised.

- On April 27, 2023, we acquired Dedicaid GmbH. We issued 207,207 ordinary shares at a price of A$8.73 per share to fund the purchase price of A$1.8 million. We also have an obligation to pay an additional €1.1 million as an earn-out subject to achievement of regulatory approval in the United States, which is payable in cash or equity, at our election.
- On November 1, 2023, we acquired Lightpoint's radio-guided surgery business. As part of the purchase price, we issued 3,298,073 ordinary shares at a price of A$9.3659 per share for an aggregate purchase price of A$30.9 million. We also issued 2,523,720 performance rights, which will convert into fully paid ordinary shares (or be paid in cash, at our election) upon achievement of specified milestone events associated with the acquisition. The number of any ordinary shares issued will be calculated by converting the U.S. dollar amount of performance rights being satisfied into Australian dollars on the relevant date and dividing that amount by the 20-trading day volume weighted average price.
- On April 9, 2024, we acquired IsoTherapeutics. As part of the purchase price, we issued 717,587 ordinary shares at a price per share of A$12.72 for an aggregate amount of A$9.2 million.
- On April 11, 2024, we acquired ARTMS Inc. As part of the purchase price, we issued 5,674,635 ordinary shares at a price per share of A$11.50 for an aggregate amount of A$64.2 million.
- On May 3, 2024, we acquired QSAM Biosciences, Inc. As part of the purchase price, we issued 3,671,120 ordinary shares at a price per share of A$11.61 for an aggregate amount of A$42.6 million. Upon the completion of the post-closing price adjustment process, on July 4, 2024, we issued 409,026 additional ordinary shares to satisfy transaction costs. We also issued 4,284,000 performance rights, which will convert into fully paid ordinary shares (or be paid in cash, at our election) upon achievement of specified milestone events associated with the acquisition. The number of any ordinary shares issued will be calculated by converting the U.S. dollar amount of performance rights being satisfied into Australian dollars on the relevant date and dividing that amount by the 20-trading day volume weighted average price.

B. Memorandum and Articles of Association

Incorporation

We are a public company limited by shares and incorporated in Australia and operate under, and are subject to, the Australian Corporations Act. We were incorporated on January 3, 2017.

Constitution

Our constituent document is a Constitution. Our Constitution is subject to the terms of the ASX Listing Rules and the Australian Corporations Act. Our Constitution may be amended, or repealed and replaced, by a special resolution of shareholders, which is a resolution of which notice has been given and that has been passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution. Our Constitution is subject to many of the key provisions contained in the Australian Corporations Act. Where there is an inconsistency between the provisions of our Constitution and the Australian Corporations Act or ASX Listing Rules, the provisions of the Australian Corporations Act and ASX Listing Rules will prevail over any inconsistent provisions of our Constitution.

Purposes and Objects

As a public company limited by share, we have all the rights, powers and privileges of a natural person. Our Constitution does not provide for or prescribe any specific objects or purposes.

The Powers of the Directors and Management of the Company

We have a Board Charter that outlines the manner in which the board of director's constitutional powers and responsibilities will be exercised and discharged, having regard to principles of good corporate governance, best corporate governance practice and applicable laws. Our Board Charter defines the role and responsibilities of the board of directors and responsibilities delegated by the board of directors to management.

Shareholder Approval to Significant Changes

We must not make a significant change (either directly or indirectly) to the nature and scale of our activities except after having disclosed full details to the ASX in accordance with the requirements of the ASX Listing

Rules (and if required by the ASX, subject to us obtaining the approval of shareholders in a general meeting). We must not sell or otherwise dispose of the main undertaking of our company without the approval of shareholders in a general meeting. We need not comply with the above obligations if the ASX grants us an applicable waiver to be relieved of our obligations.

Interested Directors

Unless a relevant exception applies, the Australian Corporations Act requires our directors to disclose any material personal interest in a matter that relates to the affairs of our company and prohibits them from being present while the matter is being considered at the board meeting and from voting on the matter. However, a director with a material personal interest may be present at the board meeting and vote on the matter if directors who do not have a material personal interest in the relevant matter have passed a resolution:

- identifying that director, the nature and extent of the director's interest in the matter and its relation to our affairs; and
- stating that those directors are satisfied that the interest should not disqualify the director from voting on the matter or being present at the board meeting.

Additionally, under our Board Charter:

- Directors must ensure that no decision or action is taken that has the effect of prioritizing their personal interests over the Company's interests.
- Directors must: (i) disclose to the board of directors any actual or potential conflict of interest or duty or matter that may bear on their independence, that might reasonably be thought to exist as soon as the situation arises; (ii) take all necessary and reasonable action to resolve or avoid any actual or potential conflict of interest or duty; and (iii) comply with all applicable law and our Constitution in relation to disclosing material personal interests and restrictions on voting.
- If a conflict exists, it is expected that any director to whom the conflict relates will recuse himself or herself when the board of directors is discussing any matter to which the conflict relates.
- Directors are expected to inform the Chairman of any proposed appointment to the board of directors or executive of another company as soon as practicable.

Non-Executive Directors' Compensation

Our non-executive directors are paid remuneration for their services, reflecting the obligations, responsibilities and demands which are made on directors. Non-executive directors enter into a letter of appointment, which summarizes obligations, policies and terms of appointment, including remuneration, relevant to each director. Our board of directors has resolved that the remuneration of non-executive directors should only be paid as cash fees and that fees will be determined and reviewed periodically by our board of directors. In conducting these reviews, our board of directors considers market information to seek to ensure that fees are in line with the market, as well as the financial position of the Company.

In accordance with our Constitution and the ASX Listing Rules, the maximum aggregate remuneration of the board of directors is determined from time to time by a general meeting of shareholders. The last determination occurred at an annual general meeting of shareholders held on May 22, 2024, where shareholders approved an aggregate annual maximum remuneration pool for non-executive directors of A$1,350,000 (inclusive of superannuation, where applicable) to be applied from January 1, 2024. Non-executive directors receive a base fee for being a director of our board of directors, and additional annual fees for: (i) chairing a committee of our board of directors and (ii) membership of a committee of the board of directors. Effective January 1, 2024, the Chairman receives A$230,000 per annum for his role as Chairman of the Company and members of the board of directors receive A$115,000 per annum.

Committee fees for chairs are A$30,000 for the Audit and Risk Committee and A$20,000 for the People, Culture, Nomination and Remuneration Committee. Fees for membership of a committee are A$10,000 for each committee. The non-executive director fees are inclusive of any required superannuation from January 1, 2024.

Borrowing Powers Exercisable by Directors

Pursuant to our Constitution, the business and affairs of our Company are managed by or under the direction of our board of directors and delegated to the Managing Director and Group CEO for the day-to-day operations of the business. Subject to the ASX Listing Rules, our board of directors has the power to borrow or raise money in any other way for the purposes of the Company, to charge any of the Company's property or business or any of its uncalled capital and to issue debentures or give any security for a debt, liability or obligation of the Company or of any other person.

Retirement of Directors

As noted above, in accordance with the ASX Listing Rules, a director (other than the CEO) must not hold office, without re-election, past the third annual general meeting following the director's appointment or three years, whichever is longer. In addition, under our Constitution, a director appointed by the board of directors who is not a CEO holds office until the next annual general meeting of the Company following his or her appointment and no director who is not the CEO may hold office without re-election beyond the third annual general meeting of the Company following the meeting at which such director was last elected (or re-elected). Under our Constitution, to the extent that the ASX Listing Rules require an election of directors to be held and no director would otherwise be required to submit for election or re-election, the director to retire is any director who wishes to retire (whether or not he or she intends to stand for re-election), otherwise it is the director who has been longest in office since their last election or appointment (excluding the CEO). As between directors who were last elected or appointed on the same day, the director to retire must be decided by lot (unless they can agree among themselves).

The retirement of a director from office, and the re-election of a director or the election of another person to that office, takes effect at the conclusion of the relevant annual general meeting.

Rights Attached to Our Ordinary Shares

All of our issued shares are ordinary shares and as such the rights attached to these ordinary shares are the same. As at the date of this registration statement, there are no ordinary shares that have superior or inferior rights.

The concept of authorized share capital no longer exists in Australia and as a result, our authorized share capital is unlimited. All our ordinary shares on issue are validly issued, fully paid and rank *pari-passu* (equally). The rights attached to our ordinary shares are as follows:

- *Dividend Rights.* Under our Constitution, subject to the rights of persons (if any) entitled to shares with special rights to dividends, our board of directors may pay an interim or final dividend that, in its judgment, the financial position of the Company justifies. No dividend carries interest as against us. Under the Australian Corporations Act, we must not pay a dividend unless: (i) our assets exceed our liabilities immediately before the dividend is declared and the excess is sufficient for the payment of the dividend; (ii) the payment of the dividend is fair and reasonable to our shareholders as a whole; and (iii) the payment of the dividend does not materially prejudice our ability to pay our creditors. Unless any share is issued on terms providing to the contrary, all dividends are to be apportioned and paid proportionately to the amounts paid, or credited as paid on the relevant shares.
- *Voting Rights.* Holders of ordinary shares have one vote per person on a show of hands, or one vote for each fully paid ordinary share held (or for a partly paid share, a fraction of a vote equal to the proportion which the amount paid up bears to the total issue price of the share) on all matters submitted to a vote of shareholders conducted by way of a poll.

  The quorum required for a general meeting of shareholders is at least two members present at the meeting and entitled to vote on a resolution at the meeting pursuant to our Constitution. A meeting at which there is a lack of a quorum after 30 minutes (excluding a meeting convened on the requisition of shareholders) will be adjourned to the date, time and place as the Directors present may by notice to shareholders decide, or failing any decision, to the same day in the following week at the same time and place. The meeting is dissolved if a quorum is not present within 30 minutes from the time appointed for the reconvened meeting.

Under the Australian Corporations Act, an ordinary resolution requires approval by the shareholders by a simple majority of the votes cast (namely, a resolution passed by more than 50% of the votes cast by shareholders entitled to vote on the resolution). Under our Constitution and the Australian Corporations Act, a special resolution (such as in relation to amending our Constitution, approving any variation of rights attached to any class of shares or our voluntary winding-up), requires approval of a special majority (namely a resolution that has been passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution).

- *Rights in the Event of Liquidation.* Under our Constitution, in the event of our liquidation, after satisfaction of liabilities to creditors and other statutory obligations prescribed by the laws of Australia, and the passing of a special resolution giving effect to the following, our assets will be distributed to the holders of ordinary shares in proportion to the shares held by them respectively. This right may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights, such as the right in winding up to payment in cash of the amount then paid up on the share, and any arrears of dividend in respect of that share, in priority to any other class of shares.

Changing Rights Attached to Shares

Under the Australian Corporations Act and our Constitution, the rights attached to any class of shares, unless otherwise provided by the terms of the class, may be varied with either the written consent of the holders of not less than 75% of the issued shares of that class or the sanction of a special resolution passed at a separate meeting of the holders of the shares of that class.

Annual and Extraordinary General Meetings

Under the Australian Corporations Act, our board of directors must convene an annual general meeting of shareholders at least once every calendar year and within five months after the end of our last financial year. Under the Australian Corporations Act, notice of at least 28 days prior to the date of the meeting is required. An extraordinary general meeting may be convened by Board resolution or as otherwise provided in the Australian Corporations Act.

Limitations on the Rights to Own Securities in Our Company

Other than certain limitations imposed by the takeover provisions in the Australian Corporations Act which, in general terms, prohibit a person from acquiring a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%, unless the person relies on an exception, neither our Constitution nor the laws of Australia (excluding the Foreign Acquisitions and Takeovers Act and related regulations, as discussed further below) restrict in any way the ownership of shares in our Company.

Changes in Our Capital

Pursuant to the ASX Listing Rules, we may in our discretion issue securities without the approval of shareholders, if such issue of securities, when aggregated with securities issued by us during the previous 12-month period would be an amount that would not exceed 15% of the number of ordinary shares on issue at the commencement of the 12-month period, subject to certain adjustments and permitted exceptions. Issues of securities in excess of this limit or the issue of securities to our related parties, certain substantial shareholders and their respective associates require approval of shareholders (unless otherwise permitted under the ASX Listing Rules or unless we have obtained a waiver from the ASX in relation to the 15% limit).

At a general meeting of shareholders on April 5, 2024, our shareholders ratified or approved certain agreed issuances of equity securities, including issuances of ordinary shares and performance rights to ordinary shares if we elect to settle in certain obligations that are tied to the achievement of agreed upon milestones through the issuance of shares, under and in respect of agreements pursuant to which we have acquired or have agreed to acquire certain entities, businesses and/or assets. The securities issued or agreed to be issued in connection with each such agreement are excluded from our 15% placement capacity, provided that the equity securities are issued no later than three months after the date of shareholder approval at the general meeting. At an annual

general meeting of shareholders on May 22, 2024, our shareholders approved issuances of equity securities under our Equity Incentive Plan for the purposes of ASX Listing Rule 7.1 and Listing Rule 7.2, exception 13(b). A maximum of 32,405,821 equity securities to be issued under the Equity Incentive Plan are excluded from our available placement capacity, provided that the equity securities are issued no later than three years after the date of shareholder approval at the general meeting.

Change of Control

Takeovers of listed Australian public companies, including us, are regulated by the Australian Corporations Act, which prohibits the acquisition of a "relevant interest" in issued voting shares in a listed company if the acquisition will lead to that person's or someone else's voting power in our company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, which we refer to as the Takeovers Prohibition, subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities (other than if the person holds those securities as a bare trustee);
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities.

If, at a particular time,

- a person has a relevant interest in issued securities;
- the person (whether before or after acquiring the relevant interest) has:
  - entered or enters into an agreement with another person with respect to the securities;
  - given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities (whether the right is enforceable presently or in the future and whether or not on the fulfillment of a condition); or
  - granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; and
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised,

then the other person is taken to have a relevant interest in the relevant securities.

There are a number of exceptions to the Takeover Prohibition. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder during the bid period for a full takeover bid that is unconditional or only conditional on certain 'prescribed' matters set out in the Australian Corporations Act;
- when the acquisition has been previously approved by our shareholders by resolution passed at a general meeting;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other person has had voting power in our company of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in our company more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a rights issue;
- when the acquisition results from the issue of securities under a dividend reinvestment scheme or bonus share plan;
- when the acquisition results from the issue of securities under certain underwriting arrangements;
- when the acquisition results from the issue of securities through a will or through operation of law;

- an acquisition that arises through the acquisition of a relevant interest in another listed company which is listed on a prescribed financial market or a financial market approved by ASIC;
- an acquisition arising from an auction of forfeited shares conducted on-market; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

Breaches of the takeover provisions of the Australian Corporations Act are criminal offenses. ASIC and the Australian Takeovers Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders, canceling contracts, freezing transfers of, and rights attached to, securities and forcing a party to dispose of securities. There are certain defenses to breaches of the Takeover Prohibition provided in the Australian Corporations Act.

Foreign Acquisitions and Takeovers Act

Australia's foreign investment regime is set out in the Foreign Acquisitions and Takeovers Act 1975 (Cth), or FATA, Foreign Acquisitions and Takeovers Regulation 2015 (Cth), or FATR, and Australia's Foreign Investment Policy, or the Policy. The Australian Treasurer administers the FATA, FATR and the Policy with the advice and assistance of the Foreign Investment Review Board, or FIRB.

In the circumstances set out below in the section entitled 'Mandatory notification requirements', foreign persons must make a mandatory notification and receive a prior statement of no objection, or FIRB Clearance, from the Australian Treasurer.

The Australian Treasurer has powers under the FATA to make orders, including prohibition of a proposed transaction, ordering disposal of an interest acquired in a specified time or imposing conditions on a proposed transaction if he or she considers it to be contrary to Australia's national interest. The receipt of FIRB Clearance removes the risk of the exercise of the Australian Treasurer's powers.

The obligation to make a mandatory notification and obtain FIRB Clearance is upon the acquirer of the interest, and not the Company. There are criminal and civil penalties for breaches of Australia's foreign investment regime. A breach includes failure to give notice to the Australian Treasurer and obtain FIRB Clearance, where notification is mandatory.

Investor's Responsibility

It is the responsibility of any persons who wish to acquire shares of the Company to satisfy themselves as to their compliance with the FATA, the FATR, the Policy, guidance issued by FIRB and with any other necessary approval and registration requirement or formality, before acquiring an interest in the Company.

Mandatory Notification Requirements

Broadly, FIRB Clearance is required for the following transactions involving the acquisition of shares in an Australian corporation:

- the acquisition by a foreign person who is not a foreign government investor of a substantial interest in an Australian corporation which has a total asset value in excess of the applicable monetary threshold (see below);
- any direct investment by a foreign government investor, regardless of value;
- any acquisition by a foreign person of shares in an Australian corporation that is a national security business, regardless of value; and
- any acquisition by a foreign person of shares in an Australian land corporation, which exceeds certain thresholds.

As of January 1, 2024, the prescribed threshold is A$330 million though a higher threshold of A$1.427 billion applies for certain acquirers from the United States, the United Kingdom, Canada, New Zealand, China, Japan, South Korea, Singapore, Hong Kong, Malaysia, Vietnam, Mexico, Peru and Chile unless the Australian corporation is in a sensitive sector or operates a national security business.

Application of these Requirements to the Company

As of June 30, 2024, we are not an Australian land corporation and we are not a national security business. However, our assets and market capitalization were valued above A$330 million (being the prescribed threshold that applied at June 30, 2024). Accordingly, the only circumstances in which an investor in the Company would currently be subject to the mandatory notification and FIRB Clearance requirements are if they are a foreign government investor acquiring a direct interest in the Company or a foreign person (other than a foreign government investor) acquiring a substantial interest in the Company. Applications for FIRB Clearance may be made by prospective investors in accordance with the information on FIRB's website.

The Company as a Foreign Person

If foreign persons have a substantial interest in the Company, it would be considered to be a foreign person under the FATA. In such event, we would be required to obtain FIRB Clearance for our own transactions involving certain acquisitions of interests in Australian corporations, businesses and land. If FIRB Clearance is required and not given in relation to a proposed investment, we will not be able to proceed with that investment. There can be no assurance that we will be able to obtain any required FIRB Clearances in the future.

Defined Terms Used in this Section

Foreign Persons

A foreign person is generally:

- a natural person not ordinarily resident in Australia;
- a corporation in which a natural person not ordinarily resident in Australia, or a corporation incorporated outside of Australia, holds direct or indirect, actual or potential, voting power of 20% or more;
- a corporation in which two or more persons, each of whom is either a non-Australian resident or a non-Australian corporation, hold direct or indirect, actual or potential, voting power in aggregate of 40% or more;
- a trustee of a trust in which a non-Australian resident or non-Australian corporation holds 20% or more;
- a trustee of a trust estate in which two or more persons, each of whom is either a non-Australian resident or a non-Australian corporation, hold in aggregate 40% or more; or
- a foreign government or foreign government investor.

Associates

Associate is broadly defined to include:

- the person's spouse or de facto partner, and relatives of the person;
- any person with whom the person is acting, or proposes to act, in concert in relation to an action;
- any partner of the person;
- any corporation of which the person is an officer, any officer of a corporation (where the person is a corporation), employers and employees, any employee of a natural person of whom the person is an employee;
- any corporation whose directors are accustomed or under an obligation, whether formal or informal, to act in accordance with the directions, instructions or wishes of the person or, where the person is a corporation, of the directors of the person;
- any corporation in accordance with the directions, instructions or wishes of which, or of the directors of which, the person is accustomed or under an obligation, whether formal or informal, to act;
- any corporation in which the person holds a substantial interest;

- where the person is a corporation, a person who holds a substantial interest in the corporation;
- the trustee of a trust in which the person holds a substantial interest;
- where the person is the trustee of a trust, a person who holds a substantial interest in the trust estate; and
- any person who is an associate of any other person who is an associate of the person.

Australian Land Corporation

An Australian land corporation, or ALC, is a corporation where the value of its total assets comprising interests in Australian land exceeds 50% of the value of its total assets. An ALC is not necessarily a company registered in Australia. It may be registered anywhere. It is the composition of the assets of the corporation that will make it an ALC for the purposes of the Australian foreign investment regime.

Substantial Interest

A substantial interest is:

- an interest in at least 20% or more of the actual or potential voting power or issued shares in an entity by a single foreign person (together with associates); or
- an interest in at least 40% or more of the actual or potential voting power or issued shares in an entity by multiple foreign persons (together with associates).

Direct Interest

An interest of 10% or more is considered to be a direct interest. A direct interest also includes:

- an interest of 5% or more if the acquirer has entered into a legal arrangement relating to the acquirer's business and the target's business; and
- a no minimum interest if the person who acquired the interest is in a position to influence or control the target.

Foreign Government Investor

A Foreign Government Investor is:

- a foreign government or separate government entity;
- entities in which governments, their agencies or related entities from a single foreign country have an aggregate interest (direct or indirect) of 20% or more;
- entities in which governments, their agencies or related entities from more than one foreign country have an aggregate interest (direct or indirect) of 40% or more; or
- entities that are otherwise controlled by foreign governments, their agencies or related entities, and any associates, or could be controlled by them including as part of a controlling group.

Our Constitution does not contain any additional limitations on a non-resident's right to hold or vote our securities. Under current stamp duty legislation, no Australian stamp duty will be payable in Australia on the issue or transfer of shares in the Company while it continues to satisfy the requirements of a listed company for the purposes of Australian duties legislation, provided that the shares issued or transferred do not represent 90% or more of our total issued shares.

Differences in Corporate Law

Set forth below is a comparison of certain shareholder rights and corporate governance matters under Delaware law and Australian law:

Corporate Law	Delaware Law	Australian Law
Special Meetings of Shareholders	Shareholders generally do not have the right to call meetings of shareholders unless that right is granted in the certificate of incorporation or by-laws. However, if a corporation fails to hold its annual meeting within a period of 30 days after the date designated for the annual meeting, or if no date has been designated for a period of 13 months after its last annual meeting, the Delaware Court of Chancery may order a meeting to be held upon the application of a shareholder.	The Australian Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the vote that may be cast at the general meeting. Shareholders with at least 5% of the votes that may be cast at the general meeting may also call and arrange to hold a general meeting. The shareholders calling the meeting must pay the expenses of calling and holding the meeting.
Interested Director Transactions	Interested director transactions are permissible and may not be legally voided if: • either a majority of disinterested directors, or a majority in interest of holders of shares of the corporation's capital shares entitled to vote upon the matter, approves the transaction upon disclosure of all material facts; or • the transaction is determined to have been fair as to the corporation as of the time it is authorized, approved or ratified by the board of directors, a committee thereof or the shareholders	Unless a relevant exception applies, the Australian Corporations Act requires our directors to provide disclosure of any material personal interest in a matter that relates to the affairs of the company, and prohibits directors from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered, unless directors who do not have a material personal interest in the relevant matter have passed a resolution that identifies the director, the nature and extent of the director's interest in the matter and its relation to our affairs and states that those directors are satisfied that the interest should not disqualify the director from voting or being present. In addition, the Australian Corporations Act may require shareholder approval (in the way set out in the Australian Corporations Act) of any provision of related party benefits to our directors, unless a relevant exception applies. The ASX Listing Rules also restrict us (including any of our subsidiaries) from acquiring a "substantial asset" from, or disposing of a "substantial asset" to, certain related parties (including our directors) without shareholder approval, and from issuing securities to certain related parties (including our directors) without shareholder approval, subject to exceptions.

Corporate Law	Delaware Law	Australian Law
Cumulative Voting	The certificate of incorporation of a Delaware corporation may provide that shareholders of any class or classes or of any series may vote cumulatively either at all elections or at elections under specified circumstances.	No cumulative voting concept.
Approval of Corporate Matters by Written Consent	Unless otherwise specified in a corporation's certificate of incorporation, shareholders may take action permitted to be taken at an annual or special meeting, without a meeting, notice, or a vote, if consents, in writing, setting forth the action, are signed by shareholders with not less than the minimum number of votes that would be necessary to authorize the action at a meeting. All consents must be dated and are only effective if the requisite signatures are collected within 60 days of the earliest dated consent delivered.	Australian public companies cannot under the Australian Corporations Act pass resolutions by circulating written resolutions.
Business Combinations	With certain exceptions, a merger, consolidation, or sale of all or substantially all the assets of a Delaware corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon.	Various provisions of the Australian Corporations Act and ASX Listing Rules may impact a business combination involving the company and create a need for shareholder approval. For example: • securities may not be issued which exceed 15% of our issued capital in any 12-month period without shareholder approval, unless an exception applies; • while the ASX Listing Rules apply to it, the company will not be able to make a significant change to the nature or scale of its activities (including by selling all or a substantial proportion of its assets) without shareholder approval; and • the acquisition of a "relevant interest" in issued voting shares of the company by a person is prohibited if the acquisition would result in the person's or someone else's voting power in the company increasing from 20% or more to more than 20%, or from a starting point that is above 20% and below 90%, unless an exception applies (which includes making a takeover bid or with shareholder approval).

Corporate Law	Delaware Law	Australian Law
Limitations on Director's Liability and Indemnification of Directors and Officers	A Delaware corporation may include in its certificate of incorporation provisions limiting the personal liability of its directors to the corporation or its shareholders for monetary damages for many types of breach of fiduciary duty. However, these provisions may not limit liability for any breach of the duty of loyalty, acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, the authorization of unlawful dividends, stock purchases, or redemptions, or any transaction from which a director derived an improper personal benefit. Moreover, these provisions would not be likely to bar claims arising under U.S. federal securities laws. A Delaware corporation may indemnify a director or officer of the corporation against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred in defense of an action, suit, or proceeding by reason of his or her position if (i) the director or officer acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and (ii) with respect to any criminal action or proceeding, the director or officer had no reasonable cause to believe his or her conduct was unlawful.	Australian law provides that a company or a related body corporate must not exempt a person from a liability to the company incurred as an officer or auditor of the company. However, a company or a related body corporate of the company may provide for indemnification of officers (including directors) and auditors, except to the extent of any of the following liabilities (other than for legal costs) incurred as an officer or auditor of the company: • a liability owed to the company or a related body corporate of the company; • a liability for a pecuniary penalty order made under section 1317G or a compensation order under section 961M, 1317H, 1317HA, 1317HB, 1317HC or 1317HE of the Australian Corporations Act; or • a liability that is owed to someone other than the company or a related body corporate of the company and did not arise out of conduct in good faith. An indemnity for legal costs in defending an action for a liability incurred as an officer or auditor of the company will not be allowed if the costs are incurred: • in defending or resisting proceedings in which the person is found to have a liability for which they cannot be indemnified as set out above; • in defending or resisting criminal proceedings in which the person is found guilty; • in defending or resisting proceedings brought by ASIC or a liquidator for a court order if the grounds for making the order are found by the court to have been established (except costs incurred in responding to actions taken by ASIC or a liquidator as part of an investigation before commencing proceedings for a court order); or

Corporate Law	Delaware Law	Australian Law
		• in connection with proceedings for relief to the person under the Australian Corporations Act in which the court denies the relief.
Appraisal Rights	A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights under which the shareholder may receive cash in the amount of the fair value of the shares held by that shareholder (as determined by a court) in lieu of the consideration the shareholder would otherwise receive in the transaction.	No equivalent concept under Australian law, subject to general minority oppression rights under which shareholders can apply to the courts for an order in respect of company actions that are either: contrary to the interests of the members as a whole, or oppressive to, unfairly prejudicial to, or unfairly discriminatory against, a member or members whether in that capacity or in any other capacity.
Shareholder Suits	Class actions and derivative actions generally are available to the shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste, and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.	Shareholders have a number of statutory protections and rights available to them, regardless of the quantity of shares they hold. These include: • the ability to bring legal proceedings in the company's name, including against the directors of the company, with the permission of the court; • the ability to inspect the company's books, with the permission of the court; and • the ability to apply to the court for orders in cases where company actions are oppressive to, unfairly prejudicial to or discriminatory against a shareholder, or contrary to the interest of the shareholders as a whole. The right to apply to the court for orders in cases of oppressive prejudicial actions does not have a minimum shareholding requirement, and can result in a broad range of orders, including: • the winding up of the company; • modification of the company's constitution; and • regulating the conduct of the company's affairs.
Inspection of Books and	All shareholders of a Delaware corporation have the right, upon written demand, to	Any shareholder of the company has the right to inspect our share register kept

Corporate Law	Delaware Law	Australian Law
Records	inspect or obtain copies of the corporation's shares ledger and its other books and records for any purpose reasonably related to such person's interest as a shareholder.	under the Australian Corporations Act without charge, and to obtain copies of the same if the person makes an application to the company and pays a prescribed fee. Books containing the minutes of general meetings will be kept at our registered office and will be open to inspection of shareholders at all times when the office is required to be open to the public. Generally, other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders (who are not directors). A shareholder may apply to the court to make an order for inspection and making copies of our books, and the court may only grant the order if it is satisfied that the shareholder is acting in good faith and that the inspection is to be made for a proper purpose. All public companies are required to prepare annual financial reports, directors' reports and an auditor's report for each financial year, and to file these reports with ASIC. The reports, and a concise report for the relevant financial year, must also be provided to members.
Amendments to Charter	Amendments to the certificate of incorporation of a Delaware corporation require the affirmative vote of the holders of a majority of the outstanding shares entitled to vote thereon or such greater vote as is provided for in the certificate of incorporation. A provision in the certificate of incorporation requiring the vote of a greater number or proportion of the directors or of the holders of any class of shares than is required by Delaware corporate law may not be amended, altered or repealed except by such greater vote. Any amendment to the certificate of incorporation that would alter or change the special rights, powers or preferences of one or more classes or series of stock so as to affect them adversely must, in addition to any other vote required by law or under the company's certificate of incorporation, be approved by the adversely affected class or series by a majority of all votes entitled to be cast by the holders of the outstanding shares of the class or series, voting as a separate class or series.	Amending or replacing the company's constitution requires a special resolution (≥75%) of the shareholders. The Australian Corporations Act allows a company to set out in its constitution the procedure for varying or cancelling rights attached to shares in a class of shares and provides the procedure should a company not have the procedure set out in the constitution.

Nasdaq Global Select Market Listing

We have applied to list our ADSs on the Nasdaq Global Select Market under the trading symbol "TLX."

C. Material Contracts

Please see "Item 4. Information on the Company — B. Business Overview — Collaboration and License Agreements" and "Item 5. Operating and Financial Review and Prospects — B. Liquidity and Capital Resources" for a discussion of material contracts. Except as otherwise disclosed in this registration statement (including the exhibits), we are not currently, and have not been in the preceding two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars or other currencies. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Transaction Reports and Analysis Centre, or AUSTRAC, which monitors such transactions, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply and under such there are either exemptions or limitations on the level of tax to be withheld.

E. Taxation

The following is a summary of material U.S. federal and Australian income tax considerations to U.S. Holders, as defined below, of the acquisition, ownership and disposition of our ADSs and ordinary shares. This discussion is based on the laws in force as of the date of this registration statement, and is subject to changes in the relevant tax law, including changes that could have retroactive effect. The following summary is not a comprehensive description of all U.S. federal or Australian tax considerations that may be relevant to a decision to acquire or dispose of ADSs or ordinary shares and does not take into account or discuss the tax laws of any country or other taxing jurisdiction other than the United States and Australia. Holders are advised to consult their tax advisors concerning the overall tax consequences of the acquisition, ownership and disposition of ADSs and ordinary shares in their particular circumstances. This discussion is not intended, and should not be construed, as legal or professional tax advice.

Material U.S. Federal Income Tax Considerations

The following summary describes the material U.S. federal income tax consequences to a U.S. Holder (as defined below) of the acquisition, ownership and disposition of the ADSs and ordinary shares as of the date hereof. This summary is limited to U.S. Holders that hold the ADSs or ordinary shares as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code.

This summary does not address the Medicare tax on net investment income, the effects of U.S. federal estate and gift tax laws, alternative minimum taxes, or any state and local tax considerations. In addition, this section does not discuss the tax consequences to any particular holder or any tax considerations that may apply to U.S. Holders subject to special tax rules, such as:

- insurance companies;
- banks or other financial institutions;
- tax-exempt entities including pension plans, "individual retirement accounts" or "Roth IRAs";
- regulated investment companies;
- real estate investment trusts;
- individuals who are former U.S. citizens or former long-term U.S. residents;
- brokers, dealers or traders in securities, commodities or currencies;
- traders that elect to use a mark-to-market method of accounting;
- except as specifically described below, persons holding the ADSs or ordinary shares through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- persons that received ADSs or ordinary shares as compensation for the performance of services;
- persons that hold ADSs or ordinary shares as a position in a straddle or as part of a hedging, constructive sale, conversion or other integrated transaction for U.S. federal income tax purposes;
- persons that have a functional currency other than the U.S. dollar;
- corporations that accumulate earnings to avoid U.S. federal income tax; or
- persons that own (directly, indirectly or constructively) 10% or more of our equity (by vote or value).

In this section, a "U.S. Holder" means a beneficial owner of our ADSs or ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a court in the United States and for which one or more U.S. persons has the authority to control all substantial decisions or (ii) that has an election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person for U.S. federal income tax purposes.

We have not received, nor do we expect to seek, a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state and local and non-U.S. tax consequences of acquiring, owning and disposing of the ADSs and ordinary shares.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes acquires, owns or disposes of ADSs or ordinary shares, the U.S. federal income tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its own tax advisor as to the U.S. federal income tax consequences of acquiring, owning and disposing of the ADSs or ordinary shares.

The discussion below is based upon the provisions of the Code, existing and proposed U.S. Treasury regulations, published rulings and judicial decisions, all as of the date hereof. Such authorities may be replaced, revoked or modified, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISOR WITH RESPECT TO THE U.S. FEDERAL, AS WELL AS STATE, LOCAL AND NON-U.S. TAX CONSEQUENCES TO YOU OF ACQUIRING, OWNING AND DISPOSING OF ADSs OR ORDINARY SHARES IN LIGHT OF YOUR PARTICULAR CIRCUMSTANCES, INCLUDING THE POSSIBLE EFFECTS OF CHANGES IN U.S. FEDERAL AND OTHER TAX LAWS.

ADSs

Assuming that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement will be complied with in accordance with their terms, a U.S. Holder of ADSs generally will be treated for U.S. federal income tax purposes as the owner of the underlying ordinary shares that are represented by such ADSs. Accordingly, no gain or loss will be recognized for U.S. federal income tax purposes if a U.S. Holder exchanges ADSs for the underlying ordinary shares represented by those ADSs.

Distributions

As described below in "– F. Dividends and Paying Agents," we do not currently anticipate paying any distributions on the ADSs or ordinary shares in the foreseeable future. However, to the extent there are any distributions made with respect to the ADSs or ordinary shares, and subject to the PFIC rules discussed below, the gross amount of any such distributions made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits, as so determined, will be treated first as a tax-free return of capital to the extent of the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares, as applicable, and thereafter, as capital gain. However, because we do not intend to calculate our earnings and profits under U.S. federal income tax principles, it is expected, and U.S. Holders should assume, that any distribution will be reported as a dividend and will constitute ordinary dividend income to a U.S. Holder. Any dividends will generally be treated as foreign-source and will not be eligible for the dividends-received deduction generally allowed to corporate U.S. Holders.

Subject to the discussion under "—Passive Foreign Investment Company Considerations," below, dividends paid to non-corporate U.S. Holders may qualify as "qualified dividend income" eligible for the preferential rates of taxation applicable to long-term capital gains if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. We generally will be considered to be a qualified foreign corporation (i) if we are eligible for the benefits of the Convention between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on August 6, 1982, as amended and currently in force, or the U.S.-Australia Tax Treaty, or (ii) the ADSs or our ordinary shares are readily tradable on an established securities market in the United States. We have applied to list our ADSs on Nasdaq, which is an established securities market in the United States, although there can be no assurance that the ADSs will be listed or remain listed on Nasdaq or be considered readily tradable on an established securities market in the United States now or in the future. In addition, we believe that we qualify as a resident of Australia for purposes of, and are eligible for the benefits of, the U.S.-Australia Tax Treaty, although there can be no assurance in this regard. Therefore, subject to the discussion under "— Passive Foreign Investment Company Considerations," below, any dividends on the ADSs or our ordinary shares generally will be "qualified dividend income" in the hands of individual

U.S. Holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met.

Distributions paid in Australian dollars, including any Australian taxes withheld, will be included in a U.S. Holder's gross income in a U.S. dollar amount calculated by reference to the spot exchange rate in effect on the date of actual or constructive receipt, regardless of whether the Australian dollars are converted into U.S. dollars at that time. A U.S. Holder will have a tax basis in the Australian dollars equal to their U.S. dollar value on the date of receipt. As a result, if a U.S. Holder converts the Australian dollars into U.S. dollars on the date of receipt, such U.S. Holder generally should not be required to recognize any foreign exchange gain or loss. If Australian dollars so received are not converted into U.S. dollars on the date of receipt, any gain or loss on a subsequent conversion or other disposition of the Australian dollars generally will be treated as ordinary income or loss and generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

Subject to certain limitations, a U.S. Holder may be able to claim as a credit against its U.S. federal income tax liability the amount of any Australian tax withheld from any dividends at a rate not exceeding an applicable rate under the U.S.-Australia Tax Treaty. Alternatively, a U.S. Holder may be able to deduct such Australian taxes from its U.S. federal taxable income, provided that the U.S. Holder elects to deduct rather than credit all foreign income taxes paid or accrued for the relevant taxable year. The rules governing U.S. foreign tax credits are complex and U.S. Treasury Regulations may further restrict the availability of any such credit based on the nature of the withholding tax imposed by the foreign jurisdiction. A notice from the IRS indicates that the IRS is considering proposing amendments to such foreign tax credit regulations. Each U.S. Holder should consult its tax advisors regarding the foreign tax credit rules, including regarding the availability of such credit or deductions.

Sale, Exchange or Other Disposition of ADSs or Ordinary Shares

A U.S. Holder generally will recognize gain or loss for U.S. federal income tax purposes upon the sale or other taxable disposition of the ADSs or the ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such disposition and the U.S. Holder's adjusted tax basis in those ADSs or ordinary shares, determined in U.S. dollars. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, any such gain or loss generally will be a capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder's holding period for such ADSs or ordinary shares is more than one year at the time of such disposition. A U.S. Holder's adjusted tax basis in the ADSs or ordinary shares generally will be equal to the amount paid for such ADSs or ordinary shares. Any long-term capital gain from the disposition of the ADSs or our ordinary shares by a non-corporate U.S. Holder generally is eligible for a preferential rate of taxation. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. Holder recognizes generally will be treated as U.S.-source gain or loss for foreign tax credit limitation purposes. U.S. Holders should consult their tax advisors regarding the tax consequences if Australian taxes are imposed on or in connection with a sale, exchange or other disposition of the ADSs or the ordinary shares and their ability to credit any Australian tax against their U.S. federal income tax liability.

In the case of a U.S. Holder that is a cash basis taxpayer, any units of foreign currency received on a disposition of the ADSs or our ordinary shares are translated into U.S. dollars at the spot exchange rate on the settlement date of the disposition if the ADSs or ordinary shares disposed of are treated as traded on an established securities market. In such case, no foreign currency exchange gain or loss will result for a cash basis taxpayer from currency fluctuations between the trade date and the settlement date of such a disposition. An accrual basis taxpayer may elect the same treatment required of cash basis taxpayers with respect to dispositions of the ADSs or our ordinary shares that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. If an accrual basis taxpayer does not make such election, or if the ADSs or our ordinary shares are not treated as traded on an established securities market, any units of foreign currency received on a disposition of the ADSs or our ordinary shares are translated into U.S. dollars at the spot exchange rate on the trade date of the disposition. In such case, the taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder recognizes will be U.S.-source ordinary income or loss.

Passive Foreign Investment Company Considerations

If we are classified as a PFIC in any taxable year, certain adverse tax consequences could apply to U.S. Holders as a result of that classification. We generally will be classified as a PFIC for any taxable year if (i) at least 75% of our gross income for the taxable year consists of certain types of passive income, or (ii) at least 50% of our gross assets during the taxable year, based on a quarterly average and generally determined by value, produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions and gains from the disposition of assets that produce or are held for the production of passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. In determining whether we are a PFIC, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of each corporation in which we own, directly or indirectly, at least a 25% interest (by value).

Based on the expected nature and amount of our estimated gross income, the anticipated nature and estimated average value of our gross assets, the anticipated cash needs of our group's operations and the nature and extent of the active businesses conducted by our "25% or greater" owned subsidiaries, we do not expect that we will be classified as a PFIC in the current taxable year or for the foreseeable future. However, the determination of our PFIC status for any taxable year will not be determinable until after the end of the taxable year, and will depend on, among other things, the composition of our income and assets (which could change significantly during the course of a taxable year) and the market value of our assets for such taxable year, which may be, in part, based on the market price of the ADSs or ordinary shares (which could be volatile). Accordingly, there can be no assurance that we will not be a PFIC for our current or any future taxable year. U.S. Holders should consult their own tax advisors regarding our PFIC status.

If we are a PFIC for any taxable year during which a U.S. Holder holds ADSs or ordinary shares, absent certain elections (including the mark-to-market election or qualified electing fund election described below), such U.S. Holder generally will be subject to adverse rules (regardless of whether we continue to be classified as a PFIC) with respect to (i) any "excess distribution" that we make to such U.S. Holder (generally, any distributions on the ADSs or ordinary shares in a taxable year that are greater than 125% of the average annual distributions received by such U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period) and (ii) any gain recognized from a sale or other disposition (including a pledge) of such ADSs or ordinary shares. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we were classified as a PFIC will be treated as ordinary income arising in the current taxable year (and would not be subject to the interest charge discussed below); and
- the amount allocated to each other taxable year will be subject to income tax at the highest marginal tax rate in effect for individuals or corporations, as applicable, for such year, and the interest charge generally applicable to underpayments of tax will be imposed with respect to the resulting tax attributable to each such year.

In addition, non-corporate U.S. Holders will not be eligible for reduced rates of taxation applicable to "qualified dividend income" on any dividends that we pay if we are a PFIC for either the taxable year in which the dividend is paid or the preceding year.

If we are classified as a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to be classified as a PFIC under the tests described above, unless we cease to be classified as a PFIC and such U.S. Holder makes a "deemed sale" election. If we cease to be classified as a PFIC and a U.S. Holder makes the "deemed sale" election, such U.S. Holder will be deemed to have sold our ADSs or ordinary shares at their fair market value on the last day of the last taxable year in which we were classified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime described above. After the "deemed sale" election, a U.S. Holder's ADSs or ordinary shares would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, and one of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions.

If a U.S. Holder owns ADSs or our ordinary shares during any taxable year in which we are a PFIC, such U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to us, generally with its U.S. federal income tax return for that year. U.S. Holders should consult their tax advisors regarding any annual filing requirements.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on our ADSs or ordinary shares if a valid "mark-to-market" election is made by the U.S. Holder for our ADSs or ordinary shares, provided that the ADSs or ordinary shares held by such U.S. Holder are "marketable."

If a U.S. Holder makes a mark-to-market election, it must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs or ordinary shares that are "marketable stock" at the close of the taxable year over such U.S. Holder's adjusted tax basis in such ADSs or ordinary shares. If a U.S. Holder makes such election, it may also claim a deduction as an ordinary loss in each such year for the excess, if any, of such U.S. Holder's adjusted tax basis in such ADSs or ordinary shares over their fair market value at the end of the year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. The U.S. Holder's adjusted tax basis in the ADSs or ordinary shares with respect to which the mark-to-market election applies would be adjusted to reflect amounts included in gross income or allowed as a deduction because of such election. If a U.S. Holder makes an effective mark-to-market election, any gain recognized upon the sale or other disposition of the ADSs or ordinary shares in a year that we are a PFIC will be treated as ordinary income and any loss will be treated first as ordinary loss (to the extent of any net mark-to-market gains for prior years) and thereafter as capital loss. However, a mark-to-market election will generally not be available with respect to a lower-tier PFIC unless the shares of such lower-tier PFIC are themselves treated as "marketable stock."

If a U.S. Holder makes a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs or ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. U.S. Holders are urged to consult their tax advisors about the availability of the mark-to-market election.

Alternatively, in certain cases, a U.S. Holder may be able to avoid the interest charge and the other adverse PFIC tax consequences described above by electing to treat the PFIC as a "qualified electing fund," or QEF, under Section 1295 of the Code. If a U.S. Holder makes a valid and timely QEF election and we provide certain required information to such U.S. Holder, then for each taxable year to which such an election applies, the U.S. Holder will be subject to U.S. federal income tax on its pro rata share of our net capital gain and ordinary earnings, regardless of whether such amounts are actually distributed to the U.S. Holder in that year or any later year. However, we do not anticipate that this election will be available to U.S. Holders because we do not expect to provide U.S. Holders with the information that would be necessary to make a valid QEF election.

Backup Withholding Tax and Information Reporting Requirements

U.S. Holders generally will be subject to information reporting requirements with respect to distributions paid on the ADSs or our ordinary shares, and on the proceeds from the sale, exchange or other disposition of the ADSs or our ordinary shares that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. Holder is an "exempt recipient." In addition, U.S. Holders may be subject to backup withholding on such payments, unless the U.S. Holder provides a correct taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. Holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Certain U.S. Holders are required to report information relating to an interest in the ADSs and our ordinary shares, subject to certain exceptions (including an exception for ADSs and ordinary shares held in accounts

maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their U.S. federal income tax return. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. U.S. Holders should consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs or our ordinary shares.

THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs AND ORDINARY SHARES AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS REGISTRATION STATEMENT, ALL OF WHICH ARE SUBJECT TO CHANGE OR DIFFERING INTERPRETATION, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN THE ADSs AND ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Material Australian Tax Considerations

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ADSs or ordinary shares. It is based upon existing Australian tax law as of the date of this registration statement, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax-exempt organizations). In addition, this summary does not discuss any non-Australian or state tax considerations, other than stamp duty.

Prospective investors are urged to consult their tax advisors regarding the Australian and non-Australian income and other tax considerations of the acquisition, ownership and disposition of the ADSs or shares. This summary is based upon the premise that the holder is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment (referred to as a "Non-Australian Holder" in this summary).

Nature of ADSs for Australian Taxation Purposes

Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding their rights and obligations under the deposit agreement with the depositary, including whether the deposit arrangement constitutes a 'bare trust' for Australian taxation purposes. Specialist Australian tax advice should also be obtained before a Non-Australian Holder surrenders ADSs to the depository for cancellation to receive the ordinary shares underlying those ADSs. Apart from certain aspects of the Australian tax legislation (for example, the Australian capital gains tax and withholding tax provisions, which are discussed below), there is no express legislative basis for disregarding "bare trusts" for Australian tax purposes generally. This summary proceeds on the assumption that the deposit arrangement constitutes a bare trust such that a Holder of an ADS is absolutely entitled (as against the depository) to the underlying share and presently entitled to dividends paid on the underlying shares.

Holders of ADSs can be treated as the owners of the underlying ordinary shares for Australian capital gains tax purposes provided that they are 'absolutely entitled' to those shares. Dividends paid on the underlying ordinary shares will also be treated as dividends derived by the holders of ADSs as the persons presently entitled to those dividends.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent they are paid out of company profits that have been subject to income tax. Fully franked dividends are not subject to dividend withholding tax. To the extent that they are unfranked, dividends payable to Non-Australian Holders will be subject to dividend withholding tax except to the extent they are declared to be conduit foreign income, or CFI. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation treaty and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not declared to be CFI to which a resident of the United States is beneficially entitled is limited to 15% where that resident is a qualified person for the purposes of the Double Taxation Convention.

Under the Double Taxation Convention between Australia and the United States, if a company that is a resident of the United States and qualifies for the benefits of the Convention directly owns a 10% or greater interest in us, the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to which the company is beneficially entitled is limited to 5%.

Character of ADSs for Australian Taxation Purposes

The Australian tax treatment of a sale or disposal of the ADSs will depend on whether they are held on revenue or capital account. ADSs may be held on revenue rather than capital account, for example, where they are held by share traders or where the shares are acquired for the purposes of sale by the holder at a profit. Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding the characterization of any gain or loss on a sale or disposal of the ADSs as revenue or capital in nature.

Tax on Sales or other Dispositions of Shares—Capital Gains Tax

A Non-Australian Holder who is treated as the owner of the underlying shares on the basis that they are absolutely entitled to those shares will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of ordinary shares unless the shares are "taxable Australian property." The shares will be "taxable Australian property" under current law where:

- the Non-Australian Holder, together with associates, holds 10% or more of our issued capital, at the time of disposal or for a 12-month period during the two years prior to disposal; and
- more than 50% of our assets held directly or indirectly, determined by reference to market value, consist of Australian real property (which includes land and leasehold interests) or Australian mining, quarrying or prospecting rights at the time of disposal.

However, the Australian government announced that the capital gains tax rules for non-residents will be clarified and broadened with effect from July 1, 2025 so that they apply to assets with 'a close economic connection to Australian land' (in addition to 'real property'), and to apply the 50% value test throughout a 12 month period prior to disposal rather than at the time of disposal. Non-Australian Holders should monitor developments in this regard.

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rates. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains. The 50% capital gains tax discount is not available to Non-Australian Holders on gains from assets acquired or accrued after May 8, 2012 where they were non-Australian residents during the entire holding period. Companies are not entitled to a capital gains tax discount.

Broadly, where there is a disposal of certain taxable Australian property, the purchaser will be required to withhold and remit to the Australian Taxation Office, or the ATO, 12.5% of the proceeds from the sale. On December 13, 2023, the Australian government announced that the withholding rate will be increased from 12.5% to 15% of the proceeds of sale for disposals occurring from January 1, 2025. While draft legislation has been released, this announced increase is yet to be legislated and may be subject to change. A transaction is excluded from the withholding requirements in certain circumstances, including where the transaction is an on-market transaction conducted on an approved stock exchange, a securities lending transaction, or the transaction is conducted using a broker operated crossing system. There may also be an exception to the requirement to withhold where a Non-Australian Holder provides a declaration that their ordinary shares are not 'indirect Australian real property interests,' although the Australian government is currently running a consultation process to consider whether the Australian Taxation Office should be notified in advance of such a declaration being made for transactions with a value in excess of A$20 million. The Non-Australian Holder may be entitled to receive a tax credit for the tax withheld by the purchaser which they may claim in their Australian income tax return.

Tax on Sales or other Dispositions of ADSs or Shares—Revenue Account

Non-Australian Holders who hold their ADSs on revenue account may have the gains made on the sale or other disposal of the ADSs included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia. There are no express provisions which treat holders of ADSs as the owners of the underlying shares where there is a bare trust.

Non-Australian Holders assessable under these ordinary income provisions in respect of gains made on ADSs held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 30% for individuals, and would be required to file an Australian tax return. Relief from Australian income tax may be available to a Non-Australian Holder who is resident of a country with which Australia has a double taxation treaty, qualifies for the benefits of the treaty and does not, for example, derive the gain in carrying on business through a permanent establishment in Australia.

To the extent an amount would be included in a Non-Australian Holder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount may be reduced, so that the holder may not be subject to double Australian tax on any part of the gain.

The statements under "— Tax on Sales or Other Dispositions of Shares—Capital Gains Tax" regarding a purchaser being required to withhold 12.5% tax (proposed to increase to 15% from January 1, 2025) on the acquisition of certain taxable Australian property are also relevant where the disposal of the ADSs by a Non-Australian Holder is likely to generate gains on revenue account, rather than a capital gain.

The same consequences apply for Non-Australian Holders who hold ordinary shares on revenue account.

Dual Residency

If a holder of ADSs is a resident of both Australia and the United States under those countries' domestic taxation laws, that holder may be subject to tax as an Australian resident. If, however, the holder is an individual and is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax would be subject to limitation by the Double Taxation Convention. Holders should obtain specialist taxation advice in these circumstances.

Stamp Duty

No Australian stamp duty is payable by Australian residents or non-Australian residents on the issue, transfer and/or surrender of the ADSs or ordinary shares while we continue to satisfy the requirements of a listed company for the purposes of Australian duties legislation, provided that the securities issued, transferred and/or surrendered do not represent 90% or more of our issued shares.

Australian Death Duty

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax.

Goods and Services Tax

No Australian goods and services tax will be payable on the supply of the ADSs or ordinary shares.

THE DISCUSSION ABOVE IS A SUMMARY OF THE AUSTRALIAN TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS REGISTRATION STATEMENT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

F. Dividends and Paying Agents

Due to the stage of our company and the corporate objective of building and investing in our pipeline for the future, we have not declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our operations and pipeline development activities and build the capabilities of our business to drive growth and value accretion. Future dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to applicable Australian law.

While we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, any dividend that we may declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of the ADSs, subject to the terms of the deposit agreement. See "Item 12. Description of Securities Other than Equity Securities — D. American Depositary Shares."

G. Statement by Experts

The financial statements as of December 31, 2023 and 2022 and for each of the three years in the period ended December 31, 2023 included in this registration statement have been so included in reliance on the report of PricewaterhouseCoopers, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

H. Documents on Display

When this registration statement on Form 20-F becomes effective, we will be subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. The SEC maintains a website at www.sec.gov from which our filings may be accessed.

As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and may submit to the SEC, on a Form 6-K, unaudited semi-annual financial information as required.

In addition, since our ordinary shares are traded on the ASX, we have filed periodic corporate reports, including annual and semi-annual reports with, and furnish information to, the ASX, as required under the ASX Listing Rules and the Australian Corporations Act. Copies of our filings with the ASX can be retrieved electronically at www.asx.com.au under our symbol "TLX." We also maintain a web site at www.telixpharma.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this registration statement, and the reference to our website in this registration statement is an inactive textual reference only.

I. Subsidiary Information

For information about our subsidiaries, see "Item 4. Information on the Company — C. Organizational Structure."

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily attributable to foreign currency exchange rate risk.

Interest Rate Risk

As of June 30, 2024, we had cash and cash equivalents of A$118.8 million. We have limited exposure to interest rate risk. Our cash and cash equivalents are not locked into long-term deposits at fixed rates so as to mitigate the risk of earning interest below the current floating rate.

Our exposure to market interest rates relates primarily to short-term deposits. The roll-over loan facility totaling A$3.2 million (translated from Euros based on the exchange currency rate as of June 30, 2024) carries an interest rate that is calculated using the eurozone interbank interest rate as of each interest determination date. However, all of our borrowings that have been drawn down as of June 30, 2024 bear a fixed interest rate. Therefore, we are not exposed to any significant interest rate risk under these borrowings. An immediate 10% change in current market interest rates would not have a material impact on our borrowings, financial position or results of operations.

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations, or financial condition.

Foreign Currency Exchange Rate Risk

Foreign currency risk is the risk of fluctuation in fair value or future cash flows of a financial instrument as a result of changes in foreign exchange rates. We operate internationally and are exposed to foreign exchange risk, primarily related to the U.S. dollar and Euro. Foreign exchange risk arises from commercial activities in the United States and research and development activities in Europe and the United States.

Our treasury risk management policy is to settle all U.S. dollar denominated expenditures with U.S. dollar denominated receipts from sales of Illuccix in the United States. We also manage currency risk by making decisions as to the levels of cash to hold in each currency by assessing future activities which will likely be incurred in those currencies. Any remaining foreign currency exposure has therefore not been hedged.

We have both foreign currency receivables and payables, predominantly denominated in U.S. dollar and Euro. We had a surplus of foreign currency receivables and financial assets over payables of A$26.5 million and A$28.1 million as of December 31, 2023 and June 30, 2024, respectively.

Our exposure to the risk of changes in foreign exchange rates also relates to the net investments in foreign subsidiaries, which predominantly include denominations in the Euro and the U.S. dollar. However, given the low level of current investments in foreign subsidiaries, this impact is limited.

As of June 30, 2024, we held 6.1% of our cash in Australian dollars, 83.2% in U.S. dollars, 9.8% in Euros, 0.1% in Japanese Yen, 0.1% in Canadian dollars and 0.7% in Swiss Francs. The following table sets forth the balances of our cash and cash equivalents, trade receivables and financial assets as of June 30, 2024 that give rise to currency risk exposure, as presented in Australian dollars:

	U.S. Dollars A$	Euros A$	Swiss Francs A$	Japanese Yen A$	Canadian Dollars A$
	(in thousands)				
Cash and cash equivalents	98.9	11.7	0.8	0.1	0.1
Trade receivables	87.3	1.0	—	—	0.1
Financial assets	—	10.5	—	—	—

We are primarily exposed to foreign exchange risk inherent in U.S. dollar-denominated cash and cash equivalents, trade receivables, trade payables and contingent consideration liability and in Euro-denominated cash and cash equivalents, trade payables and contingent consideration liability. We also have exposure to exchange

rate risk from the Euro attributable to our Euro-denominated loans from BNP Paribas and IMBC Group. For the six months ended June 30, 2024, an increase or decrease of the Australian dollar to U.S. dollar exchange rate by 10% would increase our profit after tax by A$2.9 million or decrease our profit after tax by A$3.5 million, respectively, and an increase or decrease of the Australian dollar to Euro exchange rate by 10% would increase our profit after tax by A$1.9 million or decrease our profit after tax by A$2.3 million, respectively. For the year ended December 31, 2023, an increase or decrease of the Australian dollar to U.S. dollar exchange rate by 10% would increase our profit after tax by A$1.7 million or decrease our profit after tax by A$2.1 million, respectively, and an increase or decrease of the Australian dollar to Euro exchange rate by 10% would increase our profit after tax by A$1.5 million or decrease our profit after tax by A$1.8 million, respectively. For more information on our currency risk exposure and sensitivity analysis, see Note 30.3 to our audited consolidated financial statements included elsewhere in this registration statement.

Liquidity Risk

We are exposed to liquidity and funding risk from operations and from external borrowings, where the risk is that we may not be able to refinance debt obligations or meet other cash outflow obligations when required. Vigilant liquidity risk management requires that we maintain sufficient liquid assets (mainly cash and cash equivalents). We manage liquidity risk by maintaining adequate cash reserves by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to us. Credit risk arises from cash and cash equivalents and credit exposures to customers, including outstanding receivables.

Credit risk is managed on a group basis. If customers are independently rated, these ratings are used. Otherwise, if there is no independent rating, we assess the credit quality of the customer, taking into account its financial position, past experience and other factors. Individual risk limits are set based on internal or external ratings. The compliance with credit limits by customers is regularly monitored. We obtain guarantees where appropriate to mitigate credit risk.

We apply the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The expected loss rates are based on historical payment profiles of sales and the corresponding historical credit losses experienced. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

Trade receivables are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with us, and the failure to make contractual payments for a period of greater than 120 days past due.

Impairment losses on trade receivables are presented within sales and marketing costs within profit or loss. Subsequent recoveries of amounts previously written off are credited against the same line item. The expected credit losses were A$0.5 million and A$0.1 million as of December 31, 2023 and June 30, 2024, respectively.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

JPMorgan Chase Bank, N.A. ("JPMorgan"), as depositary, will issue the ADSs. Each ADS will represent an ownership interest in a designated number or percentage of ordinary shares that we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary, and all holders and beneficial owners from time to time of American Depositary Receipts, or ADR, issued thereunder.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

The ADS-to-ordinary share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you.

A beneficial owner is any person or entity having a beneficial ownership interest in ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the deposit agreement solely through the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive that reflect your ownership of ADSs.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder or beneficial owner, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Australian law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder or of a beneficial owner. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. The obligations of our company and

the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the ordinary shares, you must rely on it to exercise the rights of a shareholder on your behalf.

The deposit agreement, the ADRs and the ADSs are governed by the internal laws of the State of New York without giving effect to the application of the conflict of law principles thereof. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of Australia.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR that contains the terms of your ADSs. You can read a copy of the deposit agreement, which is filed as an exhibit to this registration statement (or amendment hereto) filed with the SEC. You may find the registration statement and the attached deposit agreement on the SEC's website at http://www.sec.gov.

Distributions on Deposited Securities, Sales

How will I receive dividends and other distributions on the ordinary shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan to direct, manage and/or execute any public and/or private sale of securities and/or property under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary chargeable to holders of ADSs. All sales of securities will be handled by the depositary in accordance with its then current policies. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent. In all instances where the deposit agreement or an ADR refers to a “sale” (or words of similar import) of securities or property, the depositary may, but shall not be obligated, to effect any such sale unless the securities to be sold are listed and publicly traded on a securities exchange or there is a public market for the property to be sold. To the extent the securities are not so listed and publicly traded or there is no public market for the property so distributed by us: (i) the depositary shall, in the event the deposit agreement is terminated and the depositary holds deposited securities that are not listed and publicly traded after the termination date of the deposit agreement, act in accordance with the termination provisions of the deposit agreement and form of ADR in respect of such securities and property; and (ii) in the event the depositary or its custodian receives a distribution other than cash, our ordinary shares and/or rights to acquire our ordinary shares, and such distribution consists of securities or property that are not distributed by the depositary the depositary will be deemed to have sold the aggregate number of securities and/or property so received for nominal value and shall have no obligation to distribute such securities or any proceeds from the deemed sale thereof to the ADR holders. Furthermore, in the event the depositary endeavors to make a sale of ordinary shares, other securities or property, such securities and/or property may be sold in a block sale or single lot transaction.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash*. The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being permissible or practicable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' fees and expenses in (a) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (b) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (c) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (d) making any sale by public or private means in any commercially reasonable manner. To the extent that any of the deposited securities is not or shall not be entitled, by reason of its

date of issuance, or otherwise, to receive the full amount of such cash dividend, distribution, or net proceeds of sales, the depositary shall make appropriate adjustments in the amounts distributed to the ADR holders issued in respect of such deposited securities. To the extent we or the depositary shall be required to withhold and do withhold from any cash dividend, distribution or net proceeds from sales in respect of any deposited securities an amount on account of taxes, the amount distributed on the ADSs issued in respect of such deposited securities shall be reduced accordingly.

To the extent the depositary determines in its discretion that it would not be permitted by applicable law, rule or regulation, or it would not otherwise be practicable, to convert foreign currency into U.S. dollars and distribute such U.S. dollars to some or all of the ADR holders entitled thereto, the depositary may in its discretion distribute some or all of the foreign currency received by the depositary as it deems permissible and practicable to, or retain and hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the ADR holders entitled to receive the same. To the extent the depositary retains and holds any cash, foreign currency, securities or other property as permitted under the deposit agreement, any and all fees, charges and expenses related to, or arising from, the holding thereof shall be paid from such cash, foreign currency, securities or other property, or the net proceeds from the sale thereof, thereby reducing the amount so held. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*

- *Shares*. In the case of a distribution in ordinary shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such ordinary shares. Only whole ADSs will be issued. Any ordinary shares that would result in fractional ADSs will be sold and the net proceeds of the public or private sales of such will be distributed in the same manner as cash to the ADR holders entitled thereto.
- *Rights to receive additional ordinary shares*. In the case of a distribution of rights to subscribe for additional ordinary shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:

  (i) sell such rights if practicable and distribute the net proceeds of the public or private sales of such rights in the same manner as cash to the ADR holders entitled thereto; or

  (ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

  We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.
- *Other Distributions*. In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds of public or private sales in the same way it distributes cash.
- *Elective Distributions*. In the case of a dividend payable at the election of our shareholders in cash or in additional ordinary shares, we will notify the depositary at least 30 days prior to the proposed distribution stating whether or not we wish such elective distribution to be made available to ADR holders. The depositary shall make such elective distribution available to ADR holders only if (i) we shall have timely requested that the elective distribution is available to ADR holders, (ii) the depositary shall have determined that such distribution is reasonably practicable and (iii) the depositary shall have received satisfactory documentation within the terms of the deposit agreement including any legal opinions of counsel that the depositary in its reasonable discretion may request. If the above conditions are not satisfied, the depositary shall, to the extent permitted by law, distribute to the ADR holders, on the basis of the same determination as is made in the local market in respect of the ordinary shares for which no election is made, either (x) cash or (y) additional ADSs representing such additional ordinary

shares. If the above conditions are satisfied, the depositary shall establish procedures to enable ADR holders to elect the receipt of the proposed dividend in cash or in additional ADSs. There can be no assurance that ADR holders or beneficial owners of ADSs generally, or any ADR holder or beneficial owner of ADSs in particular, will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

If the depositary determines in its sole discretion that any distribution described above is not practicable with respect to any or all ADR holders, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of some or all of any cash, foreign currency, securities or other property (or appropriate documents evidencing the right to receive some or all of any such cash, foreign currency, security or other property), and/or it may retain some or all of such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items. To the extent the depositary does not reasonably believe it will be permitted by applicable law, rule or regulation to convert foreign currency into U.S. dollars and distribute such U.S. dollars to some or all of the ADR holders, the depositary may in its discretion distribute the foreign currency received by the depositary to, or hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the ADR holders entitled to receive the same. To the extent the depositary holds such foreign currency, any and all costs and expenses related to, or arising from, the holding of such foreign currency shall be paid from such foreign currency thereby reducing the amount so held.

Any U.S. dollars will be paid via wire transfer and/or distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, ordinary shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com").

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance.

In connection with the deposit of ordinary shares, the depositary or its custodian may require the following in a form satisfactory to it: (i) a written order directing the depositary to issue to, or upon the written order of, the person or persons designated in such order ADSs representing such deposited Shares; (ii) proper endorsements or duly executed instruments of transfer in respect of such deposited ordinary shares; (iii) instruments assigning to the depositary, its custodian or a nominee of either any distribution on or in respect of such deposited ordinary shares or indemnity therefor; and (iv) proxies entitling the custodian to vote such deposited ordinary shares. The deposited ordinary shares and any such additional items are referred to as "deposited securities." As soon as practicable after the custodian receives deposited securities pursuant to any such deposit or pursuant to a distribution or change affecting deposited securities, the custodian shall present such deposited securities for registration of transfer into the name of the depositary, its custodian or a nominee of either, in each case for the benefit of ADR holders, to the extent such registration is practicable, at the cost and expense of the person making such deposit (or for whose benefit such deposit is made) and shall obtain evidence satisfactory to it of such registration.

The custodian will hold all deposited ordinary shares for the account and to the order of the depositary, in each case for the benefit of ADR holders, to the extent not prohibited by law. ADR holders and beneficial owners thus have no direct ownership interest in the ordinary shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares.

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

Upon each deposit of ordinary shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such ADR holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, subject to the provisions of or governing our ordinary shares (including, without limitation, our governing documents and all applicable laws, rules and regulations), the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office (or from the custodian to the extent dematerialized). At your risk, expense and request, the depositary may deliver deposited securities (including any certificates therefor) at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Record Dates

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights,
- to pay any fees assessed by, or owing to, the depositary for administration of the ADR program and for any expenses as provided for in the ADR, or
- to receive any notice or to act or be obligated in respect of other matters,

all subject to the provisions of the deposit agreement.

Voting Rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the ordinary shares which underlie your ADSs. As soon as practicable after receipt from us of notice of any meeting at which the holders of ordinary shares are entitled to vote, or of our solicitation of consents or proxies from holders of ordinary shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least thirty (30) days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a "voting notice" stating (i) final information particular to such vote and meeting and any solicitation materials, (ii) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of the laws of the Commonwealth of Australia, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder's ADRs and (iii) the manner in which such instructions may be given, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder's name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders' instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for The Depository Trust Company, or DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders' ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

Under the laws of the Commonwealth of Australia and our constituent documents, voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands or on the withdrawal of any other demand for a poll) required or duly demanded. In the event that voting on any resolution or matter is conducted on a show of hands basis, the depositary will refrain from voting and the voting instructions received by the depositary from ADS holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by ADS holders.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy pursuant to the terms of the deposit agreement, or for the effect of any such vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, rule or regulation, or by the rules, regulations or requirements of any stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of or solicitation of consents or proxies from holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such ADR holders with or otherwise publicizes to such ADR holders instructions on how to retrieve such materials or receive such materials upon request (*i.e.,* by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and Other Communications

Will ADR holders be able to view our reports?

The deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities, are available for inspection by ADR holders at the offices of the depositary in the United States, on the SEC's internet website or upon request to the depositary (which request may be refused by the depositary at its discretion).

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and Expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADSs are cancelled or reduced for any other reason, a fee of up to US$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional fees, charges and expenses shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of up to US$0.05 per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of up to US$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- an amount for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian, as well as charges and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law, rule or regulation relating to foreign investment) in connection with the servicing of the ordinary shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee of up to US$0.05 per ADS held for the direct or indirect distribution of securities (other than ADSs or rights to purchase additional ADSs) or the net cash proceeds from the public or private sale of such securities, regardless of whether any such distribution and/or sale is made by, for, or received from, or (in each case) on behalf of, the depositary, us and/or any third party (which fee may be assessed against ADR holders as of a record date set by the depositary);
- stock transfer or other taxes and other governmental charges;

- a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication) as disclosed on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com") and any applicable delivery expenses (which are payable by such persons or ADR holders);
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within the banking division of JPMorgan (the "Bank") and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (i) a published benchmark rate, or (ii) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosures" page (or successor page) of ADR.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, ADR holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other fees, charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to charge and receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary anticipates reimbursing us for certain expenses incurred by us that are related to the establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary may also agree to reduce or waive certain fees that would normally be charged

on ADSs issued to or at the direction of, or otherwise held by, us and/or certain holders and beneficial owners and holders and beneficial owners of shares of ours. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of Taxes

ADR holders and/or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon such tax or other governmental charge shall be paid by the ADR holder thereof to the depositary and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect of such tax or other governmental charge. Notwithstanding the depositary's right to seek payment from current or former ADR holders and beneficial owners, each ADR holder and beneficial owner, and each prior ADR holder and beneficial owner, by holding or owning, or having held or owned, an ADR or an interest in ADSs acknowledges and agrees that the depositary has no obligation to seek payment of amounts owing from any current or prior beneficial owner. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case, the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split up or combination of ADRs or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto. Neither we nor the depositary nor any of our or its respective agents, shall be liable to ADR holders or beneficial owners of the ADSs for failure of any of them to comply with applicable tax laws, rules and/or regulations.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained, which obligations shall survive any transfer or surrender of ADSs or the termination of the deposit agreement.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any split up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, insolvency or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;

- distribute cash, securities or other property it has received in connection with such actions;
- sell by public or private sale any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least thirty (30) days' notice of any amendment that imposes or increases any fees on a per ADS basis, charges or expenses (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication), applicable delivery expenses or other such fees, charges or expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders and beneficial owners a means to access the text of such amendment. If an ADR holder or beneficial owner continues to hold an ADR or ADRs, or an interest therein, after being so notified, such ADR holder and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

Any amendments or supplements that (i) are reasonably necessary (as agreed by us and the depositary) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act or (b) the ADSs or ordinary shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations that would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the form of ADR (and all outstanding ADRs) at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADRs shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depositary's or our website or upon request from the depositary).

How may the deposit agreement be terminated?

The depositary may at any time, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least thirty (30) days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered ADR holders unless a successor depositary shall not be operating under the deposit agreement within sixty (60) days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 60th day after our notice of removal was first provided to the depositary. Notwithstanding anything to the contrary in the deposit agreement, the depositary may terminate the deposit agreement (i) without notifying us, but subject to giving thirty (30) days' notice to the ADR holders, under the following circumstances: (a) in the event of our liquidation proceedings or insolvency, (b) if our ordinary shares are delisted from a “national securities exchange” (that has

registered with the Commission under Section 6 of the Exchange Act), (c) if we effect (or will effect) a redemption of all or substantially all of the deposited securities, or a cash or share distribution representing a return of all or substantially all of the value of the deposited securities, (d) there are no deposited securities with respect to ADSs remaining, including if the deposited securities are cancelled, or the deposit securities have been deemed to have no value, or (e) there occurs a merger, consolidation, sale of assets or other transaction as a result of which securities or other property are delivered in exchange for or in lieu of deposited securities, and (ii) immediately without prior notice to the Company, any ADR holder or beneficial owner or any other person if (a) required by any law, rule or regulation relating to sanctions by any governmental authority or body, (b) the depositary would be subject to liability under or pursuant to any law, rule or regulation, or (c) required by any governmental authority or body, in each case under (ii) as determined by the depositary in its reasonable discretion.

If our shares are not listed and publicly traded on a stock exchange or in a securities market as of the date so fixed for termination or if, for any reason, the depositary does not sell the deposited securities, then after such date fixed for termination, the depositary shall use its reasonable efforts to ensure that the ADSs cease to be eligible for settlement within DTC and that neither DTC nor any of its nominees shall thereafter be an ADR holder. At such time as the ADSs cease to be DTC eligible and/or neither DTC nor any of its nominees is an ADR holder, to the extent we are not, to the depositary's knowledge, insolvent or in liquidation, the depositary shall (i) cancel all outstanding ADRs; (ii) request DTC to provide the depositary with information on those holding ADSs through DTC and, upon receipt thereof, revise the ADR register to reflect the information provided by DTC; (iii) instruct its custodian to deliver all deposited securities to us, a subsidiary or affiliate of ours (the company representative) or an independent trust company engaged by us (the trustee) to hold those deposited securities in trust for the beneficial owners of the ADRs if we are not permitted to hold any of the deposited securities under applicable law and/or we have directed the depositary to deliver such deposited securities to the company representative or trustee along with a stock transfer form and/or such other instruments of transfer covering such deposited securities as are needed under applicable law, in either case referring to the names set forth on the ADR register and (iv) provide us with a copy of the ADR register.

Upon receipt of any instrument of transfer covering such deposited securities and the ADR Register, we have agreed that we or our trustee will, depending on what is legally required under local law, either deliver to each person reflected on such ADR register appropriate documentation to effect the transfer to such persons of the deposited securities previously represented by the ADSs evidenced by their ADRs, approve the transfer of the deposited securities previously represented by their ADRs to the persons listed on the ADR register (as applicable), procure the relevant updates to the register of members of the Company to reflect the transfer of the deposited securities previously represented by their ADRs to the persons listed on the ADR register (as applicable) and provide the depositary with a certified copy of the updated register of our shareholders.

To the extent the depositary reasonably believes that we are insolvent, or if we are in receivership and/or are otherwise in insolvent restructuring, administration or liquidation, and in any such case the deposited securities are not listed and publicly traded on a securities exchange after the termination date, or if, for any reason, the depositary believes it is not able to or cannot practicably sell the deposited securities promptly and without undue effort, the deposited securities shall be deemed to have no value (and such ADR holders shall be deemed to have instructed the depositary that the deposited securities have no value). The depositary may (and, by holding an ADR or an interest therein, all holders irrevocably consent and agree that the depositary may) instruct its custodian to deliver all deposited securities to an administrator, receiver, administrative receiver, liquidator, provisional liquidator, restructuring officer, interim restructuring officer, trustee, controller or other entity overseeing the insolvency, administration, insolvent restructuring or liquidation process and notify us that the deposited ordinary shares are surrendered for no consideration. The deposit agreement requires us, subject to applicable law, to promptly ensure that such entity accepts the surrender of the deposited ordinary shares for no consideration and deliver to the depositary a written notice confirming (i) the acceptance of the surrender of the deposited securities for no consideration and (ii) the cancellation of such deposited ordinary shares. Promptly after notifying us that the deposited ordinary shares are surrendered for no consideration and irrespective of whether we have complied with the immediately preceding sentence, the depositary shall notify ADR holders that their ADSs have been cancelled with no consideration being payable to such ADR holders.

Upon the depositary's compliance with the provisions of any of the above three paragraphs, the depositary and its agents shall be discharged from all, and cease to have any, obligations under the deposit agreement and the ADRs.

If our ordinary shares are listed and publicly traded on a securities exchange and the depositary believes that it is able, permissible and practicable to sell the deposited securities without undue effort, then the depositary may endeavor to publicly or privately sell (as long as it may lawfully do so) the deposited securities, which sale may be effected in a block sale/single lot transaction and, after the settlement of such sale(s), to the extent legally permissible and practicable, distribute or hold in an account (which may be a segregated or unsegregated account) the net proceeds of such sale(s), less any amounts owing to the depositary (including, without limitation, cancellation fees), together with any other cash then held by it under the deposit agreement, in trust, without liability for interest, for the pro rata benefit of the holders entitled thereto. After making such sale, the depositary shall be discharged from all obligations in respect of the deposit agreement and the ADRs, except to account for such net proceeds and other cash.

Notwithstanding anything to the contrary, in connection with any such termination, the depositary may, in its sole discretion and without notice to us, establish an unsponsored American depositary share program (on such terms as the depositary may determine) for our ordinary shares and make available to ADR holders a means to withdraw the ordinary shares represented by the ADSs issued under the deposit agreement and to direct the deposit of such ordinary shares into such unsponsored American depositary share program, subject, in each case, to receipt by the depositary, at its discretion, of the fees, charges and expenses provided for under the deposit agreement and the fees, charges and expenses applicable to the unsponsored American depositary share program.

Limitations on Obligations and Liability

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders, beneficial owners and others

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of ordinary shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial or other ownership of, or interest in, any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement or as the depositary believes are required, necessary or advisable in order to comply with applicable laws, rules and regulations.

The issuance of ADRs, the acceptance of deposits of ordinary shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of ordinary shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed required, necessary or advisable by the depositary for any reason provided that the ability to withdraw ordinary shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities. The depositary may close the ADR register (and/or any portion thereof) at any time or from time to time when deemed expedient by it.

The deposit agreement expressly limits the obligations and liability of the depositary, the depositary's custodian or ourselves and each of our and their respective directors, officers, employees, agents and affiliates, provided, however, that no provision of the deposit agreement is intended to constitute a waiver or limitation of any rights that ADR holders or beneficial owners may have under the Securities Act or the Exchange Act, to the extent applicable. The deposit agreement provides that each of us, the depositary and our respective directors, officers, employees, agents and affiliates will:

- incur or assume no liability (including, without limitation, to ADR holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of the United States, the Commonwealth of Australia or any other country or jurisdiction, or of any governmental or regulatory authority or any securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of the Company's constituent documents, any act of God, war, terrorism, epidemic, pandemic, nationalization, expropriation, currency restrictions, extraordinary market conditions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, cyber, ransomware or malware attack, computer failure or circumstance our, the depositary's or our respective directors', officers', employees', agents' or affiliates' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by any such party (including, without limitation, voting);
- incur or assume no liability (including, without limitation, to ADR holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations specifically set forth in the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve us in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be, against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be requested;
- not be liable (including, without limitation, to ADR holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, any person presenting ordinary shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information and/or, in the case of the depositary, from us; or
- may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

The depositary shall not be a fiduciary or have any fiduciary duty to ADR holders or beneficial owners.

The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the

custodian having (i) committed fraud or willful misconduct in the provision of custodial services to the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide services such as, but not limited to, attendance at any meetings of security holders of issuers. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third-party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services.

The depositary has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of the Commonwealth of Australia, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

Additionally, none of the depositary, the custodian or us, or any of their or our respective directors, officers, employees, agents or affiliates shall be liable for the failure by any registered holder of ADRs or beneficial owner to obtain the benefits of credits or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depositary is under no obligation to provide the ADR holders and beneficial owners, or any of them, with any information about our tax status. None of us, the depositary, the custodian or any of our or their respective directors, officers, employees, agents or affiliates shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy pursuant to the terms of the deposit agreement, or for the effect of any such vote. The depositary shall endeavor to effect any sale of securities or other property and any conversion of currency, securities or other property, in each case as is referred to or contemplated in the deposit agreement or the form of ADR, in accordance with the depositary's normal practices and procedures under the circumstances applicable to such sale or conversion, but shall have no liability (in the absence of its own willful default or gross negligence or that of its agents, officers, directors or employees) with respect to the terms of any such sale or conversion, including the price at which such sale or conversion is effected, or if such sale or conversion shall not be practicable, or shall not be believed, deemed or determined to be practicable by the depositary. Specifically, the depositary shall not have any liability for the price received in connection with any public or private sale of securities (including, without limitation, for any sale made at a nominal price), the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale. The depositary shall not incur any liability in connection with or arising from any registration with the SEC of ADSs or shares, the offer or sale thereof in the United States, or any failure, inability or refusal by us or any other party, including any share registrar, transfer agent or other agent appointed by us, the depositary or any other party, to process any transfer, delivery or distribution of cash, ordinary shares, other securities or other property, including without limitation upon the termination of the deposit agreement, or otherwise to comply with any provisions of the deposit agreement that are applicable to it. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary. Neither the depositary nor us, nor any of our agents shall be liable for any indirect, special, punitive or consequential damages (excluding

reasonable legal fees and expenses) or lost profits, in each case of any form incurred by any person or entity (including, without limitation, ADR holders or beneficial owners), whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADSs.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of, or interest in, deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. For instance, we reserve the right to instruct you to deliver your ADSs for cancellation and withdrawal of the deposited securities so as to permit us to deal directly with you as a holder and/or beneficial owner of ordinary shares.

Books of Depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other ADR holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register (and/or any portion thereof) may be closed at any time or from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Appointment

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs,
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and
- acknowledge and agree that (i) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (ii) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (iii) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (iv) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us, ADR holders, or beneficial owners may have interests, (v) nothing contained in the deposit agreement or any ADR(s) shall (a) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (b) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships or to account for any profit made or payment received in any such transactions or relationships, (vi) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (vii) notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs

evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

Consent to Jurisdiction

In the deposit agreement, we have submitted to the non-exclusive jurisdiction of the state and federal courts in New York, New York and appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may also be instituted by the depositary against us in any competent court in the Commonwealth of Australia, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each irrevocably agree that (i) any legal suit, action or proceeding against or involving holders or beneficial owners brought by us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may be instituted in a state or federal court in New York, New York, and by holding or owning an ADR or ADS or an interest therein each irrevocably waives any objection that it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding and (ii) any legal suit, action or proceeding against or involving us and/or the depositary brought by holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including, without limitation, claims under the Securities Act of 1933, may be instituted only in the United States District Court for the Southern District of New York (or in the state courts of New York County in New York if either (a) the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a particular dispute or (b) the designation of the United States District Court for the Southern District of New York as the exclusive forum for any particular dispute is, or becomes, invalid, illegal or unenforceable). In the deposit agreement each holder and beneficial owner irrevocably waives any objection which it may at any time have to the laying of venue of any such proceeding, and irrevocably submits to the jurisdiction of such courts in any such suit, action or proceeding. This forum provision may increase your costs and limit your ability to bring a claim in a judicial forum that you find favorable for disputes with the depositary or us, or the depositary's or our respective directors, officers or employees, which may discourage such lawsuits against the depositary, us and the depositary's and our respective directors, officers or employees. However, it is possible that a court could find this choice of forum provision to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings.

Jury Trial Waiver

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each ADR holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of, based on or relating in any way to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory), including any claim under the U.S. federal securities laws.

The waiver of jury trial provision applies to all holders of ADSs, including purchasers who acquire ADSs on the secondary market. As the waiver relates to claims arising as a matter of contract in relation to the ADSs, we believe that, as a matter of construction of the clause, the waiver would likely to continue to apply to ADS holders who withdraw the ordinary shares represented by the ADSs from the ADS facility with respect to claims arising before the withdrawal, and the waiver would most likely not apply to ADS holders who subsequently withdraw the ordinary shares represented by ADSs from the ADS facility with respect to claims arising after the withdrawal. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a trial by jury.

The waiver to right to a trial by jury in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of our or the depositary's compliance with any provisions of U.S. federal securities laws or the rules and regulations promulgated thereunder.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

Not applicable.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Not applicable.

ITEM 16B. CODE OF ETHICS

Not applicable.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Not applicable.

ITEM 16D. EXEMPTIONS FROM LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASE OF EQUITY SECURITIES BY ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Not applicable.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Not applicable.

ITEM 16K. CYBERSECURITY

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to furnish financial statements and related information specified in Item 18.

ITEM 18. FINANCIAL STATEMENTS

Financial statements are filed as part of this registration statement, beginning on page F-1.

ITEM 19. EXHIBITS

The following documents are filed as part of this registration statement.

Exhibit Number	Description of Exhibit
1.1*	Certificate of Registration of the Registrant.
1.2*	Constitution of the Registrant.
2.1*	Form of Deposit Agreement.
2.2*	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 2.1).
4.1*†	License Agreement between Telix International Pty Ltd. and Eli Lilly Kinsale Limited, dated as of April 8, 2022, as amended.
4.2*†	License Agreement between Telix International Pty Ltd. and Wilex AG, dated as of January 16, 2017, as amended.
4.3*	Form of Deed of Indemnity, Insurance and Access.
4.4*	Lease Agreement, dated November 30, 2022, by and between Collan Investment Limited and Telix International Pty Ltd.
4.5*	Lease Agreement, dated April 22, 2022, by and between Crew HQ, LLC and Telix Pharmaceuticals (US), Inc.
4.6*	Loan Agreement, dated March 3, 2022, by and between Telix Pharmaceuticals (Belgium) SPRL and BNP Paribas Fortis.
4.7*	Loan Agreement, dated March 3, 2022, by and between Telix Pharmaceuticals (Belgium) SPRL and IMBC.
4.8*+	Equity Incentive Plan Rules.
4.9*+	Employment Agreement, dated January 16, 2017, by and between Telix Pharmaceuticals Limited and Christian Behrenbruch.
4.10*+	Employment Agreement, dated August 1, 2022, by and between Telix Pharmaceuticals Limited and Darren Smith.
4.11*+	Employment Agreement, dated December 20, 2023, by and between Telix Pharmaceuticals Limited and David Cade.
4.12*+	Employment Agreement, dated March 5, 2024, by and between Telix Pharmaceuticals (US) Inc. and Darren Patti.
4.13*+	Form of Non-Executive Director Agreement.
4.14*	Agreement and Plan of Merger, dated as of February 7, 2024, by and among Telix Pharmaceuticals Limited, QSAM Biosciences, Inc., Cyclone Merger Sub I, Inc., Cyclone Merger Sub II, Inc. and David H. Clarke.
4.15*†	Share Purchase Agreement, dated as of March 4, 2024, between ARTMS Inc. and Telix Pharmaceuticals Limited.
4.16*	Trust Deed, dated as of July 30, 2024, between Telix Pharmaceuticals Limited and The Hongkong and Shanghai Banking Corporation Limited.
4.17*†	Stock Purchase Agreement, dated as of September 20, 2024, by and among Telix Pharmaceuticals Limited, RLS Group Ltd., RLS (USA) Inc. and Perceptive Credit Holdings III, LP.
8.1*	List of subsidiaries.
15.1	Consent of PricewaterhouseCoopers, independent registered public accounting firm.

* Previously filed.

\+ Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

TELIX PHARMACEUTICALS LIMITED

By: /s/ Dr. Christian Behrenbruch
Name: Dr. Christian Behrenbruch
Title: Group Chief Executive Officer and Managing Director

Date: October 29, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements as of December 31, 2022 and 2023 and for the years ended December 31, 2021, 2022 and 2023:

Interim Consolidated Financial Statements as of June 30, 2024 and for the six months ended June 30, 2023 and 2024 (Unaudited):

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Telix Pharmaceuticals Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated statement of financial position of Telix Pharmaceuticals Limited and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of comprehensive income or loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2023, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers
Melbourne, Australia
September 13, 2024

We have served as the Company's auditor since 2017.

Consolidated statement of comprehensive income or loss for the years ended December 31, 2023, 2022 and 2021

	Note	2023 A$'000	2022 A$'000	2021 A$'000
Continuing operations				
Revenue from contracts with customers	4	502,547	160,096	7,596
Cost of sales		(188,157)	(65,170)	(6,371)
Gross profit		**314,390**	**94,926**	**1,225**
Research and development costs		(128,537)	(80,687)	(48,114)
Selling and marketing expenses		(50,109)	(36,313)	(5,706)
Manufacturing and distribution costs		(9,869)	(3,949)	(460)
General and administration costs		(74,181)	(47,156)	(28,192)
Other (losses)/gains (net)	5	(35,854)	(18,751)	6,000
Operating profit/(loss)		**15,840**	**(91,930)**	**(75,247)**
Finance income		1,019	1	—
Finance costs	6	(13,772)	(6,693)	(5,218)
Profit/(loss) before income tax		**3,087**	**(98,622)**	**(80,465)**
Income tax benefit/(expense)	7	2,124	(5,457)	(45)
Profit/(loss) for the year		**5,211**	**(104,079)**	**(80,510)**
Profit/(loss) for the year attributable to:				
Owners of Telix Pharmaceuticals Limited		5,211	(104,079)	(80,510)
Other comprehensive (loss)/income:				
Items that will not be reclassified to profit or loss in subsequent periods:				
Changes in the fair value of equity investments at fair value through other comprehensive income	14	(895)	—	—
Items to be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations		(4,852)	591	(1,452)
Total comprehensive loss for the year		**(536)**	**(103,488)**	**(81,962)**
Total comprehensive loss for the year attributable to:				
Owners of Telix Pharmaceuticals Limited		(536)	(103,488)	(81,962)

	Note	2023 Cents	2022 Cents	2021 Cents
Basic earnings/(loss) per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	8.1	1.63	(33.50)	(28.50)
Diluted earnings/(loss) per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	8.2	1.61	(33.50)	(28.50)

The above consolidated statement of comprehensive income or loss should be read in conjunction with the accompanying notes.

Consolidated statement of financial position as at December 31, 2023 and 2022

	Note	2023 A$'000	2022 A$'000
Current assets			
Cash and cash equivalents		123,237	116,329
Trade and other receivables	11	64,777	39,354
Inventories	12	17,310	8,477
Current tax asset		7,656	—
Other current assets	13	19,524	9,073
Total current assets		**232,504**	**173,233**
Non-current assets			
Trade and other receivables	11	586	327
Financial assets	14	12,260	—
Deferred tax assets	15.1	20,452	3,971
Property, plant and equipment	16	23,170	12,032
Right-of-use assets	17	7,323	6,806
Intangible assets	18	109,663	58,984
Total non-current assets		**173,454**	**82,120**
Total assets		**405,958**	**255,353**
Current liabilities			
Trade and other payables	20	81,704	49,519
Borrowings	21	964	—
Current tax payable		19,164	7,320
Contract liabilities	22	10,995	4,940
Lease liabilities	23	595	641
Provisions	24	577	402
Contingent consideration	25	37,153	15,183
Employee benefit obligations	26	13,912	7,551
Total current liabilities		**165,064**	**85,556**
Non-current liabilities			
Borrowings	21	8,209	3,312
Contract liabilities	22	12,162	22,522
Lease liabilities	23	7,677	6,493
Provisions	24	8,004	7,482
Contingent consideration	25	55,601	49,766
Employee benefit obligations	26	330	215
Total non-current liabilities		**91,983**	**89,790**
Total liabilities		**257,047**	**175,346**
Net assets		**148,911**	**80,007**
Equity			
Share capital	27.1	446,268	370,972
Share capital reserve	27.2	(62,829)	(26,909)
Foreign currency translation reserve		(5,414)	(562)
Share-based payments reserve	27.3	35,446	9,321
Financial assets at FVOCI reserve	27.4	(895)	—
Accumulated losses		(263,665)	(272,815)
Total equity		**148,911**	**80,007**

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

Consolidated statement of changes in equity for the years ended December 31, 2023, 2022 and 2021

	Note	Share capital	Share capital reserve	Foreign currency translation reserve	Share-based payments reserve	Financial assets at FVOCI reserve	Accumulated losses	Total equity
		A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Balance as at January 1, 2023		**370,972**	**(26,909)**	**(562)**	**9,321**	**—**	**(272,815)**	**80,007**
Profit for the year		—	—	—	—	—	5,211	5,211
Other comprehensive loss		—	—	(4,852)	—	(895)	—	(5,747)
Total comprehensive (loss)/income		**—**	**—**	**(4,852)**	**—**	**(895)**	**5,211**	**(536)**
Issue of shares on acquisitions	27.1	32,724	—	—	—	—	—	32,724
Issue of shares on exercise of options	27.1, 27.2	42,572	(35,920)	—	—	—	—	6,652
Share based payments	27.3	—	—	—	8,786	—	—	8,786
Share based payments associated with acquisitions	27.3	—	—	—	21,278	—	—	21,278
Transfer on exercise of options	27.3	—	—	—	(3,939)	—	3,939	—
		75,296	**(35,920)**	**—**	**26,125**	**—**	**3,939**	**69,440**
Balance as at December 31, 2023		**446,268**	**(62,829)**	**(5,414)**	**35,446**	**(895)**	**(263,665)**	**148,911**
Balance as at January 1, 2022		**170,840**	**—**	**(1,153)**	**5,942**	**—**	**(173,471)**	**2,158**
Loss for the year		—	—	—	—	—	(104,079)	(104,079)
Other comprehensive income		—	—	591	—	—	—	591
Total comprehensive loss		**—**	**—**	**591**	**—**	**—**	**(104,079)**	**(103,488)**
Contributions of equity	27.1	175,000	—	—	—	—	—	175,000
Transaction costs arising on new share issues		(7,816)	—	—	—	—	—	(7,816)
Issue of shares on exercise of options	27.1, 27.2	32,948	(26,909)	—	—	—	—	6,039
Share based payments	27.3	—	—	—	8,114	—	—	8,114
Transfer on exercise of options	27.3	—	—	—	(4,735)	—	4,735	—
		200,132	**(26,909)**	**—**	**3,379**	**—**	**4,735**	**181,337**
Balance as at December 31, 2022		**370,972**	**(26,909)**	**(562)**	**9,321**	**—**	**(272,815)**	**80,007**
Balance as at January 1, 2021		**167,058**	**—**	**299**	**4,620**	**—**	**(92,961)**	**79,016**
Loss for the year		—	—	—	—	—	(80,510)	(80,510)
Other comprehensive loss		—	—	(1,452)	—	—	—	(1,452)
Total comprehensive loss		**—**	**—**	**(1,452)**	**—**	**—**	**(80,510)**	**(81,962)**
Issue of shares on exercise of options		3,782	—	—	—	—	—	3,782
Share based payments		—	—	—	1,322	—	—	1,322
		3,782	**—**	**—**	**1,322**	**—**	**—**	**5,104**
Balance as at December 31, 2021		**170,840**	**—**	**(1,153)**	**5,942**	**—**	**(173,471)**	**2,158**

The above consolidated statement of changes of equity should be read in conjunction with the accompanying notes.

Consolidated statement of cash flows for the years ended December 31, 2023, 2022 and 2021

	Note	2023 A$'000	2022 A$'000	2021 A$'000
Cash flows from operating activities				
Receipts from customers		463,654	124,095	4,158
Receipts in relation to R&D tax incentive		—	18,909	12,123
Payments to suppliers and employees		(414,079)	(204,289)	(75,420)
Payments for contingent consideration		(16,282)	—	—
Income taxes paid		(10,253)	(2,278)	—
Interest received		1,629	1	—
Interest paid		(785)	(408)	(189)
Net cash generated from/(used in) operating activities	**29.1**	**23,884**	**(63,970)**	**(59,328)**
Cash flows from investing activities				
Payments for investments in financial assets		(13,155)	—	—
Payments for acquisition of subsidiary, net of cash acquired		—	(973)	—
Purchases of intangible assets		(1,115)	(6,823)	—
Payments for contingent consideration		(1,484)	—	—
Purchases of property, plant and equipment		(9,679)	(7,038)	(1,339)
Payments for decommissioning liability		(56)	(2,163)	(1,387)
Net cash used in investing activities		**(25,489)**	**(16,997)**	**(2,726)**
Cash flows from financing activities				
Proceeds from borrowings		5,756	3,014	—
Repayment of borrowings		—	(13)	(340)
Principal element of lease payments		(2,222)	(1,264)	(596)
Proceeds from issue of shares and other equity		6,652	181,039	3,782
Transaction costs of capital raising		—	(7,816)	—
Net cash provided by financing activities		**10,186**	**174,960**	**2,846**
Net increase in cash held		**8,581**	**93,993**	**(59,208)**
Net foreign exchange differences		(1,673)	299	3,300
Cash and cash equivalents at the beginning of the financial year		116,329	22,037	77,945
Cash and cash equivalents at the end of the financial year		**123,237**	**116,329**	**22,037**

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

Notes to the consolidated financial statements

1. Corporate information

Telix Pharmaceuticals Limited (Telix or the Company) is a for profit company incorporated and domiciled in Australia. It is limited by shares that are publicly traded on the Australian Securities Exchange (ASX: TLX). These consolidated financial statements comprise the results of Telix and its subsidiaries (together referred to as the Group). The consolidated financial statements were authorized for issue in accordance with a resolution of the Directors on September 13, 2024.

2. Summary of significant accounting policies

The significant accounting policies that have been used in the preparation of these financial statements are summarized below.

2.1. Going concern

For the year ended December 31, 2023, the Group generated a profit of $5,211,000 (2022: loss of $104,079,000, 2021: loss of $80,510,000) and cash generated from operating activities of $23,884,000 (2022: cash used in operating activities of $63,970,000, 2021: cash used in operating activities of $59,328,000). As at December 31, 2023 the net assets of the Group were $148,911,000 (2022: $80,007,000), with cash on hand of $123,237,000 (2022: $116,329,000).

Cash on hand and future cash inflows from commercial activities is considered sufficient to meet the Group's forecast cash outflows in relation to research and development activities currently underway and other committed business activities for at least 12 months from the date of these financial statements.

On this basis, the Directors are satisfied that the Group continues to be a going concern as at the date of these financial statements. Further, the Directors are of the opinion that no asset is likely to be realized for an amount less than the amount at which it is recorded in the consolidated statement of financial position as at December 31, 2023.

As such, no adjustment has been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should the Group not continue as a going concern.

2.2. Basis of preparation

Telix Pharmaceuticals Limited is a for-profit entity for the purpose of preparing the financial statements.

These general purpose financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS).

The financial statements have been prepared on a historical cost basis, except for certain financial instruments, which have been measured at fair value.

a. Comparatives

Where necessary, comparative information has been re- classified to achieve consistency in disclosure with current financial amounts and other disclosures.

b. New and amended standards adopted by the Group

The Group has adopted all relevant new and amended standards and interpretations issued by the International Accounting Standards Board which are effective for annual reporting periods beginning on January 1, 2023. The new standards and amendments did not have any impact on the amounts recognized in the current and prior periods.

c. New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for December 31, 2023 reporting periods and have not been early adopted by the Group. These standards are not expected to have a material impact on the Group in the current or future reporting periods or on foreseeable future transactions.

2.3. Significant changes in the current reporting period

The Group updated the classification of expenses to make the consolidated statement of comprehensive income more relevant to users of the financial statements, particularly as the Group has moved to commercial operations. This has resulted in the reclassification of some expenses for the years ended December 31, 2022 and December 31, 2021. However, it has not impacted the reported loss for the year or earnings per share.

From 2023, the Group has determined that a functional presentation of its consolidated statement of comprehensive income or loss is most appropriate. In accordance with IAS 1 *Presentation of Financial Statements*, within a functional consolidated statement of comprehensive income or loss, costs directly associated with generating revenues are included in cost of sales. Cost of sales includes direct material and labor costs, distribution fees incurred to ensure delivery of the product to the end customer and indirect costs that are directly attributed to generating revenue, such as amortization of intangible assets associated with commercialized products.

In addition to the above, the Group has disclosed an additional line item of manufacturing and distribution costs on its consolidated statement of comprehensive income or loss. This line item represents departments and associated costs of the business that were previously included within selling and marketing expenses. These functions are ancillary in nature and indirectly support manufacturing, supply chain, logistics, facilities and quality activities.

2.4. Principles of consolidation

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. If the Group loses control of a subsidiary, the Group derecognizes the assets and liabilities of the former subsidiary from the consolidated statement of financial position and recognizes the gain or loss associated with the loss of control attributable to the former controlling interest.

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated on consolidation. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

2.5. Foreign currency translation

a. Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Australian dollars.

b. Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss. Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statement of comprehensive income or loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive income or loss on a net basis within other income or other expenses.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss.

c. Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each consolidated statement of financial position presented are translated at the closing rate at the date of that consolidated statement of financial position
- income and expenses for each consolidated statement of comprehensive income or loss are translated at actual exchange rates at the dates of the transactions, and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale. Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

2.6. Business combinations

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the:

- fair values of the assets transferred
- liabilities incurred to the former owners of the acquired business
- equity interests issued by the Group
- fair value of any asset or liability resulting from a contingent consideration arrangement, and
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. Acquisition-related costs are expensed as incurred. The excess of the consideration transferred, amount of any non-controlling interest in the acquired entity, and acquisition-date fair value of any previous equity interest in the acquired entity over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the subsidiary acquired, the difference is recognized directly in profit or loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The post-tax discount rate used is the entity’s incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions. Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

The acquisition date carrying value of the Group's previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognized in profit or loss. If the initial accounting for a business combination is incomplete by the end of the reporting period in which the combination occurs, the Group reports provisional amounts for the items for which the accounting is incomplete. Those provisional amounts are adjusted during the measurement period (see below), or additional assets or liabilities are recognized, to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the amounts recognized as of that date. The measurement period is the period from the date of acquisition to the date the Group obtains complete information about facts and circumstances that existed as of the acquisition date and is subject to a maximum of one year.

2.7. Current and non-current classification

Assets and liabilities are presented in the consolidated statement of financial position based on current and non-current classification.

An asset is current when it is expected to be realized or intended to be sold or consumed in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realized within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is current when it is expected to be settled in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current. For instances where a liability is based on sales volumes, the payment expected to be realized within 12 months is current based on the underlying estimate of the timing of sales.

Deferred tax assets and liabilities are always classified as non-current.

2.8. Cash and cash equivalents

For the purpose of presentation in the consolidated statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the consolidated statement of financial position.

2.9. Trade and other receivables

Trade receivables and other receivables are all classified as financial assets held at amortized cost. Trade receivables are recognized initially at the amount of consideration that is unconditional, unless they contain significant financing components when they are recognized at fair value.

a. Impairment of trade and other receivables

The collectability of trade and other receivables is reviewed on an ongoing basis. Individual debts which are known to be uncollectible are written off when identified. The Group recognizes an impairment provision based upon anticipated lifetime losses of trade receivables.

The anticipated losses are determined with reference to historical loss experience (when it is available) and are regularly reviewed and updated. They are subsequently measured at amortized cost using the effective interest method, less loss allowance. See note 30.4 for further information about the Group's accounting for trade receivables and description of the Group's impairment policies.

2.10. Inventories

Raw materials and stores, work in progress and finished goods

Raw materials and stores, work in progress and finished goods are stated at the lower of cost and net realizable value. Cost comprises direct materials, direct labor and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Cost includes the reclassification from equity of any gains or losses on qualifying cash flow hedges relating to purchases of raw material but excludes borrowing costs. Costs are assigned to individual items of inventory on the basis of weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

2.11. Property, plant and equipment

All property, plant and equipment is stated at historical cost less accumulated depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Cost may also include transfer from equity of any gains or losses on qualifying cash flow hedges of foreign currency purchases of property,

plant and equipment. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably.

The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate the cost, net of the residual values, over the estimated useful lives. The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

The useful lives of assets are as follows:

- Buildings: 18 years
- Plant and equipment: 3-5 years
- Furniture, fittings and equipment: 3-5 years
- Leased plant and equipment: 3-5 years

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in profit or loss. When revalued assets are sold, it is Group policy to transfer any amounts included in other reserves in respect of those assets to accumulated losses.

2.12. Lease liabilities

Liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payments that are based on an index or a rate, initially measured using the index or rate as at the commencement date
- amounts expected to be payable by the Group under residual value guarantees
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

2.13. Right-of-use assets

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date less any lease incentives received
- any initial direct costs, and
- restoration costs.

Right-of-use assets are depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

2.14. Non-current financial assets

Non-current financial assets held for long-term strategic purposes are classified within non-current assets on the consolidated statement of financial position. The financial impacts related to these financial assets are recorded in other comprehensive income.

Non-current financial assets are initially recorded at fair value on their trade date, which is different from the settlement date when the transaction is ultimately effected. Quoted securities are remeasured at each reporting date to fair value based on current market prices. If the market for a financial asset is not active or no market is available, fair values are established using valuation techniques.

Equity securities held as strategic investments are generally designated at the date of acquisition as financial assets valued at fair value through other comprehensive income with no subsequent recycling through profit or loss. Unrealized gains and losses, including exchange gains and losses, are recorded as a fair value adjustment in the consolidated statement of comprehensive income. They are reclassified to retained earnings when the equity security is sold.

2.15. Intangible assets

a. Goodwill

Goodwill on acquisitions of subsidiaries is included in intangible assets. Goodwill is not amortized, but is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold. Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or group of cash- generating units that are expected to benefit from the business combination in which the goodwill arose.

b. Patents, trademarks, licenses and customer contracts

Separately acquired trademarks and licenses are shown at historical cost. Trademarks, licenses and customer contracts acquired in a business combination are recognized at fair value at the acquisition date. They have a finite useful life and are subsequently carried at cost less accumulated amortization and impairment losses. The useful life of these intangibles assets is 5 to 20 years.

c. Intellectual property

Intellectual property arising from business combinations is recognized at fair value when separately identifiable from goodwill. Intellectual property is recorded as an indefinite life asset when it is not yet ready for use. At the point the asset is ready for use, the useful life is reassessed as a definite life asset and amortized over a period of 5 to 20 years. Amortization and impairment charges related to currently marketed products are recognized in cost of goods sold.

Assets not available for use are tested annually for impairment. Assets are carried at cost less accumulated impairment losses and/or accumulated amortization. An impairment trigger assessment is performed annually for assets available for use.

d. Research and development

Research expenditure on internal projects is recognized as an expense as incurred. Costs incurred on development projects (relating to the design and testing of new or improved products) are recognized as intangible assets when it is probable that the project will, after considering its commercial and technical feasibility, be completed and generate future economic benefits and its costs can be measured reliably. The expenditure that could be recognized comprises all directly attributable costs, including costs of materials, services, direct labor and an appropriate proportion of overheads.

Other expenditures that do not meet these criteria are recognized as an expense as incurred. As the Group has not met the requirement under the standard to recognize costs in relation to development as intangible assets, these amounts have been expensed within the financial statements.

2.16. Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or Groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

2.17. Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the reporting date which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

2.18. Provisions

Provisions are recognized when the Group has a present (legal or constructive) obligation as a result of a past event, it is probable the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the reporting date, taking into account the risks and uncertainties surrounding the obligation. If the time value of money is material, provisions are discounted using a current pre-tax rate specific to the liability. The increase in the provision resulting from the passage of time is recognized as a finance cost.

a. Decommissioning liability

The Group has recognized a provision for its obligation to decommission its radiopharmaceutical production facility at the end of its operating life. At the end of a facility's life, costs are incurred in safely removing certain assets involved in the production of radioactive isotopes. The Group recognizes the full discounted cost of decommissioning as an asset and liability when the obligation to restore sites arises. The decommissioning asset is included within property, plant and equipment with the cost of the related installation. The liability is included within provisions. Revisions to the estimated costs of decommissioning which alter the level of the provisions required are also reflected in adjustments to the decommissioning asset. The amortization of the asset is included in the consolidated statement of comprehensive income or loss and the unwinding of discount of the provision is included within finance costs. Further detail has been provided in note 24.2.

2.19. Contingent consideration

The contingent consideration liabilities associated with business combinations are measured at fair value which has been calculated with reference to our judgement of the expected probability and timing of the potential future milestone payments, which is then discounted to a present value using appropriate discount rates with reference to the Group's weighted average cost of capital. Subsequent changes in estimates for contingent consideration liabilities are recognized in Other losses (net). The effect of unwinding the discount over time is recognized in Finance costs.

Contingent consideration in connection with the purchase of individual assets outside of business combinations is recognized as a liability only when a non-contingent obligation arises (i.e. when a milestone is met). Where the contingent consideration is payable in shares, or the group has an election to pay in shares, it is accounted for as an equity settled share-based payment. Equity settled share- based payments are recognized at their fair value at the date control of the asset is obtained. The determination of whether the payment should be capitalized or expensed is usually based on the reason for the contingent payment. If the contingent payment is based on

regulatory approvals received (i.e. development milestone), it will generally be capitalized as the payment is incidental to the acquisition so the asset may be made available for its intended use. If the contingent payment is based on period volumes sold (i.e. sales related milestone), it will generally be expensed.

Changes in the fair value of liabilities from contingent consideration will be capitalized or expensed based on the nature of the asset acquired (refer above), except for the effect from unwinding discounts. Interest rate effects from unwinding of discounts are recognized as finance costs. The fair value of equity-settled share-based payments is not reassessed once the asset has been recognized.

2.20. Employee benefits

Employee benefits are recognized as an expense, unless the cost qualifies to be capitalized as an asset.

a. Short-term obligations

Liabilities for wages and salaries, including non-monetary benefits and annual leave that is expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period. These liabilities are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the consolidated statement of financial position.

b. Other long-term employee benefit obligations

The liabilities for long service leave are not expected to be settled wholly within 12 months after the end of the period in which the employees render the related service. They are therefore measured as the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting period using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the end of the reporting period of high-quality corporate bonds with terms and currencies that match, as closely as possible, the estimated future cash outflows. Remeasurements as a result of experience adjustments and changes in actuarial assumptions are recognized in profit or loss.

The obligations are presented as current liabilities in the consolidated statement of financial position if the entity does not have an unconditional right to defer settlement for at least 12 months after the reporting period, regardless of when the actual settlement is expected to occur.

c. Share-based payments

Equity-settled share-based compensation benefits are provided to certain employees. Equity-settled transactions are awards of shares, options or performance rights over shares, that are provided to employees. The cost of equity-settled transactions is measured at fair value on grant date. Fair value is determined using the Black- Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option and volatility. No account is taken of any other vesting conditions.

If the non-vesting condition is within the control of the consolidated entity or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the consolidated entity or employee and is not satisfied during the vesting period, any remaining expense for the award is recognized over the remaining vesting period, unless the award is forfeited. If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognized immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new awards are treated as if they were a modification.

d. Termination benefits

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates:

- when the Group can no longer withdraw the offer of those benefits, and
- when the entity recognizes costs for a restructuring that is within the scope of IAS 37 *Provisions, Contingent Liabilities and Contingent Assets* and involves the payment of termination benefits. In the case of an offer made to encourage voluntary redundancy, the termination benefits are measured based on the number of employees expected to accept the offer. Benefits falling due more than 12 months after the end of the reporting period are discounted to present value.

2.21. Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw- down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowing costs that are directly attributable to the construction of qualifying assets are capitalized as part of the cost of the relevant asset.

Borrowings are removed from the consolidated statement of financial position when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognized in profit or loss as other income or finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

2.22. Revenue

Revenue is measured at the fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns, trade allowances, rebates and amounts collected on behalf of third parties.

Revenue is recognized using a five step approach in accordance with IFRS 15 *Revenue from Contracts with Customers* to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration the Group expects to be entitled to from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities. Amounts expected to be recognized as revenue within the 12 months following the consolidated statement of financial position date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the consolidated statement of financial position date are classified within non-current liabilities.

a. Sales of goods

Sales are recognized at a point-in-time when control of the products has transferred, being when the products are delivered to the customer. Further, in determining whether control has transferred, Telix considers if there is a

present right to payment and legal title, along with risks and rewards of ownership having transferred to the customer. Revenue from sales is recognized based on the price specified in the contract, net of the estimated volume discounts and government rebates.

Accumulated experience is used to estimate and provide for discounts, using the expected value method, and revenue is recognized to the extent that it is highly probable that a significant reversal will not occur. No element of financing is deemed present as the sales are made with credit terms ranging from 30 to 45 days, which is consistent with market practice.

Where distributors are used to facilitate the supply of a product a distribution fee is charged. This fee represents a cost of satisfying the performance obligation to the customer and expensed within Cost of sales in the Consolidated statement of comprehensive income or loss.

b. Licenses of intellectual property

When licenses of intellectual property are distinct from other goods or services promised in the contract, the transaction price is allocated to the license as revenue upon transfer of control of the license to the customer. All other promised goods or services in the license agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a ‘right to access’ license. This is where the Group performs activities that significantly affect the intellectual property to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of the Group’s activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a ’right to use’ license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

c. Research and development services

Where research and development (R&D) services do not significantly modify or customize the license nor are the license and development services significantly interrelated or interdependent, the provision of R&D services is considered to be distinct. The transaction price is allocated to the R&D services based on a cost-plus margin approach. Revenue is recognized over time based on the costs incurred to date as a percentage of total forecast costs. Reforecasting of total costs is performed at the end of each reporting period to ensure that costs recognized represent the goods or services transferred.

d. Financing component

The existence of a significant financing component in the contract is considered under the five-step method under IFRS 15 *Revenue from Contracts with Customers*.

If the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the Group with a significant benefit of financing the transfer of goods or services to the customer, the promised amount of consideration will be adjusted for the effects of the time value of money when determining the transaction price.

e. Milestone revenue

The five-step method under IFRS 15 *Revenue from Contracts with Customers* is applied to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration.

The transaction price of the contingent milestone is estimated using the most likely amount method. Within the transaction price, some or all of the amount of the contingent milestone is included only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.

Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations. When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of intellectual property (such as cumulative net sales targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

f. Sales-based or usage-based royalties

Licenses of intellectual property can include royalties that are based on the customer's usage of the intellectual property or sale of products that contain the intellectual property. The specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based or usage-based royalties promised in a license of intellectual property is applied. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

2.23. Government grants

Income from government grants is recognized at fair value where there is a reasonable assurance that the grant will be received, and the Group will comply with all attached conditions. Income from government grants is recognized in the consolidated statement of comprehensive income or loss on a systematic basis over the periods in which the Group recognizes as an expense the related costs for which the grants are intended to compensate.

2.24. Income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled. Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Included in income tax expense for the period is the effect of Australian R&D tax credits which may only be offset against Australian taxable income. As such, they are recognized as a component of income tax expense.

Tax consolidation regime

Telix Pharmaceuticals Limited and its wholly owned Australian resident entities have formed a tax-consolidated group and are therefore taxed as a single entity. The head entity within the tax-consolidated group is Telix Pharmaceuticals Limited. As a consequence, the deferred tax assets and deferred tax liabilities of these entities have been offset in the consolidated financial statements.

2.25. Sales Taxes and Goods and Services Tax (GST)

Revenues, expenses and assets are recognized net of the amount of associated sales taxes and GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognized as part of the cost of acquisition of the asset or as part of the expense.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flows.

2.26. Earnings per share

a. Basic earnings per share

Basic earnings per share is calculated by dividing: the profit attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial period, adjusted for bonus elements in ordinary shares issued during the period and excluding treasury shares.

b. Diluted earnings per share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account: the after-income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

2.27. Fair value measurement

Certain judgements and estimates are made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards. The different levels have been defined as follows:

- **Level 1:** fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets is the current bid price.
- **Level 2:** fair value of financial instruments that are not traded in an active market is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.
- **Level 3:** if one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

There were no transfers between level 1, 2 and 3 for recurring fair value measurements during the year. The Group’s policy is to recognize transfers into and transfers out of fair value hierarchy levels at the end of the reporting period. Certain judgements and estimates are made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements.

2.28. Key judgements and estimates

In the process of applying the Group's accounting policies, a number of judgements and estimates of future events are required.

Accrued R&D expenditure

The Group is required to estimate its accrued expenses at each reporting date, which involves reviewing open contracts and purchase orders, communicating with program directors and managers to identify services that have already been performed, estimating the level of services performed with associated costs incurred for the service for which the Group has not yet been invoiced, or otherwise notified of the actual cost. The majority of service providers invoice the Group monthly in arrears for services performed or when contractual milestones are met. The Group estimates accrued expenses at each reporting date based on facts and circumstances known at that time. The Group periodically confirms the accuracy of estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include fees paid to:

- Contract Research Organizations (CROs) in connection with clinical studies
- investigative sites in connection with clinical studies
- vendors in connection with preclinical development activities, and
- vendors related to product manufacturing, process development and distribution of clinical supplies, all of which are in connection with products for use in clinical trials.

Impairment assessment – carrying value of goodwill and intangible assets

The assessment of impairment of the goodwill and intangible assets has required estimates and judgements to be made. The inputs for these have been outlined in note 18.

Contingent consideration and decommissioning liabilities

The Group has identified the contingent consideration and decommissioning liabilities as balances requiring estimates and significant judgements. These estimates and judgements have been outlined in note 24 and note 25.

3. Segment reporting

The Group has operations in the Americas, Asia Pacific, and Europe, Middle East and Africa regions.

Reportable segments

The Group previously presented two reportable segments at December 31, 2023. However, following the acquisitions of ARTMS and IsoTherapeutics in April 2024 and as reported as part of the interim consolidated financial statements as of June 30, 2024 and for the six months ended June 30, 2024 and 2023, the Group presented four reportable segments. As a result, the prior period segment information has been retrospectively revised to reflect the current segment presentation. There is no change to the total revenue or profit/(loss) after tax of the Group.

The Group's operating segments are based on the reports reviewed by the Group Chief Executive Officer who is considered to be the chief operating decision maker.

Segment performance is evaluated based on Adjusted earnings before interest, tax, depreciation and amortization (Adjusted EBITDA). Adjusted EBITDA excludes the effects of the remeasurement of contingent consideration and government grant liabilities and other income and expenses which may have an impact on the quality of earnings such as impairments where the impairment is the result of an isolated, non-recurring event. Interest income and finance costs are not allocated to segments as this activity is managed by a central treasury function, which manages the cash position of the Group.

Segment assets and liabilities are measured in the same way as in the financial statements. The assets and liabilities are allocated based on the operations of the segment. Finance costs are not allocated to segments, as this type of activity is driven by head office, which manages the cash position of the Group.

Reportable segment	Principal activities
Commercial	Commercial sales of Illuccix and other products subsequent to obtaining regulatory approvals.
Product development	Developing radiopharmaceutical products for commercialization. This segment includes revenue received from license agreements prior to commercialization and research and development services.
Medical technologies	Developing complementary artificial intelligence (AI) and robotic technologies. This segment includes costs and assets associated with the Group's development of AI molecular imaging and guided robotic surgical technologies and includes Dedicaid, Lightpoint Surgical, and QDOSE[1].
Manufacturing services	Telix Manufacturing Solutions business. This segment comprises costs to operate our facilities and assets associated with the Group's vertically integrated manufacturing and supply chain. This business includes facilities at Brussels South, IsoTherapeutics[1], Optimal Tracers and ARTMS[1].

1. Acquired in 2024

Reconciling items includes head office and centrally managed costs (which includes any remeasurements of contingent consideration liabilities).

3.1. Segment performance

2023	Commercial	Product development	Medical technologies	Manufacturing services	Total segment
	A$'000	A$'000	A$'000	A$'000	A$'000
Revenue from contracts with customers	497,051	5,496	—	—	502,547
Cost of sales	(188,157)	—	—	—	(188,157)
Gross profit	**308,894**	**5,496**	**—**	**—**	**314,390**
Research and development costs	(282)	(128,212)	—	—	(128,494)
Selling and marketing expenses	(49,925)	—	—	—	(49,925)
Manufacturing and distribution costs	(7,127)	—	(3)	(586)	(7,716)
General and administration costs	(30,151)	—	(394)	(2,646)	(33,191)
Other losses (net)	(863)	—	—	—	(863)
Operating profit/(loss)	**220,546**	**(122,716)**	**(397)**	**(3,232)**	**94,201**
Other losses (net)	863	—	—	—	863
Depreciation and amortization	5,594	237	1	370	6,202
Adjusted earnings before interest, tax, depreciation and amortization	**227,003**	**(122,479)**	**(396)**	**(2,862)**	**101,266**

2022	Commercial	Product development	Medical technologies	Manufacturing services	Total segment
	A$'000	A$'000	A$'000	A$'000	A$'000
Revenue from contracts with customers	156,369	3,727	—	—	160,096
Cost of sales	(65,170)	—	—	—	(65,170)
Gross profit	**91,199**	**3,727**	**—**	**—**	**94,926**
Research and development costs	(704)	(80,000)	—	—	(80,704)
Selling and marketing expenses	(36,217)	—	—	—	(36,217)
Manufacturing and distribution costs	(2,139)	—	—	(322)	(2,461)
General and administration costs	(17,207)	—	—	—	(17,207)
Other (losses)/gains (net)	(791)	11	—	—	(780)
Operating profit/(loss)	**34,141**	**(76,262)**	**—**	**(322)**	**(42,443)**
Other (losses)/gains (net)	791	(11)	—	—	780
Depreciation and amortization	4,694	172	—	322	5,188
Adjusted earnings before interest, tax, depreciation and amortization	**39,626**	**(76,101)**	**—**	**—**	**(36,475)**

2021	Commercial	Product development	Medical technologies	Manufacturing services	Total segment
	A$'000	A$'000	A$'000	A$'000	A$'000
Revenue from contracts with customers	5,408	2,188	—	—	7,596
Cost of sales	(6,371)	—	—	—	(6,371)
Gross profit	**(963)**	**2,188**	**—**	**—**	**1,225**
Research and development costs	—	(48,114)	—	—	(48,114)
Selling and marketing expenses	(5,692)	—	—	—	(5,692)
Manufacturing and distribution costs	(170)	—	—	(290)	(460)
General and administration costs	(9,512)	—	—	—	(9,512)
Other gains (net)	2,064	18,574	—	—	20,638
Operating profit/(loss)	**(14,273)**	**(27,352)**	**—**	**(290)**	**(41,915)**
Other gains (net)	(2,064)	(18,574)	—	—	(20,638)
Depreciation and amortization	596	—	—	—	596
Adjusted earnings before interest, tax, depreciation and amortization	**(15,741)**	**(45,926)**	**—**	**(290)**	**(61,957)**

3.2. Reconciliation of total segment adjusted EBITDA to profit/(loss) before income tax

	Note	2023 A$'000	2022 A$'000	2021 A$'000
Total segment adjusted EBITDA		**101,266**	**(36,475)**	**(61,957)**
Unallocated income and expenses:				
Research and development costs		(43)	18	—
Selling and marketing expenses		(184)	(96)	(14)
Manufacturing and distribution costs		(2,153)	(1,488)	—
General and administration costs		(40,990)	(29,950)	(18,680)
Other (losses)/gains (net)	5	(35,854)	(18,751)	6,000
Finance income		1,019	1	—
Finance costs		(13,772)	(6,693)	(5,218)
Depreciation and amortization		(6,202)	(5,188)	(596)
Profit/(loss) before income tax		**3,087**	**(98,622)**	**(80,465)**

General and administration costs predominantly comprise of employment costs of $24,151,000 (2022: $18,225,000, 2021: $8,738,000) and other centrally managed IT, legal and other corporate costs.

3.3. Operating segment assets and liabilities

2023	Commercial	Product development	Medical technologies	Manufacturing services	Total segment	Reconciling items	Group
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Total assets	167,356	46,744	52,700	36,835	303,635	102,323	405,958
Total liabilities	65,890	40,252	275	20,172	126,589	130,458	257,047
Additions to non-current assets	12,025	5,116	54,296	—	71,437	—	71,437

2022	Commercial	Product development	Medical technologies	Manufacturing services	Total segment	Reconciling items	Group
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Total assets	126,781	36,675	—	19,976	183,432	71,921	255,353
Total liabilities	48,038	16,221	—	12,849	77,108	98,238	175,346
Additions to non-current assets	13,675	6,823	—	2,114	22,612	—	22,612

Reconciling items primarily comprise cash and cash equivalents held centrally $68,768,000 (2022: $62,668,000), investments in financial assets $12,260,000 (2022: $Nil), property, plant and equipment $3,942,000 (2022: $3,667,000) tax assets and liabilities and contingent consideration liabilities (note 25) which are managed centrally.

3.4. Geographical information

	2023 Revenue by location of customer	2023 Non-current assets by location of asset	2022 Revenue by location of customer	2022 Non-current assets by location of asset	2021 Revenue by location of customer
	A$'000	A$'000	A$'000	A$'000	A$'000
Australia	1,166	21,057	149	31,815	—
Belgium	458	77,469	564	41,174	—
China	5,291	—	3,353	—	2,188
Other countries	4,669	—	3,979	—	4,893
United Kingdom	1,306	50,346	2,045	—	—
United States	489,657	4,130	150,006	5,160	515
Total	**502,547**	**153,002**	**160,096**	**78,149**	**7,596**

The total non-current assets figure above excludes deferred tax assets.

4. Revenue from contracts with customers

Disaggregation of revenue from contracts with customers

The Group derives revenue from the sale and transfer of goods and services over time and at a point in time under the following major business activities:

	Recognition	Operating segment	2023 A$'000	2022 A$'000	2021 A$'000
Sale of goods	At a point in time	Commercial	496,241	155,984	4,894
Royalty income	At a point in time	Commercial	392	385	514
Provision of services	Over time	Commercial	418	—	—
Licenses of intellectual property	At a point in time	Product development	100	374	—
Research and development services	Over time	Product development	5,396	3,353	2,188
Total revenue from continuing operations			**502,547**	**160,096**	**7,596**

5. Other losses/(gains) (net)

	2023 A$'000	2022 A$'000	2021 A$'000
Remeasurement of contingent consideration	34,275	16,707	14,438
Remeasurement of provisions	(173)	1,017	417
Realized currency (loss)/gain	(2,460)	669	914
Impairment of intangible assets	804	—	—
Other income	(20)	(91)	(583)
Research and development tax incentive income	—	—	(18,574)
Unrealized currency loss	3,428	449	(2,612)
	35,854	**18,751**	**(6,000)**

Recognition of research and development tax incentive income

The Australian government allows a refundable research and development (R&D) tax incentive to eligible companies with an annual aggregate turnover of less than $20,000,000. Eligible companies can receive refundable amounts of their research and development expenditure. During 2021 the Department of Innovation, Industry and Science (Innovation and Science Australia) granted Telix an advance/overseas R&D tax finding providing approval for expenditure up to $320,834,000 that could be eligible for R&D tax incentives.

The research and development activities have been assessed by management and also by an independent subject matter expert to determine which areas are eligible under the R&D tax incentive scheme. This analysis includes an assessment of both the domestic and international spend. For the year ended December 31, 2021 the Group has recognized $18,574,000 in the consolidated statement of comprehensive income or loss. For the years ended December 31, 2022 and 2023, the Group did not recognize any amounts in relation to the R&D tax incentive, as a result of revenue exceeding the threshold of $20,000,000 in both financial years.

6. Finance costs

	2023 A$'000	2022 A$'000	2021 A$'000
Unwind of discount	12,782	6,287	5,029
Interest expense on lease liabilities	636	277	157
Interest expense	148	46	6
Bank fees	206	83	26
Finance costs	**13,772**	**6,693**	**5,218**

The Group recognized an unwind of discount on contingent consideration liabilities of $11,394,000 (2022: $4,957,000, 2021: $3,283,000), provisions of $419,000 (2022: $252,000, 2021: $599,000) and contract liabilities of $969,000 (2022: $1,078,000, 2021: $1,147,000).

7. Income tax (benefit)/expense

7.1. Income tax (benefit)/expense

	2023	2022	2021
	A$'000	A$'000	A$'000
Current tax expense[1]	14,357	9,428	45
Deferred tax benefit	(16,481)	(3,971)	—
	(2,124)	**5,457**	**45**

1. The current tax expense is attributable to Telix Innovations SA and Telix Pharmaceuticals US Inc and is driven by the individual entity's taxable profits.

7.2. Numerical reconciliation of prima facie tax payable to income tax benefit/(expense)

	2023	2022	2021
	A$'000	A$'000	A$'000
Profit/(loss) before income tax	3,087	(98,622)	(80,465)
Prima-facie tax at a rate of 30.0% (2022: 30.0%, 2021: 26.0%)	926	(29,587)	(20,920)
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:			
Net R&D tax incentive credit	(7,408)	(6,688)	5,644
Remeasurement of provisions	13,915	7,423	3,862
Share-based payments expense	2,636	2,434	343
Employee Share Trust payments	(10,776)	(8,073)	—
Deductible transaction costs on share issues	—	—	(305)
Sundry items	569	2	(48)
Foreign exchange translation loss	1,028	(464)	(203)
	890	**(34,953)**	**(11,627)**
Current year tax losses not recognized	35,152	46,325	10,624
Prior year tax losses recognized	—	(854)	
Adjustment for current tax of prior periods	—	561	581
Provisions recognized in international jurisdictions	—	—	45
Difference in overseas tax rates	(38,166)	(5,622)	422
Income tax (benefit)/expense	**(2,124)**	**5,457**	**45**

8. Earnings per share

8.1. Basic earnings per share

	2023	2022	2021
	Cents	Cents	Cents
Basic earnings/(loss) per share from continuing operations attributable to the ordinary equity holders of the Company	1.63	(33.50)	(28.50)
Total basic earnings/(loss) per share attributable to the ordinary equity holders of the Company	1.63	(33.50)	(28.50)

8.2. Diluted earnings per share

	2023	2022	2021
	Cents	Cents	Cents
Diluted earnings/(loss) per share from continuing operations attributable to the ordinary equity holders of the Company	1.61	(33.50)	(28.50)
Total diluted earnings/(loss) per share attributable to the ordinary equity holders of the Company	1.61	(33.50)	(28.50)

8.3. Weighted average number of shares used as the denominator

	2023 Number '000	2022 Number '000	2021 Number '000
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/loss per share[1]	319,181	310,644	282,206
Weighted average number of ordinary shares used as the denominator in calculating diluted earnings/loss per share	323,710	310,644	282,206

1. For the year ended December 31, 2022 there were 4,436,046 options (2021: 3,745,000) that were not included in the calculation of diluted earnings as they were antidilutive.

9. Employment costs

	2023 A$'000	2022 A$'000	2021 A$'000
Salaries and wages	82,108	47,302	24,618
Short term incentives	9,413	4,025	2,312
Sales commissions	7,167	3,113	748
Share based payment charge	8,786	8,114	1,319
Superannuation	1,798	1,270	642
Non-Executive Directors' fees	577	661	465
	109,849	**64,485**	**30,104**

Salaries and wages of $1,483,000 (2022: $903,000, 2021: $Nil) are included within the cost of sales in the Consolidated statement of comprehensive income or loss.

10. Depreciation and amortization

	2023 $'000	2022 $'000	2021 $'000
Amortization of intangible assets	4,344	4,098	4,179
Depreciation	2,399	1,281	995
	6,743	**5,379**	**5,174**

11. Trade and other receivables

	2023 A$'000	2022 A$'000
Trade receivables	65,310	39,354
Allowance for impairment losses	(533)	—
Deposits	586	327
	65,363	**39,681**
Current	64,777	39,354
Non-current	586	327
Total trade and other receivables	**65,363**	**39,681**

12. Inventories

	2023	2022
	A$'000	A$'000
Raw materials and stores	7,700	2,422
Work in progress	5,961	3,773
Finished goods	3,649	2,282
Total inventories	**17,310**	**8,477**

The amount of inventory recognized as an expense during the year was $22,620,000 (2022: $9,100,000, 2021: $2,549,000).

13. Other current assets

	2023	2022
	A$'000	A$'000
Other receivables	2,363	3,675
GST receivables	4,739	2,890
Prepayments	12,422	2,508
Total other current assets	**19,524**	**9,073**

14. Financial assets

	2023	2022
	A$'000	A$'000
Investment in Mauna Kea	9,497	—
Investment QSAM Biosciences	2,763	—
Total financial assets	**12,260**	**—**

Additions

Mauna Kea

On November 13, 2023, Telix announced a strategic investment in Mauna Kea of $10,130,000 (€6,000,000), to develop new hybrid pharmaceutical-device products through the combination of Telix's cancer-targeting agents with Mauna Kea's surgical endomicroscopy platform. Telix's investment in Mauna Kea will further support the development of advanced imaging techniques for minimally invasive surgery, with a specific focus on urologic oncology.

Under the deal terms, Telix purchased 11,911,852 new ordinary shares of Mauna Kea at €0.5037 per share. Telix owns 19.33% of the share capital and 19.01% of the voting rights of Mauna Kea. The investment was designated at the date of acquisition as a financial asset valued at fair value through other comprehensive income.

QSAM Biosciences

On November 14, 2023 Telix announced the proposed acquisition of QSAM Biosciences Inc (QSAM). QSAM is a U.S. based clinical stage company developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer.

Telix paid QSAM an upfront Collaboration and Option Fee of $3,025,000 (US$2,000,000) in cash to advance development efforts based on mutually agreed goals and to provide sixty days of exclusivity pending completion of diligence and execution of a definitive acquisition agreement. If the acquisition of QSAM proceeds, upon closing, Telix will pay an upfront purchase price of US$33,100,000 in equity through the issue of fully paid ordinary Telix shares. If the proposed acquisition of QSAM does not close, the Collaboration and Option Fee will be converted to QSAM common stock at US$6.70 per share. The upfront Collaboration and Option Fee has been designated at the date of acquisition as a financial asset valued at fair value through other comprehensive income.

Amounts recognized in other comprehensive income or loss

Fair values have been determined based on the quoted share prices (level 1 inputs) at December 31, 2023, resulting in a loss of $895,000 (2022: $Nil) recognized in other comprehensive income or loss.

15. Deferred tax assets and liabilities

15.1. Deferred tax assets

	2023 A$'000	2022 A$'000
The balance comprises temporary differences attributable to:		
Tax losses	—	4,400
Intangible assets	8,294	2,434
Employee benefit obligations	2,791	1,052
Lease liabilities	1,780	803
Inventories	10,976	363
Other	531	157
Total deferred tax assets	**24,372**	**9,209**
Set-off of deferred tax liabilities pursuant to set-off provisions	(3,920)	(5,238)
Net deferred tax assets	**20,452**	**3,971**

Deferred tax assets movements	Tax losses A$'000	Intangible assets A$'000	Employee benefit obligations A$'000	Lease liabilities A$'000	Inventories A$'000	Other A$'000	Total A$'000
The balance comprises temporary differences attributable to:							
Balance at January 1, 2023	**4,400**	**2,434**	**1,052**	**803**	**363**	**157**	**9,209**
(Charged)/credited:							
to profit and loss	(4,400)	5,860	1,739	977	10,613	374	15,163
Balance at December 31, 2023	**—**	**8,294**	**2,791**	**1,780**	**10,976**	**531**	**24,372**
Balance at January 1, 2022	**4,692**	**—**	**—**	**756**	**—**	**—**	**5,448**
(Charged)/credited:							
to profit and loss	(292)	2,434	1,052	47	363	157	3,761
Balance at December 31, 2022	**4,400**	**2,434**	**1,052**	**803**	**363**	**157**	**9,209**

15.2. Deferred tax liabilities

	2023 A$'000	2022 A$'000
The balance comprises temporary differences attributable to:		
Intangible assets	2,376	3,634
Right-of-use assets	1,544	1,604
Total deferred tax liabilities	**3,920**	**5,238**
Set-off of deferred tax assets pursuant to set-off provisions	(3,920)	(5,238)
Net deferred tax liabilities	—	—

Deferred tax liabilities movements	Intangible assets A$'000	Right-of-use assets A$'000	Total A$'000
The balance comprises temporary differences attributable to:			
Balance at January 1, 2023	**3,634**	**1,604**	**5,238**
Charged/(credited):			
to profit and loss	(1,258)	(60)	(1,318)
Balance at December 31, 2023	**2,376**	**1,544**	**3,920**

Deferred tax liabilities movements	Intangible assets A$'000	Right-of-use assets A$'000	Total A$'000
Balance at January 1, 2022	**4,734**	**714**	**5,448**
Charged/(credited):			
to profit and loss	(1,100)	890	(210)
Balance at December 31, 2022	**3,634**	**1,604**	**5,238**

15.3. Unrecognized deferred tax assets

The composition of the Group's unrecognized deferred tax assets is as follows:

Unrecognized deferred tax assets	2023 A$'000	2022 A$'000
Tax losses and tax credits	84,412	62,833
Temporary differences in relation to provisions	212	1,600
Temporary differences in relation to employee benefit obligations	97	898
Temporary differences in relation to intangible assets	—	2,127
Temporary differences in relation to lease liabilities	211	838
Temporary differences in relation to share based payments	8,940	10,508
Total unrecognized deferred tax assets	**93,872**	**78,804**

15.4. Unrecognized tax losses

	2023 A$'000	2022 A$'000	2021 A$'000
Unused tax losses and carried forward tax credits for which no deferred tax asset has been recognized:			
Australia	82,908	61,330	17,882
Other countries	1,504	1,503	2,538
Unrecognized income tax benefit	**84,412**	**62,833**	**20,420**

16. Property, plant and equipment

	Land and buildings A$'000	Plant and equipment A$'000	Furniture, fittings and equipment A$'000	Leasehold improvements A$'000	Total A$'000
Balance at January 1, 2023	**9,611**	**576**	**441**	**1,404**	**12,032**
Additions	8,912	96	168	503	9,679
Acquisition of business	—	37	—	—	37
Reclassifications	2,021	(12)	490	(142)	2,357
Depreciation charge	(91)	(207)	(422)	(222)	(942)
Exchange differences	(11)	9	3	6	7
Balance at December 31, 2023	**20,442**	**499**	**680**	**1,549**	**23,170**
Cost	20,752	895	1,600	1,908	25,155
Accumulated depreciation	(310)	(396)	(920)	(359)	(1,985)
Net book amount	**20,442**	**499**	**680**	**1,549**	**23,170**
Balance at January 1, 2022	**2,203**	**991**	**461**	**296**	**3,951**
Additions	6,717	152	203	1,165	8,237
Acquisition of business	—	258	—	—	258
Reclassifications	766	(766)	—	—	—
Depreciation charge	(70)	(63)	(230)	(57)	(420)

	Land and buildings	Plant and equipment	Furniture, fittings and equipment	Leasehold improvements	Total
	A$'000	A$'000	A$'000	A$'000	A$'000
Exchange differences	(5)	4	7	—	6
Balance at December 31, 2022	**9,611**	**576**	**441**	**1,404**	**12,032**
Cost	9,830	765	939	1,541	13,075
Accumulated depreciation	(219)	(189)	(498)	(137)	(1,043)
Net book amount	**9,611**	**576**	**441**	**1,404**	**12,032**

17. Right-of-use assets

	Properties	Motor vehicles	Total
	A$'000	A$'000	A$'000
Balance at January 1, 2023	**6,327**	**479**	**6,806**
Additions	1,188	1,158	2,346
Reclassifications	(336)	—	(336)
Depreciation charge	(1,006)	(451)	(1,457)
Exchange differences	(39)	3	(36)
Balance at December 31, 2023	**6,134**	**1,189**	**7,323**
Cost	8,959	2,195	11,154
Accumulated depreciation	(2,825)	(1,006)	(3,831)
Net book amount	**6,134**	**1,189**	**7,323**
Balance at January 1, 2022	2,067	311	2,378
Additions	5,054	384	5,438
Acquisition of business	423	—	423
Depreciation charge	(640)	(221)	(861)
Disposals	(580)	—	(580)
Exchange differences	3	5	8
Balance at December 31, 2022	**6,327**	**479**	**6,806**
Cost	8,104	1,034	9,138
Accumulated depreciation	(1,777)	(555)	(2,332)
Net book amount	**6,327**	**479**	**6,806**

The consolidated statement of comprehensive income or loss shows the following amounts relating to right-of- use assets:

Depreciation charge on right-of-use assets	2023	2022	2021
	A$'000	A$'000	A$'000
Properties	1,006	640	515
Motor vehicles	451	221	141
	1,457	**861**	**656**

18. Intangible assets

	Goodwill	Intellectual property	Software	Patents	Licenses	Total
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Balance at January 1, 2023	**5,519**	**41,060**	**—**	**300**	**12,105**	**58,984**
Additions	—	57,410	1,659	266	77	59,412
Reclassifications	—	—	—	—	(2,021)	(2,021)
Amortization charge	—	(4,005)	—	(37)	(302)	(4,344)
Impairments	—	(804)	—	—	—	(804)
Changes in provisions	(672)	489	—	—	282	99
Exchange differences	—	(1,933)	(37)	—	307	(1,663)
Balance at December 31, 2023	**4,847**	**92,217**	**1,622**	**529**	**10,448**	**109,663**
Cost	4,847	114,048	1,622	949	11,604	133,070
Accumulated amortization	—	(21,831)	—	(420)	(1,156)	(23,407)
Net book amount	**4,847**	**92,217**	**1,622**	**529**	**10,448**	**109,663**
Balance at January 1, 2022	**4,097**	**44,486**	**—**	**337**	**6,809**	**55,729**
Acquisition of business	1,433	—	—	—	—	1,433
Additions	—	—	—	—	6,823	6,823
Amortization charge	—	(3,742)	—	(34)	(322)	(4,098)
Changes in provisions	—	256	—	—	(1,120)	(864)
Exchange differences	(11)	60	—	(3)	(85)	(39)
Balance at December 31, 2022	**5,519**	**41,060**	**—**	**300**	**12,105**	**58,984**
Cost	5,519	58,875	—	675	12,835	77,904
Accumulated amortization	—	(17,815)	—	(375)	(730)	(18,920)
Net book amount	**5,519**	**41,060**	**—**	**300**	**12,105**	**58,984**

Cash generating units

The allocation of intangible assets to each cash-generating unit (CGU) is summarized below:

CGU	Useful life	Status	2023 A$'000	2022 A$'000
TLX591-CDx (Illuccix)	Definite	Commercial	10,876	14,709
TLX591	Indefinite	Product development	17,912	12,796
TLX101	Definite	Product development	1,613	1,676
TLX66	Indefinite	Product development	15,569	15,080
TLX66-CDx	Definite	Commercial	—	898
TLX300	Indefinite	Product development	6,823	6,823
Manufacturing services	Definite	Manufacturing services	4,298	6,702
Medical technologies	Indefinite	Medical technologies	52,043	—
Patents	Definite	Product development	529	300
			109,663	**58,984**

Impairment test for goodwill and indefinite life intangible assets

Goodwill and indefinite life intangible assets are tested annually for impairment. At December 31, 2023, the Directors used a fair value less costs to sell approach to assess the carrying value of goodwill and indefinite life intangible assets. No impairment was recognized by the Group.

Key assumptions used for the fair value less costs to sell approach

The Group has identified the estimate of the recoverable amount as a significant judgement for the year ended December 31, 2023. In determining the recoverable amount of goodwill and indefinite life intangible assets, the Group has used discounted cash flow forecasts and the following key assumptions (classified as level 3 inputs in the fair value hierarchy):

- discounted expected future cash flows of each program which span 10 years from marketing authorization, reflecting the anticipated product life cycle, and include cash inflows and outflows determined using further assumptions below
- risk adjusted post-tax discount rate – 15.0% (2022: 15.0%)
- regulatory/marketing authorization approval dates, these are re-assessed in conjunction with Senior Management and Commercial teams
- expected sales volumes, these are determined by applying a target market share to cancer incidence rates across countries within Americas, European and APAC regions, sourced from data provided by the World Health Organization's International Agency for Research on Cancer
- net sales price per unit, for commercialized products forecast average selling price is used and for products in development a target sales price is used
- approval for marketing authorization probability success factor, this varies depending on the clinical trial stage of each program
- in relation to cash outflows consideration has been given to cost of sales, selling and marketing expenses, general and administration costs and the anticipated research and development costs to reach commercialization. Associated expenses such as royalties, milestone payments and license fees are included, and
- costs of disposal were assumed to be immaterial at December 31, 2023.

Impact of possible changes in key assumptions

The Group has considered reasonable possible changes in the key assumptions and has not identified any instances that could cause the carrying amounts of the intangible assets at December 31, 2023 to exceed their recoverable amounts.

Whilst there is no impairment, the key sensitivities in the valuation remain the continued successful development and commercialization of core programs. If the Group is unable to successfully develop each product, this may result in an impairment of the carrying amount of our intangible assets.

Impairment triggers for definite life intangible assets

TLX66-CDx (Scintimun) manufacturing uses Triton X-100, which can no longer be used in Europe without an exemption authorization from the Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH). This may indicate that the carrying amount of TLX66-CDx of $898,000 may not be recoverable at December 31, 2023 and the intangible asset was impaired.

Management is currently exploring whether Scintimun could be used for dosimetry to support the TLX66 program, subject to clinical testing. Improvements to the manufacturing process in response to these events could also result in a significant increase in productivity and a reduction in manufacturing costs, which could benefit both Scintimun and TLX66 in the future.

Other than the impairment trigger on TLX66-CDx, there were no other internal or external factors identified that could result in an impairment of definite life intangible assets at December 31, 2023.

19. Acquisitions

Dedicaid GmbH

The Group completed the acquisition of Vienna-based Dedicaid GmbH on April 27, 2023. The acquisition does not meet the definition of a business in IFRS 3 *Business Combinations* and the transaction has been recognized as an asset acquisition. The fair values of identifiable assets on acquisition are outlined below:

Consideration	2023 A$'000
Equity issued	1,829
Total consideration	**1,829**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Trade and other receivables	111
Software	1,659
Cash and cash equivalents	123
Trade and other payables	(64)
Total identifiable assets	**1,829**

Lightpoint Medical

The Group completed the acquisition of Lightpoint Medical's RGS business, assets and operations, through the purchase of Lightpoint Medical Limited's wholly owned subsidiary, Lightpoint Surgical Limited on November 1, 2023. Lightpoint Medical – a technology leader in precision-guided robotic cancer surgery – develops and markets miniaturized imaging and sensing tools for advanced intra-operative cancer detection. The acquisition will support and expand Telix's late- stage urologic pipeline and, together with its complementary AI technologies, will strengthen Telix's capabilities in deploying molecular imaging in the surgical setting.

The upfront consideration was $31,522,000 (US$20,000,000) of which $30,895,000 (US$19,600,000) has been paid to Lightpoint Medical in equity through the issue of 3,298,073 fully paid ordinary Telix shares at $9.3659 per share, with the balance paid in cash. A further $23,624,000 (US$15,000,000) is payable via an earn-out in the form of rights (Performance Rights). Performance Rights will be settled in cash or equity (at Telix's election) upon achievement of certain milestones (Milestone Events) relating to the ongoing development and commercialization of the SENSEI probe and amounts have been recognized based on the probability of achieving the milestones.

The Group has determined that substantially all of the fair value of the gross assets acquired is concentrated in a single asset or a group of similar assets. The Group has applied the optional concentration of fair value test in IFRS 3 *Business Combinations* and concluded that the components acquired will be treated as an asset acquisition.

The Performance Rights have been recognized as an equity settled share based payment at a fair value of $21,278,000, which has been included in the fair value of intellectual property. Each milestone has a fixed dollar amount which can be settled either in cash or shares. The fair value of the Performance Rights was determined based on management's assessment of the likelihood of each milestone being reached against the fixed dollar amount for that milestone. The likelihood of the milestones being attained are considered non-vesting conditions as there are no further services or obligations of the counterparty, thus being reflected in the fair value.

The fair values of identifiable assets on acquisition are outlined below:

Consideration	2023 A$'000
Cash paid	627
Equity issued	30,895
Performance Rights issued	21,278
Total consideration	**52,800**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Intellectual property	52,294
Inventory	406
Patents	266
Property, plant and equipment	37
Other current assets	32
Trade payables	(235)
Total identifiable assets	**52,800**

20. Trade and other payables

	2023	2022
	A$'000	A$'000
Trade creditors	32,837	16,806
Accruals	37,895	22,325
Other creditors	6,738	3,148
Accrued royalties	3,205	1,919
Payroll liabilities	899	972
Government rebates payable	130	4,349
Total trade and other payables	**81,704**	**49,519**

21. Borrowings

	2023	2022
	A$'000	A$'000
Current	964	—
Non-current	8,209	3,312
Total borrowings	**9,173**	**3,312**

All borrowings outstanding at December 31, 2023 are in relation to the build-out of the Brussels South radiopharmaceutical production facility. Telix Pharmaceuticals (Belgium) SPRL (a wholly owned subsidiary of Telix) entered into two loan agreements, one with BNP Paribas and IMBC Group totaling €10,100,000 on a 10-year term, and a second loan with BNP Paribas totaling €2,000,000 on a two-year extendable term. All loans have a two-year repayment holiday period, with repayments due to commence from March 2024. The loans are secured by a fixed charge over the facility.

The loan agreements entitle BNP Paribas and IMBC Group to suspend or terminate all or part of the undrawn portion of the loan facilities with immediate effect and without prior notice. At December 31, 2023, the undrawn portion under the agreements was €6,455,000 ($10,488,000). As at the reporting date Telix has not received any notice to this effect.

The loan agreements require Telix Pharmaceuticals (Belgium) SPRL to comply with various covenants relating to the conduct of the business, including non-payment of required repayments, specified cross-defaults (in the event of the use of trade bills) and ensuring cumulative losses of Telix Pharmaceuticals (Belgium) SPRL do not exceed 25% of its capital and reserves. Upon the occurrence of an event of default and in the event of a change of control, BNP Paribas and IMBC Group may accelerate payments due under the loan agreements or terminate the loan agreements. There were no events of default or changes of control during the year.

2023

Lenders	Loan balance	Due < 1 year	Due > 1 year	Maturity date
	A$'000	A$'000	A$'000	
BNP Paribas	9,173	964	8,209	29-Feb-32
Total	**9,173**	**964**	**8,209**	

2022

Lenders	Loan balance	Due < 1 year	Due > 1 year	Maturity date
	A$'000	A$'000	A$'000	
BNP Paribas	3,312	—	3,312	29-Feb-32
Total	**3,312**	—	**3,312**	

Fair value: For all borrowings, the fair values are not materially different to their carrying amounts, since the interest payable on those borrowings is either close to current market rates or the borrowings are of a short-term nature.

Capital risk management: Capital is defined as the combination of shareholders' equity, reserves and net debt. The key objective of the Group when managing its capital is to safeguard its ability to continue as a going concern, so that the Group can continue to provide benefits for stakeholders and maintain an optimal capital and funding structure. The aim of the Group's capital management framework is to maintain, monitor and secure access to future funding arrangements to finance the necessary research and development activities being performed by the Group. Consistent with others in the industry, the Group monitors capital on the basis of the following gearing ratio: Debt as divided by Equity. At December 31, 2023 the Group's on-balance sheet gearing and leverage ratio was less than 1% (2022: less than 1%).

Reconciliation of liabilities arising from financing activities:

	Opening balance	Net cash inflow/ (outflow)	Other non-cash movements	Closing balance
	A$'000	A$'000	A$'000	A$'000
For the year ended December 31, 2023				
Borrowings	3,312	5,756	105	9,173
Lease liabilities	7,134	(2,858)	3,996	8,272
	10,446	**2,898**	**4,101**	**17,445**
For the year ended December 31, 2022				
Borrowings	19	3,293	—	3,312
Lease liabilities	2,520	(1,541)	6,155	7,134
	2,539	**1,752**	**6,155**	**10,446**

Other non-cash movements include new leases entered into during the year, leases acquired via acquisitions of a business, disposal of leases and exchange differences.

22. Contract liabilities

The Group has recognized the following liabilities related to contracts with customers in licensing arrangements and non-reimbursable government grants received:

	2023	2022
	A$'000	A$'000
Balance at January 1	**27,462**	**29,199**
Consideration received	—	537
Revenue recognized	(5,291)	(3,352)
Exchange differences	17	—
Unwind of discount	969	1,078
Balance at December 31	**23,157**	**27,462**
Current	10,995	4,940
Non-current	12,162	22,522
Total contract liabilities	**23,157**	**27,462**

Grand Pharma strategic partnership

On November 2, 2020, the Group entered into a strategic commercial partnership with Grand Pharmaceutical Group Limited (Grand Pharma or GP, formerly known as China Grand Pharma or CGP) for the Group's portfolio of targeted radiation products. A non-refundable upfront payment of US$25,000,000 was received upon signing of the contract with GP. The strategic partnership with GP is accounted for as a revenue contract comprising the grant of a sublicence of the Group's existing intellectual property and the provision of research and development services. The Group has

measured its contractual liability to undertake the identified future performance obligations relating to research and development services using a cost plus margin approach. As the performance obligation relating to research and development services is expected to be completed over several years from execution, a financing component has been recognized within Finance costs in profit or loss on an effective interest basis.

Walloon Region non-reimbursable grant

On August 29, 2022, Telix Innovations SA received a non-reimbursable government grant to support research efforts associated with 211At-TLX591/TLX592. The first installment received was for €365,000. This amount will be released to the Consolidated statement of comprehensive income or loss as the associated expenditure is incurred.

23. Lease liabilities

The consolidated statement of financial position shows the following amounts relating to leases:

Lease liabilities	2023 A$'000	2022 A$'000
Current	595	641
Non-current	7,677	6,493
Total lease liabilities	**8,272**	**7,134**

	2023 A$'000	2022 A$'000
Balance at January 1	7,134	2,520
Additions	3,436	6,164
Acquisition of business	—	423
Interest expense	636	277
Lease payments (principal and interest)	(2,858)	(1,541)
Disposals	—	(633)
Exchange differences	(76)	(76)
Balance at December 31	**8,272**	**7,134**

The consolidated statement of comprehensive income shows the following amounts relating to leases:

Interest expense relating to leases	2023 A$'000	2022 A$'000	2021 A$'000
Properties	604	244	126
Motor vehicles	32	33	31
Total lease interest	**636**	**277**	**157**

The total cash outflow for leases in 2023 comprises $2,222,000 (2022: $1,264,000, 2021: $596,000) principal and $636,000 (2022: $277,000, 2021: $157,000) interest payments.

24. Provisions

	Government grant liability	Decommissioning liability	Total
	A$'000	A$'000	A$'000
Balance at January 1, 2023	**2,551**	**5,333**	**7,884**
Remeasurement of provisions	(173)	—	(173)
Unwind of discount	238	181	419
Charged to profit or loss	**65**	**181**	**246**
Exchange differences	48	173	221
Amounts adjusted to intangible assets	—	286	286
Provision utilized	—	(56)	(56)
Balance at December 31, 2023	**2,664**	**5,917**	**8,581**
Current	577	—	577
Non-current	2,087	5,917	8,004
Total provisions	**2,664**	**5,917**	**8,581**
Balance at January 1, 2022	**1,539**	**8,532**	**10,071**
Remeasurement of provisions	1,017	—	1,017
Unwind of discount	115	137	252
Charged to profit or loss	**1,132**	**137**	**1,269**
Exchange differences	(59)	(73)	(132)
Acquisition of business	—	—	—
Amounts adjusted to intangible assets	—	(1,100)	(1,100)
Provision utilized	(61)	(2,163)	(2,224)
Balance at December 31, 2022	**2,551**	**5,333**	**7,884**
Current	402	—	402
Non-current	2,149	5,333	7,482
Total provisions	**2,551**	**5,333**	**7,884**

24.1. Government grant liability

Telix Innovations has received grants from the Walloon regional government in Belgium. These grants meet the definition of a financial liability as defined in IFRS 9 *Financial Instruments* and were designated to be measured at fair value through profit and loss.

The grants are repayable to the Walloon government based on a split between fixed and variable repayments. The fixed proportion is based on contractual cash flows agreed with the Walloon government. The variable cash flows are based on a fixed percentage of future sales and are capped at an agreed upon level.

The Group has estimated that the full variable repayments will be made up to the pre-agreed capped amount. The key inputs into this calculation are the risk adjusted discount rate of 3.3% (2022: 3.2%), the expected sales volumes and the net sales price per unit. The expected sales volumes and net sales price per unit assumptions are consistent with those utilized by the Group in the calculation of the contingent consideration liability and intellectual property valuation.

24.2. Decommissioning liability

Telix purchased the radiopharmaceutical production facility in Belgium on April 27, 2020. The site had cyclotrons installed in concrete shielded vaults which also contained some nuclear contamination associated with past manufacturing activities. As part of this transaction, Telix assumed the obligation to remove the cyclotrons and restore the site.

The Group removed the cyclotrons from the site during 2022. Other decommissioning activities not required to upgrade the production facility have been deferred to the end of the operating life of the facility in 2041. The

decommissioning costs expected to be incurred in 2041 of €6,021,000 (2022: €6,021,000) have been discounted using the Belgium risk-free rate of 3.3% (2022: 3.2%) and translated to Australian dollars at the exchange rate at December 31, 2023.

The provision represents the best estimate of the expenditures required to settle the present obligation at December 31, 2023. While the Group has made its best estimate in establishing its decommissioning liability, because of potential changes in technology as well as safety and environmental requirements, plus the actual timescale to complete decommissioning, the ultimate provision requirements could vary from the Group's current estimates. Any subsequent changes in estimate which alter the level of the provision required are also reflected in adjustments to the intangible license asset. Each year, the provision is increased to reflect the unwind of discount and to accrue an estimate for the effects of inflation, with the charges being presented in the consolidated statement of comprehensive income or loss. Actual payments for commencement of decommissioning activity are disclosed as provision utilized in the above table.

25. Contingent consideration

	ANMI	TheraPharm	Optimal Tracers	Contingent consideration
	A$'000	A$'000	A$'000	A$'000
Balance at January 1, 2023	**62,541**	**1,690**	**718**	**64,949**
Remeasurement of contingent consideration	34,275	—	—	34,275
Unwind of discount	11,033	278	83	11,394
Charged to profit or loss	**45,308**	**278**	**83**	**45,669**
Exchange differences	410	(279)	(46)	85
Amounts adjusted to intangible assets	—	489	(672)	(183)
Payments for contingent consideration	(17,766)	—	—	(17,766)
Balance at December 31, 2023	**90,493**	**2,178**	**83**	**92,754**
Current	37,070	—	83	37,153
Non-current	53,423	2,178	—	55,601
Total contingent consideration	**90,493**	**2,178**	**83**	**92,754**
Balance at January 1, 2022	**40,635**	**1,275**	**—**	**41,910**
Remeasurement of contingent consideration	16,707	—	—	16,707
Unwind of discount	4,798	159	—	4,957
Charged to profit or loss	**21,505**	**159**	**—**	**21,664**
Exchange differences	401	—	—	401
Acquisition of business	—	—	718	718
Amounts adjusted to intangible assets	—	256	—	256
Balance at December 31, 2022	**62,541**	**1,690**	**718**	**64,949**
Current	14,811	—	372	15,183
Non-current	47,730	1,690	346	49,766
Total contingent consideration	**62,541**	**1,690**	**718**	**64,949**

Telix Innovations (formerly ANMI)

The Group acquired ANMI on December 24, 2018. The Group is liable for future variable payments which are calculated based on the percentage of net sales for five years following the achievement of marketing authorization of the product. The percentage of net sales varies depending on the net sales achieved in the United States and the rest of the world. The Group also holds an option to buy-out the remaining future variable payments in the third year following the achievement of marketing authorization, if specified sales thresholds are met.

As at consolidated statement of financial position date, the Group has remeasured the contingent consideration to its fair value. The remeasurement is as a result of changes to the key assumptions such as risk adjusted post-tax discount rate, expected sales volumes and net sales price per unit.

The contingent consideration liability has been valued using a discounted cash flow model that utilizes certain unobservable level 3 inputs. These key assumptions include risk adjusted post-tax discount rate 15.0% (2022: 15.0%), expected sales volumes over the forecast period and net sales price per unit.

The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	December 31, 2023
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase in the post-tax discount rate would decrease the contingent consideration by 0.4% and a 0.5% decrease in the post-tax discount rate would increase the contingent consideration by 0.4%.
Expected sales volumes	This is determined using actual sales volumes for 2023 and forecasting sales volumes for 2024 and beyond for each region.	A 10% increase in sales volumes across all regions would increase the contingent consideration by 5.5% and a 10% decrease in sales volumes would decrease the contingent consideration by 5.5%
Net sales price per unit	This is determined using actual sales prices for 2023 and forecasting sales prices for 2024 and beyond for each region.	A 10% increase in net sales price per unit across all regions would increase the contingent consideration by 5.6% and a 10% decrease in sales prices would decrease the contingent consideration by 5.6%.

Telix Switzerland (formerly TheraPharm)

Telix acquired TheraPharm on December 14, 2020. Part of the consideration for the acquisition was in the form of future payments contingent on certain milestones. These are:

- €5,000,000 cash payment upon successful completion of a Phase III pivotal registration trial
- €5,000,000 cash payment upon achievement of marketing authorization in the Europe or the United States, whichever approval comes first, and
- 5% of net sales for the first three years following marketing authorization in the Europe or the United States, whichever approval comes first.

The valuation of the contingent consideration has been performed utilizing a discounted cash flow model that uses certain unobservable assumptions. These key assumptions include risk adjusted post-tax discount rate of 15.0% (2022: 15.0%), marketing authorization date, expected sales volumes over the forecast period, net sales price per unit and approval for marketing authorization probability success factor.

The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	December 31, 2023
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase in the post-tax discount rate would decrease the contingent consideration by 2.0% and a decrease in the post-tax discount rate by 0.5% would increase the contingent consideration by 2.0%.

Unobservable input	Methodology	December 31, 2023
Expected sales volumes	This is determined through assumptions on target market population, penetration and growth rates in the United States and Europe.	A 10% increase in the sales volumes would increase the contingent consideration by 0.7% and a 10% decrease in sales volumes would decrease the contingent consideration by 0.7%.
Net sales price per unit	The net sales price per unit is estimated based on comparable products currently in the market.	A 10% increase in the net sales price per unit would increase the contingent consideration by 1.6% and a 10% decrease in net sales price per unit would decrease the contingent consideration by 1.6%.
Approval for marketing authorization probability success factor	This assumption is based on management's estimate for achieving regulatory approval and is determined through benchmarking of historic approval rates.	An increase in the probability of success factor by 10% would increase the contingent consideration by 50.0% and a 10% decrease in the probability of success factor would decrease the contingent consideration to nil.

Telix Optimal Tracers

The Group acquired the assets of Optimal Tracers on December 31, 2022. The consideration includes two contingent payments based on a percentage of revenue from existing customers for the years ending December 31, 2023 and 2024.

The valuation of the contingent consideration has been performed utilizing a discounted cash flow model that uses certain unobservable assumptions. These key assumptions include risk adjusted post-tax discount rate of 15.0% and expected revenue from existing customers over the next year.

The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	December 31, 2023
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase in the post-tax discount rate would decrease the contingent consideration by 0.6% and a 0.5% decrease in the post-tax discount rate would increase the contingent consideration by 0.6%.
Expected revenue	This is determined using actual revenue for 2023 and forecasting revenue for 2024.	A 10% increase in revenue would increase the contingent consideration by 10.0% and a 10% decrease in revenue would decrease the contingent consideration by 10.0%

26. Employee benefit obligations

	2023	2022
	A$'000	A$'000
Bonus	10,630	5,101
Annual leave	3,282	2,450
Long service leave	330	215
Balance at December 31	**14,242**	**7,766**
Current	13,912	7,551
Non-current	330	215
Total employee benefit obligations	**14,242**	**7,766**

27. Equity

27.1. Share capital

	2023	2023	2022	2022	2021	2021
	Number '000	A$'000	Number '000	A$'000	Number '000	A$'000
Balance at January 1	**316,343**	**370,972**	**285,073**	**170,840**	**280,405**	**167,058**
Shares issued through the exercise of share options and warrants[1]	3,879	42,572	8,543	32,948	4,668	3,782
Contributions of equity[2]	—	—	22,727	175,000	—	—
Shares issued for Dedicaid GmbH[3]	207	1,829	—	—	—	—
Shares issued for Lightpoint transaction[4]	3,298	30,895	—	—	—	—
Transaction costs arising on new share issues	—	—	—	(7,816)	—	—
Balance at December 31	**323,727**	**446,268**	**316,343**	**370,972**	**285,073**	**170,840**

1. Options exercised during the year through the employee Equity Incentive Plan resulted in 3,879,000 (2022: 8,543,000, 2021: $4,668,000) shares being issued of total value of $42,572,000 (2022: $32,948,000, 2021: $3,782,000).
2. On January 27, 2022, the Group completed a $175,000,000 institutional placement of 22,727,000 new, fully paid ordinary shares at a price of $7.70 per share. As part of this placement, the Group also incurred $7,816,000 of associated transaction costs.
3. On April 27, 2023, the Group completed the acquisition of Dedicaid GmbH. The consideration for the acquisition comprised 207,000 in Telix shares at a 10-day volume weighted average price of shares on the execution date of $8.73 per share.
4. On November 1, 2023, the Group completed the acquisition of Lightpoint through the issue of 3,298,000 fully paid ordinary Telix shares at $9.3659 per share.

The weighted average ordinary shares for the period January 1, 2023 to December 31, 2023 is 319,180,783 (2022: 310,644,169). The Company does not have a limited amount of authorized capital under Australian law.

Rights applying to securities:

1. *Ordinary shares:* Ordinary shares entitle the holder to participate in dividends, and to share in the proceeds of winding up the Company in proportion to the number of and amounts paid on the shares held.
2. *Options and rights:* Holders of Options and rights have no voting rights. Information relating to the Company's Employee Incentive Plan (EIP), including details of Options issued, exercised and lapsed during the financial year, is set out in note 28.

27.2. Share capital reserve

	2023	2023	2022	2022	2021	2021
	Number '000	A$'000	Number '000	A$'000	Number '000	A$'000
Balance at January 1	—	(26,909)	—	—	—	—
Treasury shares acquired	3,877	(35,920)	4,054	(26,909)	—	—
Shares allocated to employees	(3,877)	—	(4,054)	—	—	—
Balance at December 31	**—**	**(62,829)**	**—**	**(26,909)**	**—**	**—**

Ordinary shares in the Company were purchased by the Telix Pharmaceuticals Employee Share Trust for the purpose of issuing shares under the Equity Incentive Plan, these shares are allocated to employees and are not held within the Employee Share Trust (see note 28 for further information).

27.3. Share-based payments reserve

	2023 Number '000	2023 A$'000	2022 Number '000	2022 A$'000	2021 Number '000	2021 A$'000
Balance at January 1	**11,736**	**9,321**	**17,148**	**5,942**	**20,226**	**4,620**
EIP options issued	6,689	8,786	4,436	8,114	3,745	1,322
Performance Rights issued[1]	2,524	21,278	—	—	—	
Options exercised	(4,524)	(3,939)	(8,843)	(4,735)	(4,716)	—
Options lapsed	(1,824)	—	(1,005)	—	(2,107)	—
Balance at December 31	**14,601**	**35,446**	**11,736**	**9,321**	**17,148**	**5,942**

1. Relates to the acquisition of Lightpoint.

27.4. Financial assets at FVOCI reserve

The group has elected to recognize changes in the fair value of certain investments in equity securities in Other comprehensive income (OCI), as explained in note 14. These changes are accumulated within the FVOCI reserve within equity.

The table below shows how the FVOCI reserve relates to equity securities:

	2023 A$'000	2022 A$'000	2021 A$'000
Balance at January 1	—	—	—
Revaluation - gross	(895)	—	—
Deferred tax	—	—	—
Balance at December 31	**(895)**	—	—

28. Share based payments

Equity Incentive Plan and Options

The Equity Incentive Plan (EIP) was established to allow the Board of Telix to make offers to Eligible Employees to acquire securities in the Company and to otherwise incentivize employees. 'Eligible Employees' includes full time, part time or casual employees of a Group Company, a Non-Executive Director of a Group Company, a Contractor, or any other person who is declared by the Board to be eligible.

The Board may, from time to time and in its absolute discretion, invite Eligible Employees to participate in a grant of Incentive Securities, which may comprise Rights (including Performance Share Appreciation Rights), Options, and/or Restricted Shares. Vesting of Incentive Securities under the EIP is subject to any vesting or performance conditions determined by the Board. Incentive Securities are normally granted under the EIP for no consideration and carry no dividend or voting rights. When exercised, each Incentive Security is convertible into one Share.

Non-Executive Directors are able to participate in the Equity Incentive Plan, under which equity may be issued subject to Shareholder approval. Options are however normally issued to Non-Executive Directors not as an 'incentive' under the EIP but as a means of cost-effective consideration for agreeing to join the Board. The details of Incentive Securities on issue to individual Directors can be found in the Remuneration report for the year ended December 31, 2023. For the purposes of this table and to illustrate the total number of Incentive Securities on issue under the rules of the EIP, all Incentive Securities issued to Non-Executive Directors, Executive Directors, employees and contractors are included.

Incentive Securities contain a cashless exercise clause that allows employees to exercise the securities for an exercise price of $0.00 in exchange for forfeiting a portion of their vested securities.

	2023 Number '000	2023 WAEP[1]	2022 Number '000	2022 WAEP[1]
Balance at January 1	**11,736**	**3.62**	**17,148**	**2.03**
Granted during the year	6,689	6.64	4,436	5.10
Exercised during the year	(4,524)	2.68	(8,843)	1.25
Lapsed/forfeited during the year	(1,824)	4.00	(1,005)	3.80
Balance at December 31	**12,077**	**5.59**	**11,736**	**3.62**
Vested and exercisable at December 31	**2,221**	**3.73**	**3,199**	**3.93**

1. WAEP - weighted average exercise price

Expense arising from share based payments transactions:

	2023 A$'000	2022 A$'000	2021 A$'000
Options issued under EIP	8,786	8,114	1,322
Total	**8,786**	**8,114**	**1,322**

Equity Incentive Plan and Options

Details of the number of options issued under the EIP outstanding at the end of the year:

Grant date	Vesting date	Expiry date	Exercise price	Options on issue at January 1, 2023 '000	Issued during the year '000	Vested during the year '000	Exercised during the year '000	Lapsed during the year '000	Options on issue at December 31, 2023 '000
11-Jun-18	11-Jun-20	11-Jun-22	0.85	—	—	—	—	—	—
11-Jun-18	11-Jun-21	11-Jun-22	0.85	—	—	—	—	—	—
24-Jan-19	24-Jan-22	24-Jan-23	1.09	450	—	—	(200)	(250)	—
4-Nov-19	4-Nov-22	3-Nov-23	2.30	430	—	—	(330)	—	100
13-Jan-20	13-Jan-23	12-Jan-24	2.23	3,080	—	3,080	(2,210)	(135)	735
1-Jul-20	1-Jul-23	30-Jun-24	1.83	1,300	—	1,300	(762)	(450)	88
27-Jan-21	28-Oct-22	26-Jan-26	4.38	1,386	—	—	(674)	—	712
27-Jul-21	28-Oct-22	27-Jul-26	5.37	933	—	—	(348)	—	585
27-Jul-21	27-Jul-25	27-Jul-26	0.00	100	—	—	—	—	100
5-Apr-22	31-Dec-24	4-Apr-27	4.95	2,452	—	—	—	(374)	2,078
5-Apr-22	31-Dec-24	4-Apr-27	0.00	205	—	—	—	(55)	150
24-Oct-22	31-Dec-24	24-Oct-27	6.15	1,400	—	—	—	(141)	1,259
2-May-23	31-Dec-25	27-Mar-28	6.90	—	3,362	—	—	(286)	3,076
6-Jul-23	31-Dec-25	16-May-28	10.04	—	817	—	—	(38)	779
6-Jul-23	31-Mar-25 or 31-Dec-25	15-Jun-25, 15-Jun-28	0.00	—	260	—	—	(15)	245
18-Oct-23	30-Jun-26	20-Sep-28	11.37	—	508	—	—	(42)	466
31-Oct-23	31-Dec-26	1-Nov-28	0.00	—	466	—	—	—	466
31-Oct-23	31-Dec-27	1-Nov-29	0.00	—	466	—	—	—	466
30-Nov-23	30-Jun-26	14-Nov-28	8.91	—	810	—	—	(38)	772
				11,736	**6,689**	**4,380**	**(4,524)**	**(1,824)**	**12,077**

The assessed fair value of recent tranches of options granted are outlined below. The fair value at grant date is independently determined using the Black Scholes Model. The model inputs for options granted during the years ended December 31, 2023 and December 31, 2022 are included below.

	Apr-22	Oct-22	May-23	Jul-23	Oct-23	Nov-23
Fair value	$2.43	$3.08	$3.79	$6.44	$6.33	$5.21
Consideration	$NIL	$NIL	$NIL	$NIL	$NIL	$NIL
Exercise price	$4.95	$6.15	$6.90	$10.04	$11.37	$8.91
Grant date	5-Apr-22	24-Oct-22	2-May-23	6-Jul-23	18-Oct-23	30-Nov-23
Expiry date	4-Apr-27	24-Oct-27	27-Mar-28	16-May-28	20-Sep-28	14-Nov-28
Term	5 years	5 years	5 years	5 years	6 years	7 years
Share price at grant date	$4.53	$6.97	$7.03	$11.36	$11.50	$9.28
Volatility	60%	60%	60%	60%	60%	60%
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Risk-free rate	2.62%	3.52%	2.91%	3.15%	3.98%	4.36%

29. Cash flow information

29.1. Reconciliation of profit/(loss) after income tax to net cash from/(used in) operating activities

	2023	2022	2021
	A$'000	A$'000	A$'000
Profit/(loss) before income tax	3,087	(98,622)	(80,465)
Adjustments for			
Depreciation and amortization	6,743	5,379	5,174
Impairment of intangible assets	804	—	—
Fair value remeasurement of contingent consideration	34,275	16,707	14,855
Fair value remeasurement of provisions	(173)	1,017	—
Unwind of discount	12,782	6,287	5,029
Share based payments	8,786	8,114	1,322
Foreign exchange losses	1,339	433	(2,613)
Income taxes paid	(10,253)	(2,278)	—
Change in assets and liabilities			
(Increase) in trade and other receivables	(27,382)	(19,934)	(7,192)
(Increase) in inventory	(9,636)	(5,023)	(2,821)
(Increase)/decrease in other current assets	(10,451)	(6,441)	198
(Increase) in other non-current assets	(259)	(115)	(29)
Increase in trade creditors	33,704	30,451	7,484
Deduct trade and other payables capitalized to intangible assets	(4,385)	—	—
Contingent consideration payments classified as operating	(16,282)	—	—
Increase in employee benefit obligations	6,476	2,870	2,428
(Decrease) in contract liabilities	(5,291)	(2,815)	(2,698)
Net cash from/(used in) operating activities	**23,884**	**(63,970)**	**(59,328)**

30. Financial risk management

The Group's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk. The overall risk management program focuses on the unpredictability of markets and seeks to minimize potential adverse effects on the financial performance of the Group. The Group uses different methods to measure different types of risk to which it is exposed.

30.1. Interest rate risk

The Group's borrowings that have been drawn down at December 31, 2023 have fixed interest rates, and therefore the Group is not exposed to any significant interest rate risk.

30.2. Price risk

The Group is not exposed to any significant price risk as contracts are in place to meet current estimated material requirements.

30.3. Foreign currency risk

Foreign currency risk is the risk of fluctuation in fair value or future cash flows of a financial instrument as a result of changes in foreign exchange rates. The Group operates internationally and is exposed to foreign exchange risk, primarily the U.S. dollar and Euro. Foreign exchange risk arises from commercial activities in the United States and research and development activities in Europe and the United States

The Group's treasury risk management policy is to settle all U.S. dollar denominated expenditure with U.S. dollar denominated receipts from sales of Illuccix in the United States. The Group also manages currency risk by making decisions as to the levels of cash to hold in each currency by assessing its future activities which will likely be incurred in those currencies. Any remaining foreign currency exposure has therefore not been hedged.

The Group has both foreign currency receivables and payables, predominantly denominated in U.S. dollar and Euro. The Group had a surplus of foreign currency receivables over payables of $26,488,000 at December 31, 2023 (2022: $24,176,000).

The Group’s exposure to the risk of changes in foreign exchange rates also relates to the Group’s net investments in foreign subsidiaries, which predominantly include denominations in Euro and U.S. dollar, however given the level of current investments in foreign subsidiaries, the impact is limited.

As at December 31, 2023, the Group held 6.7% (2022: 44.5%) of its cash in Australian dollars, 77.5% (2022: 52.1%) in U.S. dollars, 15.4% (2022: 3.2%) in EUR, 0.1% (2022: 0.1%) in Japanese Yen (JPY) and 0.3% (2022: 0.1%) in Swiss Francs (CHF).

Exposure

The balances held at December 31, 2023 that give rise to currency risk exposure are presented in Australian dollars below:

	USD	EUR	CHF	JPY	SGD	GBP	CAD
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Cash and cash equivalents	95,543	18,953	315	134	—	—	72
Trade receivables	63,634	403	—	—	—	—	—
Financial assets	2,763	9,497	—	—	—	—	—
Trade payables	(37,843)	(11,765)	(192)	(12)	—	3	—
Government grant liability	—	(2,663)	—	—	—	—	—
Decommissioning liability	—	(5,917)	—	—	—	—	—
Contingent consideration liability	(72,314)	(17,100)	—	—	—	—	—
Borrowings	—	(9,173)	—	—	—	—	—

The balances held at December 31, 2022 that give rise to currency risk exposure are presented in Australian dollars below:

	USD	EUR	CHF	JPY	SGD	GBP	CAD
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Cash and cash equivalents	60,659	3,678	118	133	—	—	—
Trade receivables	37,131	1,168	—	—	—	—	—
Trade payables	(9,224)	(4,721)	—	(8)	—	(162)	(8)
Government grant liability	—	(2,550)	—	—	—	—	—
Decommissioning liability	—	(5,333)	—	—	—	—	—
Contingent consideration liability	—	(64,231)	—	—	—	—	—
Borrowings	—	(3,312)	—	—	—	—	—

Sensitivity

Outlined below is a sensitivity analysis which assesses the impact that a change of +/- 10% in the exchange rates as at each reporting date would have on the Group's reported profit/(loss) after income tax and/or equity balance.

Impact on post-tax profit/(loss)

	2023 +10% Profit/ (loss) A$'000	2023 —10% Profit/ (loss) A$'000	2023 +10% Equity A$'000	2023 —10% Equity A$'000	2022 +10% Profit/ (loss) A$'000	2022 —10% Profit/ (loss) A$'000	2022 +10% Equity A$'000	2022 —10% Equity A$'000
USD	1,699	(2,076)	(7,860)	9,606	(2,036)	2,488	(6,016)	7,352
EUR	1,496	(1,828)	(231)	283	5,837	(7,134)	1,009	(1,233)
CHF	—	—	(29)	35	(11)	13	—	—
JPY	—	—	(12)	14	(11)	14	—	—
SGD	—	—	—	—	—	—	—	—
GBP	—	1	—	—	15	(18)	—	—
CAD	—	—	(7)	8	1	(1)	—	—
Total	**3,195**	**(3,903)**	**(8,139)**	**9,946**	**3,795**	**(4,638)**	**(5,007)**	**6,119**

30.4. Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. Credit risk arises from cash and cash equivalents and credit exposures to customers, including outstanding receivables.

Credit risk is managed on a group basis. If customers are independently rated, these ratings are used. Otherwise, if there is no independent rating, the Group assesses the credit quality of the customer, taking into account its financial position, past experience and other factors. Individual risk limits are set based on internal or external ratings. The compliance with credit limits by customers is regularly monitored. The Group obtains guarantees where appropriate to mitigate credit risk.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The expected loss rates are based on historical payment profiles of sales and the corresponding historical credit losses experienced. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

Trade receivables are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group, and the failure to make contractual payments for a period of greater than 120 days past due.

Impairment losses on trade receivables are presented within selling, general and administration costs within profit or loss. Subsequent recoveries of amounts previously written off are credited against the same line item.

As at December 31, 2023, the expected credit losses are $533,000 (2022: $Nil). The following tables sets out the ageing of trade receivables, according to their due date:

Aged trade receivables

	Expected credit losses		Gross carrying amount	
	2023	2022	2023	2022
	A$'000	A$'000	A$'000	A$'000
Not past due:	—	—	57,576	37,145
Past due:				
30 days	—	—	4,298	1,599

	Expected credit losses		Gross carrying amount	
	2023	2022	2023	2022
	A$'000	A$'000	A$'000	A$'000
60 days	(1)	—	381	121
90 days	(4)	—	932	34
120 days	(528)	—	2,123	455
Total	**(533)**	**—**	**65,310**	**39,354**

Credit risk concentration profile

The Group has a significant credit risk exposure to three distributors of 81% (2022: 89% to three distributors). The Group defines major credit risk as exposure to a concentration exceeding 10% of a total class of such asset.

30.5. Liquidity risk

The Group is exposed to liquidity and funding risk from operations and from external borrowings, where the risk is that the Group may not be able to refinance debt obligations or meet other cash outflow obligations when required. Vigilant liquidity risk management requires the Group to maintain sufficient liquid assets (mainly cash and cash equivalents). The Group manages liquidity risk by maintaining adequate cash reserves by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

Remaining contractual maturities:

The following tables detail the Group's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid. The tables include both interest and principal cash flows disclosed as remaining contractual maturities and therefore these totals may differ from their carrying amount in the consolidated statement of financial position.

As at December 31, 2023	1-6 months	6-12 months	1-5 years	Over 5 years	Total contractual cash flows	Carrying amount of liabilities
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Non-derivatives						
Trade and other payables	81,704	—	—	—	81,704	81,704
Borrowings	1,105	1,105	8,839	6,859	17,908	9,173
Lease liabilities	1,044	1,057	6,744	1,264	10,109	8,272
Government grant liability	376	577	3,169	593	4,715	2,664
Contingent consideration	—	38,382	65,229	2,352	105,963	92,754
Total financial liabilities	**84,229**	**41,121**	**83,981**	**11,068**	**220,399**	**194,567**

As at December 31, 2022	1-6 months	6-12 months	1-5 years	Over 5 years	Total contractual cash flows	Carrying amount of liabilities
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Non-derivatives						
Trade and other payables	49,519	—	—	—	49,519	49,519
Borrowings	58	58	5,080	1,800	6,996	3,312
Lease liabilities	815	802	6,419	1,862	9,898	7,134
Government grant liability	330	550	1,490	368	2,738	2,551
Contingent consideration	15,331	—	63,793	2,130	81,254	64,949
Total financial liabilities	**66,053**	**1,410**	**76,782**	**6,160**	**150,405**	**127,465**

30.6. Fair value

30.6.1. Financial assets

Financial assets are categorized as level 1 financial assets and remeasured at each reporting date with movements recognized in other comprehensive income. The inputs used in the fair value calculations are with reference to published price quotations for the associated equity instruments in an active market.

Sensitivity of level 1 financial assets

An increase/(decrease) of 10% in the share price of each financial asset while holding all other variables constant will increase/(decrease) other comprehensive income by $1,178,000 (2022: $Nil).

30.6.2. Financial liabilities

Contingent consideration liabilities are categorized as level 3 financial liabilities and remeasured at each reporting date with movements recognized in profit or loss, except in instances where changes are permitted to be added to/reduce an associated asset. The inputs used in fair value calculations are determined by Management.

The carrying amount of financial liabilities measured at fair value is principally calculated based on inputs other than quoted prices that are observable for these financial liabilities, either directly (i.e. as unquoted prices) or indirectly (i.e. derived from prices). Where no price information is available from a quoted market source, alternative market mechanisms or recent comparable transactions, fair value is estimated based on the management's views on relevant future prices, net of valuation allowances to accommodate liquidity, modelling and other risks implicit in such estimates.

Sensitivity of level 3 financial liabilities

The potential effect of using reasonably possible alternative assumptions in valuation models, based on a change in the most significant input, such as sales volumes, by an increase/(decrease) of 10% while holding all other variables constant will increase/(decrease) profit before tax by $5,061,000 (2022: $4,510,000).

Valuation processes

The finance team of the Group performs the valuation of contingent consideration liabilities required for financial reporting purposes, including level 3 fair values. This team reports directly to the Chief Financial Officer (CFO). Discussions of valuation processes and results are held between the CFO and Board at least once every six months, in line with the Group's half-yearly reporting periods.

The main level 3 inputs used by the Group in measuring the fair value of contingent consideration liabilities are derived and evaluated as follows:

- discount rates are determined by an independent third party using a weighted average cost of capital model to calculate a post-tax rate that reflects current market assessments of the time value of money and the risk specific to the asset
- regulatory/marketing authorization approval dates and approval for marketing authorization probability risk factors are derived in consultation with the Group's regulatory team
- expected sales volumes and net sales price per unit are estimated based on market information on annual incidence rates and information for similar products and expected market penetration, and
- contingent consideration cash flows are estimated based on the terms of the sale contract. Changes in fair values are analyzed at the end of each reporting period during the half-yearly valuation discussion between the CFO and Board. As part of this discussion the CFO presents a report that explains the reason for the fair value movement.

31. Contingent liabilities

The Group has entered into collaboration arrangements, including in-licensing arrangements with various companies. Such collaboration agreements may require the Group to make payments on achievement of stages of development, launch or revenue milestones and may include variable payments that are based on unit sales or profit (e.g. royalty and profit share payments). The amount of variable payments under the arrangements are inherently uncertain and difficult to predict, given the direct link to future sales, profit levels and the range of outcomes.

The Group also has certain take or pay arrangements with contract manufacturers or service providers which serve as commercial manufacturers and suppliers for certain products. To the extent a commitment is determined to be onerous, these are provided for within provisions in the consolidated statement of financial position.

On March 18, 2021, the Group entered into a non-exclusive global clinical and commercial supply agreement with Garching-based ITM Isotopen Technologien München AG (ITM) for the supply of highly pure no-carrier-added lutetium-177, a therapeutic isotope. ITM will supply the product for use in the Group's investigational programs in prostate and kidney cancer therapy and subject to approval of the Group's drug candidates for therapeutic use, also provide the product for scale-up and commercialization. At December 31, 2023 there is a possible obligation for the Group to pay €1,000,000 to ITM on the approval of the product for therapeutic use by the relevant regulatory authority in either the United States, France, Germany, Spain, Italy or the UK and €1,000,000 when the Group makes a commercial arms-length sale of the product. The existence of the obligation will be confirmed only by the occurrence of one or more uncertain future events not wholly within the control of the Group.

On December 19, 2023, the Group submitted its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its investigational positron emission tomography (PET) imaging agent TLX250-CDx in clear cell renal cell carcinoma (ccRCC). As at December 31, 2023, there are potential milestone payments of US$1,850,000 to a licensor should the Group be successful in obtaining regulatory approval and commercialization in the United States.

32. Commitments

At December 31, 2023 and at the date of these financial statements, the Group had commitments against existing R&D and capital commitments relating to the construction of the Brussels South manufacturing facility. R&D commitments in future years are estimated based on the contractual obligations included within agreements entered into by the Group.

	Due < 1 year	Due > 1 year
	A$'000	A$'000
At December 31, 2023		
Capital commitments[1]	16,572	40,000
R&D commitments	28,112	20,403
	44,684	**60,403**
December 31, 2022		
Capital commitments[2]	6,764	—
R&D commitments	15,583	2,293
	22,347	**2,293**

1. Includes the three year supply of Ytterbium-176 isotope.
2. Restated to exclude Brussels South radiopharmaceutical production facility buildout costs incurred to December 31, 2022.

33. Related party transactions

33.1. Key management personnel compensation

	2023	2022	2021
	A$	A$	A$
Short-term employee benefits	3,092,881	2,146,954	1,635,286
Superannuation entitlements	159,017	116,922	106,294
Share-based payments	1,167,650	542,456	303,789
	4,419,548	**2,806,332**	**2,045,369**

33.2. Transactions with other related parties

	2023	2022	2021
	A$	A$	A$
Purchases of various goods and services from entities controlled by key management personnel[1]	1,256,490	3,685,543	1,997,8 36

1. Non-Executive Director, Dr Andreas Kluge, is the principal owner and Geschäftsführer (Managing Director) of ABX- CRO, a clinical research organization (CRO) that specializes in radiopharmaceutical product development.

Telix entered into a master services agreement with ABX-CRO in 2018 for the provision of project management, clinical and analytical services for its ZIRCON clinical trial. During 2023, ABX-CRO were engaged to perform close out activities relating to the Phase III Zircon trial for TLX250-CDx, including delivery of dosimetry, PK evaluation, and the imaging report.

During the year ended December 31, 2023, the total amount paid was $1,256,490 (2022: $3,411,019, 2021: $1,512,452) and the amount payable to ABX-CRO at December 31, 2023 was $Nil (2022: $274,524, 2021: $485,384) respectively. ABX-CRO's fees and charges for activities undertaken in 2023 were on an arm's length basis and competitive with quotes obtained from other CRO's for similar services.

33.3. Interests in other entities

The Group’s principal subsidiaries at December 31, 2023 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also the principal place of business.

Name of entity	Place of business/country of incorporation	Ownership interest held by the Group (%)	Principal activities
Telix Pharmaceuticals (EST) Pty Ltd	Australia	100	Dormant
Telix Pharmaceuticals (Innovations) Pty Limited (formerly Telix International Pty Ltd)[1]	Australia	100	Manufacturing and development
Telix Pharmaceuticals Holdings Pty Limited[1]	Australia	100	Holding company
Telix Pharmaceuticals International Holdings Pty Limited[1]	Australia	100	Holding company
Telix Pharmaceuticals Australia Holdings Pty Limited[1]	Australia	100	Holding company
Telix Pharmaceuticals (ANZ) Pty Ltd[1]	Australia	100	Commercial operations
Telix Pharmaceuticals (Corporate) Pty Limited[1]	Australia	100	Commercial operations
Telix Pharmaceuticals (Belgium) SRL	Belgium	100	Manufacturing and development
Telix Innovations SA	Belgium	100	Commercial operations
Telix Pharmaceuticals (Canada) Inc.	Canada	100	Clinical R&D
Telix Pharmaceuticals (France) SAS	France	100	Clinical R&D
Telix Pharmaceuticals (Germany) GmbH (formerly Telix Pharmaceuticals Holdings (Germany) GmbH)	Germany	100	Clinical R&D
Rhine Pharma GmbH (formerly Telix Pharmaceuticals (Germany) GmbH)	Germany	100	Clinical R&D
Therapeia GmbH & Co. KG	Germany	100	Clinical R&D
Dedicaid GmbH	Austria	100	Software
Telix Pharma Japan KK	Japan	100	Clinical R&D

Name of entity	Place of business/country of incorporation	Ownership interest held by the Group (%)	Principal activities
Telix Pharmaceuticals (NZ) Limited	New Zealand	100	Clinical R&D
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100	Clinical R&D
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100	Clinical R&D
Telix Pharmaceuticals (UK) Ltd (formerly Telix Life Sciences (UK) Ltd)	United Kingdom	100	Clinical R&D
Lightpoint Surgical Ltd	United Kingdom	100	Medical devices
Lightpoint Medical Espana SLU	Spain	100	Medical devices
Telix Pharmaceuticals (US) Inc.	USA	100	Commercial operations
Telix Optimal Tracers, LLC	USA	100	Manufacturing and development

1. Denotes an entity that is a party to a deed of cross guarantee, refer to note 37 for further information

TheraPharm Deutschland GmbH was wound up during the financial year.

34. Remuneration of auditor

Auditors of the Group - PricewaterhouseCoopers Australia and related network firms	2023	2022	2021
	A$	A$	A$
Audit or review of financial statements	1,380,000	367,200	310,080
Other assurance services	170,000	—	—
Other advisory services	291,861	156,857	159,657
	1,841,861	**524,057**	**469,737**

Other auditors and their related network firms	2023	2022	2021
	A$	A$	A$
Audit or review of financial statements	52,538	89,621	63,132
Other advisory services	—	9,435	—
	52,538	**99,056**	**63,132**

35. Events occurring after the reporting period

35.1. Acquisition of IsoTherapeutics Group, LLC

On April 9, 2024, Telix completed the acquisition of IsoTherapeutics Group, LLC (IsoTherapeutics). IsoTherapeutics is a commercial-stage company that provides radiochemistry and bioconjugation development and contract manufacturing services to numerous companies in the radiopharmaceutical industry, including Telix. The total consideration was $19,859,000, of which $8,912,000 has been paid in equity through the issue of 717,587 fully paid ordinary Telix shares at $12.42 per share, with $3,285,000 paid in cash. A further $7,662,000 is payable in cash for performance-related milestone payments that are subject to meeting milestone conditions within twelve months of closing.

Further performance-based payments are payable in cash to the IsoTherapeutics sellers based on 50% of net revenue during a two year revenue sharing period from the closing date. These payments are effectively a retention mechanism of key employees and as such are excluded from the acquisition consideration and instead will be recognized as an expense over the revenue sharing period within the Group's consolidated statement of comprehensive income.

The following table summarizes the consideration paid for IsoTherapeutics, the fair value of assets acquired and liabilities assumed at the acquisition date. These balances are provisional and subject to change within the 12 month measurement period.

Consideration	Provisional fair value A$'000
Cash paid	3,285
Equity issued	8,912
Contingent consideration	7,662
Total consideration	**19,859**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	394
Trade and other receivables	642
Property, plant and equipment	365
Right-of-use assets	519
Trade and other payables	(7)
Lease liabilities	(519)
Total identifiable assets and liabilities	**1,394**
Fair value adjustments	
Customer relationships	1,280
Brand name	102
Deferred tax liabilities	(332)
Total fair value adjustments	**1,050**
Goodwill	17,415
Total	**19,859**

The goodwill arising is attributable to the acquired workforce, anticipated future cost savings from utilizing IsoTherapeutics' manufacturing and radiopharmaceutical development capability and synergies of integrating the business within the Group. The goodwill arising from the acquisition has been allocated to the manufacturing services CGU.

Fair value adjustments have been recognized for acquisition-related intangible assets and related deferred tax.

Acquisition-related intangible assets of $1,280,000 relate to the valuation of the customer relationships and $102,000 relates to the value of the acquired IsoTherapeutics brand. The useful economic lives of each of these acquisition-related intangible assets is four and two years, respectively.

As a preliminary assessment, had the acquisition of IsoTherapeutics been completed on the first day of the 2024 financial year, Group revenues would have been approximately $913,000 higher and Group profit before tax attributable to equity holders of the parent would have been approximately $261,000 lower.

35.2. Acquisition of ARTMS Inc.

On April 11, 2024, Telix completed the acquisition of radioisotope production technology firm ARTMS Inc. (ARTMS). ARTMS, based in Vancouver, BC (Canada), is a commercial-stage company, which specializes in the physics, chemistry and materials science of cyclotron-produced radionuclides. The total consideration was $133,773,000, of which $71,610,000 has been paid in equity through the issue of 5,674,365 fully paid ordinary Telix shares at $12.62 per share, with $24,491,000 paid in cash. A further $37,672,000 in contingent future milestone and royalty payments is payable in cash following achievement of certain clinical or commercial milestones and sales targets. The royalties represent a low single to low double-digit percentage of net sales of ARTMS products or Telix products prepared using ARTMS products for defined periods depending on the product location where the sale occurs. All earn-outs which have not otherwise expired will terminate on the 10 year anniversary of completion.

The following table summarizes the consideration paid for ARTMS, the fair value of assets acquired and liabilities assumed at the acquisition date. These balances are provisional and subject to change within the 12 month measurement period.

Consideration	Provisional fair value A$'000
Cash paid	24,491
Equity issued	71,610
Contingent consideration	37,672
Total consideration	**133,773**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	5,810
Trade and other receivables	252
Other current assets	67
Inventories	2,869
Other non-current assets	149
Property, plant and equipment	1,422
Right-of-use assets	1,154
Trade and other payables	(4,716)
Lease liabilities	(1,154)
Total identifiable assets and liabilities	**5,853**
Fair value adjustments	
Intellectual property	39,965
Deferred tax liabilities	(10,487)
Property, plant and equipment	504
Inventories	1,478
Total fair value adjustments	**31,460**
Goodwill	96,460
Total	**133,773**

The goodwill arising is attributable to the acquired workforce, anticipated future cost savings from utilizing ARTMS' radioisotope production capabilities and synergies of vertically integrating the business within the Group. The goodwill arising from the acquisition has been allocated to the manufacturing services CGU.

Fair value adjustments have been recognized for acquisition-related intangible assets, property, plant and equipment, inventories and related deferred tax.

Acquisition-related intangible assets of $39,965,000 relate to the valuation of the acquired ARTMS intellectual property. The useful economic life of the intellectual property has not been assessed at the acquisition date, as the intellectual property is not available for commercial use until regulatory approval has been obtained.

As a preliminary assessment, had the acquisition of ARTMS been completed on the first day of the 2024 financial year, Group revenues would have been approximately $305,000 higher and Group profit before tax attributable to equity holders of the parent would have been approximately $2,477,000 lower.

35.3. Acquisition of QSAM Biosciences, Inc.

On May 3, 2024, Telix completed the acquisition of QSAM Biosciences, Inc. (QSAM) and its lead investigational drug Samarium-153-DOTMP (^{153}Sm-DOTMP). QSAM is a U.S. based company developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer. The final purchase price was $61,196,000, of which $54,470,000 was paid to QSAM in equity through the issue of 3,671,120 fully paid ordinary Telix shares and $6,726,000 paid in cash. 66,011 Telix shares were held back against any adjustments required to be made post-completion. These shares were issued in July. A further US$90,000,000 in Contingent Value Rights, or performance rights, is payable in cash and/or in ordinary shares, upon achievement of certain clinical or commercial milestones.

The Group has determined that substantially all of the fair value of the gross assets acquired is concentrated in a single asset or a group of similar assets. The Group has applied the optional concentration of fair value test in IFRS 3 Business Combinations and concluded that the components acquired will be treated as an asset acquisition.

The performance rights have been recognized as an equity settled share based payment at a fair value of $67,943,000 which has been included in the fair value of intellectual property. Each milestone has a fixed dollar amount which can be settled either in cash or shares. The fair value of the performance rights was determined based on management's assessment of the likelihood of each milestone being reached against the fixed dollar amount for that milestone. The likelihood of the milestones being attained are considered non-vesting conditions as there are no further services or obligations of the counterparty, thus being reflected in the fair value.

The fair values of identifiable assets on acquisition are outlined below:

Consideration	Fair value A$'000
Cash paid	6,726
Equity issued	54,470
Performance rights issued	67,943
Total consideration	**129,139**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	18
Trade and other receivables	52
Intellectual property	129,907
Trade and other payables	(838)
Total identifiable assets and liabilities	**129,139**

35.4. Issue of Convertible Bonds

On July 30, 2024, the Group completed the issue of $650,000,000 in convertible bonds maturing in 2029. The convertible bonds are convertible into fully paid ordinary shares in Telix Pharmaceuticals Limited. The initial conversion price of the convertible bonds is $24.78 per share, subject to anti-dilution adjustments set out in the final terms and conditions of the convertible bonds. The convertible bonds will bear interest at a rate of 2.375 per cent per annum. Interest will be payable quarterly in arrears on October 30, January 30, April 30 and July 30 in each year, beginning on October 30, 2024. The convertible bonds will mature on or about July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms. The convertible bonds are listed on the Singapore Exchange Securities Trading Limited (SGX-ST).

The net proceeds of approximately $635,000,000, after transaction costs, are intended to provide funding to bring forward proposed investment in order to accelerate key clinical development programs across the Company's theranostic portfolio. This includes label-expansion studies to expand the market opportunity across Telix's portfolio of diagnostic imaging agents and funding the pivotal trials for kidney and brain cancer therapy programs. In addition, the funding will provide financial flexibility for Telix to explore opportunities and potentially pursue strategically significant M&A transactions and continued investment in global supply chain and manufacturing capabilities.

There were no other subsequent events that required adjustment to or disclosure in the Financial statements of the Company for the year ended December 31, 2023.

36. Events subsequent to original issuance of financial statements (Unaudited)

Stock Purchase Agreement with RLS (USA) Inc.

On September 20, 2024, Telix entered into a conditional agreement to acquire RLS (USA) Inc. The purchase price for the potential acquisition consists of:

- US$230.0 million upfront consideration, payable in cash at closing of the acquisition, which will be adjusted for transaction expenses, cash and cash equivalents (net of restricted cash), debt and debt equivalents and working capital, and

- further milestone payments of up to US$20.0 million in the aggregate, payable in cash upon the achievement of certain commercial milestones related to the demonstration of accretive financial and operational performance during the four-quarters following closing.

Telix expects to fund the purchase price and related transaction costs from existing cash reserves. The acquisition is expected to close in the first quarter of 2025. The closing of the acquisition is subject to various conditions including regulatory approvals, RLS shareholder approval, license transfer approvals and certain-third party consents. Either party may terminate the acquisition agreement if the acquisition has not been consummated by February 17, 2025.

Interim consolidated statement of comprehensive income or loss for the periods ended June 30, 2024 and 2023 (Unaudited)

	Note	Six months ended June 30, 2024 A$'000	Six months ended June 30, 2023 A$'000
Continuing operations			
Revenue from contracts with customers	4.1	363,964	220,834
Cost of sales		(124,938)	(81,791)
Gross profit		**239,026**	**139,043**
Research and development costs	4.2	(84,190)	(48,726)
Selling and marketing expenses		(37,311)	(24,171)
Manufacturing and distribution costs		(13,327)	(4,302)
General and administration costs	4.3	(59,341)	(30,315)
Other losses (net)	4.6	(2,870)	(38,159)
Operating profit/(loss)		**41,987**	**(6,630)**
Finance income		1,373	453
Finance costs	4.7	(8,678)	(6,123)
Profit/(loss) before income tax		**34,682**	**(12,300)**
Income tax expense		(5,028)	(2,020)
Profit/(loss) for the half-year		**29,654**	**(14,320)**
Profit/(loss) for the half-year attributable to:			
Owners of Telix Pharmaceuticals Limited		29,654	(14,320)
Other comprehensive income:			
Items that will not be reclassified to profit or loss in subsequent periods:			
Changes in the fair value of investments at fair value through other comprehensive income		(618)	—
Items to be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		12,517	4,302
Total comprehensive income/(loss) for the half-year		**41,553**	**(10,018)**
Total comprehensive income/(loss) for the half-year attributable to:			
Owners of Telix Pharmaceuticals Limited		41,553	(10,018)

	Six months ended June 30, 2024 Cents	Six months ended June 30, 2023 Cents
Basic earnings/(loss) per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	9.05	(4.51)
Diluted earnings/(loss) per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	8.75	(4.51)

The above interim consolidated statement of comprehensive income or loss is to be read in conjunction with the notes to the interim consolidated financial statements.

Interim consolidated statement of financial position as at June 30, 2024 (Unaudited)

	Note	June 30, 2024 A$'000	December 31, 2023 A$'000
Current assets			
Cash and cash equivalents		118,837	123,237
Trade and other receivables	5	89,328	64,777
Inventories	6	30,803	17,310
Current tax asset		7,945	7,656
Other current assets		8,348	19,524
Total current assets		**255,261**	**232,504**
Non-current assets			
Financial assets	7	10,462	12,260
Deferred tax assets		36,699	20,452
Property, plant and equipment	8	29,070	23,170
Right-of-use assets		9,185	7,323
Intangible assets	9	399,483	109,663
Other non-current assets		5,798	586
Total non-current assets		**490,697**	**173,454**
Total assets		**745,958**	**405,958**
Current liabilities			
Trade and other payables	11	84,277	81,704
Borrowings		1,900	964
Current tax payable		33,965	19,164
Contract liabilities		12,380	10,995
Lease liabilities		1,880	595
Provisions		734	577
Contingent consideration	12	109,670	37,153
Employee benefit obligations		13,567	13,912
Total current liabilities		**258,373**	**165,064**
Non-current liabilities			
Borrowings		9,952	8,209
Contract liabilities		6,830	12,162
Lease liabilities		8,411	7,677
Deferred tax liabilities		9,615	—
Provisions		7,847	8,004
Contingent consideration	12	40,507	55,601
Employee benefit obligations		449	330
Total non-current liabilities		**83,611**	**91,983**
Total liabilities		**341,984**	**257,047**
Net assets		**403,974**	**148,911**
Equity			
Share capital	14.1	587,408	446,268
Share capital reserve		(68,343)	(62,829)
Foreign currency translation reserve		7,103	(5,414)
Share-based payments reserve	14.2	112,823	35,446
Financial assets at FVOCI reserve		(1,513)	(895)
Accumulated losses		(233,504)	(263,665)
Total equity		**403,974**	**148,911**

The above interim consolidated statement of financial position is to be read in conjunction with the notes to the interim consolidated financial statements.

Interim consolidated statement of changes in equity for the periods ended June 30, 2024 and 2023 (Unaudited)

	Note	Share capital	Share capital reserve	Foreign currency translation reserve	Share-based payments reserve	Financial assets at FVOCI reserve	Accumulated losses	Total equity
		A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Balance as at January 1, 2024		**446,268**	**(62,829)**	**(5,414)**	**35,446**	**(895)**	**(263,665)**	**148,911**
Profit for the half-year		—	—	—	—	—	29,654	29,654
Other comprehensive income/(loss)		—	—	12,517	—	(618)	—	11,899
Total comprehensive income/(loss) for the half-year		**—**	**—**	**12,517**	**—**	**(618)**	**29,654**	**41,553**
Issue of shares on acquisitions	14.1	134,992	—	—	—	—	—	134,992
Issue of shares on exercise of options	14.1	6,148	(5,514)	—	—	—	—	634
Share based payments to employees	14.2	—	—	—	9,941	—	—	9,941
Share based payments associated with acquisitions	14.2	—	—	—	67,943	—	—	67,943
Transfer on exercise of options	14.2	—	—	—	(507)	—	507	—
		141,140	**(5,514)**	**—**	**77,377**	**—**	**507**	**213,510**
Balance as at June 30, 2024		**587,408**	**(68,343)**	**7,103**	**112,823**	**(1,513)**	**(233,504)**	**403,974**
Balance as at January 1, 2023		**370,972**	**(26,909)**	**(562)**	**9,321**	**—**	**(272,815)**	**80,007**
Loss for the half-year		—	—	—	—	—	(14,320)	(14,320)
Other comprehensive income		—	—	4,302	—	—	—	4,302
Total comprehensive loss for the half-year		**—**	**—**	**4,302**	**—**	**—**	**(14,320)**	**(10,018)**
Issue of shares on acquisitions		1,829	—	—	—	—	—	1,829
Issue of shares on exercise of options		19,095	(16,167)	—	—	—	—	2,928
Share based payments to employees		—	—	—	1,311	—	—	1,311
Transfer on exercise of options		—	—	—	(1,914)	—	1,914	—
		20,924	**(16,167)**	**—**	**(603)**	**—**	**1,914**	**6,068**
Balance as at June 30, 2023		**391,896**	**(43,076)**	**3,740**	**8,718**	**—**	**(285,221)**	**76,057**

The above interim consolidated statement of changes of equity is to be read in conjunction with the notes to the interim consolidated financial statements.

Interim consolidated statement of cash flows for the periods ended June 30, 2024 and 2023 (Unaudited)

	Six months ended June 30, 2024	Six months ended June 30, 2023
	A$'000	A$'000
Cash flows from operating activities		
Receipts from customers	343,336	195,330
Payments to suppliers and employees	(298,174)	(176,311)
Income taxes paid	(6,783)	(5,857)
Interest received	1,373	453
Interest paid	(671)	(356)
Net cash generated from operating activities	**39,081**	**13,259**
Cash flows from investing activities		
Payments for investments in financial assets	(1,988)	—
Payments for acquisition of subsidiaries, net of cash acquired	(23,188)	123
Purchases of intangible assets	(11,749)	—
Purchases of other non-current assets	(4,178)	—
Purchases of property, plant and equipment	(4,689)	(3,009)
Payments for contingent consideration	(49)	—
Net cash used in investing activities	**(45,841)**	**(2,886)**
Cash flows from financing activities		
Proceeds from borrowings	2,700	2,484
Repayment of borrowings	(441)	—
Principal element of lease payments	(740)	(711)
Proceeds from issue of shares and other equity	634	2,928
Net cash provided by financing activities	**2,153**	**4,701**
Net (decrease)/increase in cash held	**(4,607)**	**15,074**
Net foreign exchange differences	207	326
Cash and cash equivalents at the beginning of the half-year	123,237	116,329
Cash and cash equivalents at the end of the half-year	**118,837**	**131,729**

The above interim consolidated statement of cash flows is to be read in conjunction with the notes to the interim consolidated financial statements.

Notes to the interim consolidated financial statements

1. Corporate information

Telix Pharmaceuticals Limited (Telix or the Company) is a for profit company incorporated and domiciled in Australia. It is limited by shares that are publicly traded on the Australian Securities Exchange (ASX: TLX). Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases.

Telix is the ultimate parent company of the Telix Pharmaceuticals Group (the Group).

2. Basis of preparation and changes to the Company's accounting policies

These interim consolidated financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting.

These interim consolidated financial statements do not include all the notes of the type normally included in annual financial statements. Accordingly, these interim consolidated financial statements are to be read in conjunction with the consolidated financial statements for the year ended December 31, 2023.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

A number of new or amended standards became applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these standards. The Group has identified that there is no impact of new standards issued but not yet applied.

2.1. Going concern

These interim consolidated financial statements have been prepared on the basis that the Company is a going concern.

For the half-year ended June 30, 2024, the Group generated a profit after income tax of $29,654,000 (June 30, 2023: loss after income tax of $14,320,000) and cash generated from operating activities of $39,081,000 (June 30, 2023: $13,259,000). As at June 30, 2024, whilst in a net current liability position, the net assets of the Group stood at $403,974,000 (December 31, 2023: $148,911,000), with cash on hand of $118,837,000 (December 31, 2023: $123,237,000).

On July 30, 2024 the Group issued $650,000,000 in convertible bonds, maturing in 2029 and convertible into fully paid ordinary shares, refer to note 17 for further details. The net proceeds, after transaction costs, are intended to provide funding to bring forward proposed investment in order to accelerate key clinical development programs across the Group’s theranostic portfolio. This includes label-expansion studies to expand the market opportunity across our portfolio of diagnostic imaging agents and funding the pivotal trials for kidney and brain cancer therapy programs. In addition, the funding will provide financial flexibility for the Group to explore opportunities and potentially pursue strategically significant M&A transactions and continued investment in global supply chain and manufacturing capabilities.

Cash on hand, the net proceeds from the issue of convertible bonds, and anticipated future cash inflows in relation to commercial activities are considered sufficient to meet the Group’s forecast cash outflows in relation to research and development activities currently underway and other committed business activities for at least 12 months from the date of issuance of these interim consolidated financial statements

On this basis, the Directors are satisfied that the Group continues to be a going concern as at the date of issuance of these interim consolidated financial statements. Further, the Directors are of the opinion that no asset is likely to be realized for an amount less than the amount at which it is recorded in the interim consolidated statement of financial position as at June 30, 2024.

As such, no adjustment has been made to the interim consolidated financial statements relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should the Group not continue as a going concern.

2.2. Significant changes in the prior reporting period

The Group updated the classification of expenses to make the consolidated statement of comprehensive income more relevant to users of the financial statements, particularly as a result of the Group acquiring new businesses during the period. This has resulted in the reclassification of some expenses for the period ended June 30, 2023; however, it has not impacted the reported profit or loss for the period or earnings per share.

From 2023, the Group has determined that a functional presentation of its consolidated statement of comprehensive income or loss is most appropriate. In accordance with IAS 1 Presentation of Financial Statements, within a functional consolidated statement of comprehensive income or loss, costs directly associated with generating revenues are included in cost of sales. Cost of sales includes direct material and labor costs, distribution fees incurred to ensure delivery of the product to the end customer and indirect costs that are directly attributed to generating revenue, such as amortization of intangible assets associated with commercialized products.

In addition to the above, the Group has disclosed an additional line item of manufacturing and distribution costs on its consolidated statement of comprehensive income or loss. This line item represents departments and associated costs of the business that were previously included within selling and marketing expenses. These functions are ancillary in nature and indirectly support manufacturing, supply chain, logistics, facilities and quality activities.

3. Segment reporting

The Group has operations in the Americas, Asia Pacific, and Europe, Middle East and Africa regions.

Reportable segments

The Group operated four reportable segments during the half-year ended June 30, 2024. Medical Technologies and Manufacturing Services are reclassified from Unallocated to separately reportable segments from April 2024 following the acquisitions of ARTMS and IsoTherapeutics.

The Group's operating segments are based on the reports reviewed by the Group Chief Executive Officer who is considered to be the chief operating decision maker. The prior year comparatives have been restated on a consistent basis. There is no change to the total revenue or profit/(loss) after tax of the Group.

Segment performance is evaluated based on Adjusted earnings before interest, tax, depreciation and amortization (Adjusted EBITDA). Adjusted EBITDA excludes the effects of the remeasurement of contingent consideration and government grant liabilities and other income and expenses which may have an impact on the quality of earnings such as impairments where the impairment is the result of an isolated, non-recurring event. Interest income and finance costs are not allocated to segments as this activity is managed by a central treasury function, which manages the cash position of the Group.

Segment assets and liabilities are measured in the same way as in the financial statements. The assets and liabilities are allocated based on the operations of the segment. Finance costs are not allocated to segments, as this type of activity is driven by head office, which manages the cash position of the Group.

Reportable segment	Principal activities
Commercial	Commercial sales of Illuccix and other products subsequent to obtaining regulatory approvals.
Product development	Developing radiopharmaceutical products for commercialization. This segment includes revenue received from license agreements prior to commercialization and research and development services.
Medical technologies	Developing complementary artificial intelligence (AI) and robotic technologies. This segment includes costs and assets associated with the Group's development of AI molecular imaging and guided robotic surgical technologies and includes Dedicaid, Lightpoint Surgical, and QDOSE.

Reportable segment	Principal activities
Manufacturing services	Telix Manufacturing Solutions business. This segment comprises costs to operate our facilities and assets associated with the Group's vertically integrated manufacturing and supply chain. This business includes facilities at Brussels South, IsoTherapeutics, Optimal Tracers and ARTMS.

Reconciling items includes head office and centrally managed costs (which includes any remeasurements of contingent consideration liabilities).

3.1. Segment performance

June 30, 2024	Commercial A$'000	Product development A$'000	Medical technologies A$'000	Manufacturing services A$'000	Total segment A$'000
Revenue from contracts with customers	358,818	4,278	—	868	363,964
Cost of sales	(124,938)	—	—	—	(124,938)
Gross profit	**233,880**	**4,278**	**—**	**868**	**239,026**
Research and development costs	—	(83,890)	(284)	(16)	(84,190)
Selling and marketing expenses	(37,188)	—	—	(123)	(37,311)
Manufacturing and distribution costs	(5,071)	—	(182)	(8,074)	(13,327)
General and administration costs	(16,899)	—	(890)	(2,149)	(19,938)
Other losses (net)	229	—	—	65	294
Operating profit/(loss)	**174,951**	**(79,612)**	**(1,356)**	**(9,429)**	**84,554**
Other losses (net)	(229)	—	—	(65)	(294)
Depreciation and amortization	2,726	55	5	541	3,327
Adjusted earnings before interest, tax, depreciation and amortization	**177,448**	**(79,557)**	**(1,351)**	**(8,953)**	**87,587**

June 30, 2023	Commercial A$'000	Product development A$'000	Medical technologies A$'000	Manufacturing services A$'000	Total segment A$'000
Revenue from contracts with customers	218,516	2,042	—	276	220,834
Cost of sales	(81,791)	—	—	—	(81,791)
Gross profit	**136,725**	**2,042**	**—**	**276**	**139,043**
Research and development costs	—	(48,715)	—	(11)	(48,726)
Selling and marketing expenses	(24,171)	—	—	—	(24,171)
Manufacturing and distribution costs	(3,143)	—	—	(1,159)	(4,302)
General and administration costs	(14,024)	—	—	(1,626)	(15,650)
Other losses (net)	(1,248)	—	—	—	(1,248)
Operating profit/(loss)	**94,139**	**(46,673)**	**—**	**(2,520)**	**44,946**
Other losses (net)	1,248	—	—	—	1,248
Depreciation and amortization	2,700	123	—	183	3,006
Adjusted earnings before interest, tax, depreciation and amortization	**98,087**	**(46,550)**	**—**	**(2,337)**	**49,200**

3.2. Reconciliation of total segment adjusted EBITDA to profit/(loss) before income tax

	Note	June 30, 2024	June 30, 2023
		A$'000	A$'000
Total segment adjusted EBITDA		**87,587**	**49,200**
Unallocated income and expenses:			
General and administration costs		(39,403)	(14,665)
Other losses (net)	4.6	(2,870)	(38,159)
Finance income		1,373	453
Finance costs		(8,678)	(6,123)
Depreciation and amortization		(3,327)	(3,006)
Profit/(loss) before income tax		**34,682**	**(12,300)**

General and administration costs predominantly comprise of employment costs of $19,101,000 (June 30, 2023: $7,172,000) and other centrally managed IT, legal and other corporate costs. Refer to note 4.3 for further details.

3.3. Operating segment assets and liabilities

June 30, 2024	Commercial	Product development	Medical technologies	Manufacturing services	Total segment	Reconciling items	Group
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Total assets	181,286	181,748	55,630	212,599	631,263	114,695	745,958
Total liabilities	64,901	21,219	649	44,633	131,402	210,582	341,984
Additions to non- current assets	78	135,931	1,967	163,566	301,542	236	301,778

December 31, 2023	Commercial	Product development	Medical technologies	Manufacturing services	Total segment	Reconciling items	Group
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Total assets	167,356	46,744	52,700	36,835	303,635	102,323	405,958
Total liabilities	65,890	40,252	275	20,172	126,589	130,458	257,047
Additions to non- current assets	12,025	5,116	54,296	—	71,437	—	71,437

Reconciling items primarily comprise cash and cash equivalents held centrally $67,251,000 (December 31, 2023: $68,768,000), investments in financial assets $10,472,000 (December 31, 2023: $12,260,000), property, plant and equipment $1,496,000 (December 31, 2023: $3,942,000), tax assets and liabilities and contingent consideration liabilities (note 12) which are managed centrally.

Reportable segment total assets and total liabilities as at December 31, 2023 have been re-presented to reflect the reallocation of assets and liabilities relating to the Medical technologies and Manufacturing services segments and Group level adjustments between segments.

3.4. Geographical information

	June 30, 2024	June 30, 2023	June 30, 2024	December 31, 2023
	Revenue by location of customer	Revenue by location of customer	Non-current assets by location of asset	Non-current assets by location of asset
	A$'000	A$'000	A$'000	A$'000
Australia	523	426	26,805	21,057
Belgium	331	202	75,773	77,469
Canada	835	1,060	138,422	—
China	4,765	2,042	—	—
United Kingdom	236	1,101	51,497	50,346
United States	354,756	213,772	157,472	4,130
Other countries	2,518	2,231	4,029	—
Total	**363,964**	**220,834**	**453,998**	**153,002**

The total non-current assets figure above excludes deferred tax assets.

4. Profit and loss information

The Group has identified a number of items which are material due to the significance of their nature and/or amount. These are listed separately here to provide a better understanding of the financial performance of the Group.

4.1. Revenue from contracts with customers

Disaggregation of revenue from contracts with customers

The Group derives revenue from the sale and transfer of goods and services over time and at a point in time under the following major business activities:

	Recognition	Operating segment	June 30, 2024	June 30, 2023
			A$'000	A$'000
Sale of goods	At a point in time	Commercial	357,862	218,311
Royalty income	At a point in time	Commercial	956	205
Provision of services	Over time	Manufacturing services	868	276
Research and development services	Over time	Product development	4,278	2,042
Total revenue from continuing operations			**363,964**	**220,834**

4.2. Research and development costs

The following costs are included within research and development costs:

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Late-stage diagnostics	33,972	18,509
Therapeutics and other assets	24,303	11,837
General and administration costs	6,190	3,568

4.3. General and administration costs

The following costs are included within general and administration costs

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Professional fees	7,179	4,998
Acquisition related transaction costs	1,348	—
U.S. listing costs	7,618	—
IT infrastructure, hosting and support	3,415	2,267
Travel, conferences and entertainment	2,858	2,616
Rent and insurance	2,107	1,631
Marketing and sponsorship	1,465	1,218

General and administration costs incurred during the half-year includes costs associated with the withdrawn U.S. listing. Professional fees increased during the period primarily due to additional audit and review fees associated with the withdrawn U.S. listing.

Acquisition related transaction costs related to legal and professional fees associated with the acquisitions of IsoTherapeutics and ARTMS, refer to notes 10.1 and 10.2 for further details.

4.4. Employment costs

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Salaries and wages	59,017	37,229
Short term incentives	6,264	4,955
Sales commissions	4,013	2,564
Share based payment charge	9,941	1,311
Superannuation	1,456	900
Non-Executive Directors' fees	379	292
	81,070	**47,251**

Salary and wages of $1,950,000 (June 30, 2023: $553,000) are included within the cost of sales line item of the Interim consolidated statement of comprehensive income or loss.

4.5. Depreciation and amortization

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Amortization of intangible assets	2,193	2,151
Depreciation	1,505	1,043
	3,698	**3,194**

4.6. Other losses (net)

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Remeasurement of contingent consideration	3,071	36,054
Remeasurement of provisions	96	544
Realized currency gain	(87)	(2,117)
Other income	(342)	(1)
Unrealized currency loss	132	3,679
	2,870	**38,159**

4.7. Finance costs

	June 30, 2024	June 30, 2023
	A$'000	A$'000
Unwind of discount	8,006	5,681
Interest expense on lease liabilities	347	306
Interest expense	123	50
Bank fees	202	86
Finance costs	**8,678**	**6,123**

The Group recognized an unwind of discount on contingent consideration liabilities of $7,492,000 (June 30, 2023: $4,981,000), an unwind of discount on provisions of $190,000 (June 30, 2023: $197,000) and contract liabilities of $324,000 (June 30, 2023: $503,000).

5. Trade and other receivables

	June 30, 2024	December 31, 2023
	A$'000	A$'000
Trade receivables	89,448	65,310
Allowance for impairment losses	(120)	(533)
	89,328	**64,777**

6. Inventories

	June 30, 2024	December 31, 2023
	A$'000	A$'000
Raw materials and stores	11,422	7,700
Work in progress	13,823	5,961
Finished goods	10,530	3,649
Provision for obsolescence	(4,972)	—
Total inventories	**30,803**	**17,310**

The amount of inventory recognized as an expense during the period was $15,694,000 (June 30, 2023: $8,892,000).

Inventory manufactured as part of the Zircaix commercial manufacturing process qualification and validation has been capitalized as work in progress, with a corresponding provision for obsolescence recognized. This is on the basis that, prior to regulatory approval, the Group has not demonstrated that the batches produced can be sold commercially.

7. Financial assets

	2024	2023
	A$'000	A$'000
Investment in Mauna Kea	7,765	9,497
Investment in Atonco SAS	2,697	—
Investment in QSAM Biosciences[1]	—	2,763
Total financial assets	**10,462**	**12,260**

1. This investment was reclassified to intangible assets on completion of the QSAM asset acquisition, refer to note 10.3 for further details.

8. Property, plant and equipment

	Land and buildings	Plant and equipment	Furniture, fittings and equipment	Leasehold improvements	Total
	A$'000	A$'000	A$'000	A$'000	A$'000
Balance at January 1, 2024	**20,442**	**499**	**680**	**1,549**	**23,170**
Additions	40	3,216	1,305	128	4,689
Acquisition of business	—	1,416	262	644	2,322
Reclassifications	—	(3)	(7)	(6)	(16)
Changes in provisions	(388)	—	—	—	(388)
Depreciation charge	—	(58)	(217)	(125)	(400)
Exchange differences	(264)	(82)	38	1	(307)
Balance at June 30, 2024	**19,830**	**4,988**	**2,061**	**2,191**	**29,070**
Cost	20,140	5,442	3,198	2,675	31,455
Accumulated depreciation	(310)	(454)	(1,137)	(484)	(2,385)
Net book amount	**19,830**	**4,988**	**2,061**	**2,191**	**29,070**
Balance as at January 1, 2023	**9,611**	**576**	**441**	**1,404**	**12,032**
Additions	8,912	96	168	503	9,679
Acquisition of business	—	37	—	—	37
Reclassifications	2,021	(12)	490	(142)	2,357
Depreciation charge	(91)	(207)	(422)	(222)	(942)
Exchange differences	(11)	9	3	6	7
Balance at December 31, 2023	**20,442**	**499**	**680**	**1,549**	**23,170**
Cost	20,752	895	1,600	1,908	25,155
Accumulated depreciation	(310)	(396)	(920)	(359)	(1,985)
Net book amount	**20,442**	**499**	**680**	**1,549**	**23,170**

9. Intangible assets

	Goodwill	Intellectual property	Customer relationships and brands	Software	Patents	Licenses	Total
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Balance at January 1, 2024	**4,847**	**92,217**	**—**	**1,622**	**529**	**10,448**	**109,663**
Acquisition of business	113,876	39,938	1,382	—	—	—	155,196
Additions	—	135,931	—	1,967	—	—	137,898
Reclassifications	77	—	—	—	—	(77)	—
Amortization charge	—	(1,976)	(61)	—	(7)	(149)	(2,193)
Changes in provisions	—	170	—	—	—	—	170
Exchange differences	(1,055)	(164)	(26)	15	(6)	(15)	(1,251)
Balance at June 30, 2024	**117,745**	**266,116**	**1,295**	**3,604**	**516**	**10,207**	**399,483**
Cost	117,745	289,879	1,356	3,604	951	11,501	425,036
Accumulated amortization	—	(23,763)	(61)	—	(435)	(1,294)	(25,553)
Net book amount	**117,745**	**266,116**	**1,295**	**3,604**	**516**	**10,207**	**399,483**
Balance at January 1, 2023	**5,519**	**41,060**	**—**	**—**	**300**	**12,105**	**58,984**
Additions	—	57,410	—	1,659	266	77	59,412
Reclassifications	—	—	—	—	—	(2,021)	(2,021)
Amortization charge	—	(4,005)	—	—	(37)	(302)	(4,344)
Impairments	—	(804)	—	—	—	—	(804)
Changes in provisions	(672)	489	—	—	—	282	99
Exchange differences	—	(1,933)	—	(37)	—	307	(1,663)
Balance at December 31, 2023	**4,847**	**92,217**	**—**	**1,622**	**529**	**10,448**	**109,663**
Cost	4,847	114,048	—	1,622	949	11,604	133,070
Accumulated amortization	—	(21,831)	—	—	(420)	(1,156)	(23,407)
Net book amount	**4,847**	**92,217**	**—**	**1,622**	**529**	**10,448**	**109,663**

The allocation of intangible assets to each cash-generating unit (CGU) is summarized below:

Product or business unit	Useful life	CGU	June 30, 2024	December 31, 2023
			A$'000	A$'000
TLX591-CDx (Illuccix)	Definite	Commercial	8,915	10,876
QSAM (^{153}Sm-DOTMP)	Indefinite	Product development	134,821	—
TLX591	Indefinite	Product development	18,074	17,912
TLX66	Indefinite	Product development	15,739	15,569
TLX300	Indefinite	Product development	6,823	6,823
TLX101	Indefinite	Product development	1,531	1,613
Patents	Definite	Product development	515	529
ARTMS	Indefinite	Manufacturing services	135,254	—
IsoTherapeutics	Definite and indefinite	Manufacturing services	18,594	—
Brussels South and Optimal Tracers	Definite	Manufacturing services	4,153	4,298
SENSEI	Indefinite	Medical technologies	51,460	50,346
Dedicaid, QDOSE	Indefinite	Medical technologies	3,604	1,697
			399,483	**109,663**

Impairment trigger for goodwill and indefinite life intangible assets

The Group has considered reasonably possible changes in the key assumptions and has not identified any instances that could cause the carrying amounts of the intangible assets at June 30, 2024 to exceed their recoverable amounts. The intangible assets arising from the IsoTherapeutics and ARTMS acquisitions made during the half-year are provisional and subject to change within the 12 month measurement period, refer to note 10 for further details.

10. Acquisitions

10.1. IsoTherapeutics Group, LLC

On April 9, 2024, Telix completed the acquisition of IsoTherapeutics Group, LLC (IsoTherapeutics). IsoTherapeutics provides radiochemistry and bioconjugation development and contract manufacturing services to numerous companies in the radiopharmaceutical industry, including Telix.

The total consideration is $19,859,000 of which $8,912,000 has been paid in equity through the issue of 717,587 fully paid ordinary Telix shares at $12.42 per share, with $3,285,000 paid in cash. A further $7,662,000 is payable in cash for performance-related milestone payments that are subject to meeting milestone conditions within twelve months of closing.

Further performance-based payments are payable in cash to the IsoTherapeutics sellers based on 50% of net revenue during a two year revenue sharing period from the closing date. These payments are effectively a retention mechanism of key employees and as such are excluded from the acquisition consideration and instead will be recognized as an expense over the revenue sharing period within the Group's consolidated statement of comprehensive income.

The following table summarizes the consideration paid for IsoTherapeutics, the fair value of assets acquired and liabilities assumed at the acquisition date. These balances are provisional and subject to change within the 12 month measurement period.

Consideration	Provisional fair value A$'000
Cash paid	3,285
Equity issued	8,912
Contingent consideration	7,662
Total consideration	**19,859**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	394
Trade and other receivables	642
Property, plant and equipment	365
Right-of-use assets	519
Trade and other payables	(7)
Lease liabilities	(519)
Total identifiable assets and liabilities	**1,394**
Fair value adjustments	
Customer relationships	1,280
Brand name	102
Deferred tax liabilities	(332)
Total fair value adjustments	**1,050**
Goodwill	17,415
Total	**19,859**

The goodwill arising is attributable to the acquired workforce, anticipated future cost savings from utilizing IsoTherapeutics' manufacturing and radiopharmaceutical development capability and synergies of integrating the business within the Group. The goodwill arising from the acquisition has been allocated to the manufacturing services CGU.

Fair value adjustments have been recognized for acquisition-related intangible assets and related deferred tax.

Acquisition-related intangible assets of $1,280,000 relate to the valuation of the customer relationships and $102,000 relates to the value of the acquired IsoTherapeutics brand. The useful economic lives of each of these acquisition-related intangible assets is four and two years, respectively.

Acquisition costs of $1,272,000 have been charged to the statement of comprehensive income in the year relating to the acquisition of IsoTherapeutics.

IsoTherapeutics contributed $811,000 towards revenue and a net loss of $372,000 towards the Group's profit before tax attributable to equity holders of the parent for the period after the date of acquisition. As a preliminary assessment, had the acquisition of IsoTherapeutics been completed on the first day of the period, Group revenues would have been approximately $913,000 higher and Group profit before tax attributable to equity holders of the parent would have been approximately $261,000 lower.

10.2. ARTMS Inc.

On April 11, 2024, Telix completed the acquisition of radioisotope production technology firm ARTMS Inc. (ARTMS). ARTMS, based in Vancouver, BC (Canada), specializes in the physics, chemistry and materials science of cyclotron-produced radionuclides.

The total consideration is $133,773,000 of which $71,610,000 has been paid in equity through the issue of 5,674,365 fully paid ordinary Telix shares at $12.62 per share, with $24,491,000 paid in cash.

A further $37,672,000 in contingent future milestone and royalty payments is payable in cash following achievement of certain clinical or commercial milestones and sales targets. The royalties represent a low single to low double-digit percentage of net sales of ARTMS products or Telix products prepared using ARTMS products for defined periods depending on the product location where the sale occurs. All earn-outs which have not otherwise expired will terminate on the 10 year anniversary of completion.

The following table summarizes the consideration paid for ARTMS, the fair value of assets acquired and liabilities assumed at the acquisition date. These balances are provisional and subject to change within the 12 month measurement period.

Consideration	Provisional fair value A$'000
Cash paid	24,491
Equity issued	71,610
Contingent consideration	37,672
Total consideration	**133,773**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	5,810
Trade and other receivables	252
Other current assets	67
Inventories	2,869
Other non-current assets	149
Property, plant and equipment	1,422
Right-of-use assets	1,154
Trade and other payables	(4,716)
Lease liabilities	(1,154)
Total identifiable assets and liabilities	**5,853**
Fair value adjustments	
Intellectual property	39,965
Deferred tax liabilities	(10,487)
Property, plant and equipment	504
Inventories	1,478
Total fair value adjustments	**31,460**
Goodwill	96,460
Total	**133,773**

The goodwill arising is attributable to the acquired workforce, anticipated future cost savings from utilizing ARTMS' radioisotope production capabilities and synergies of vertically integrating the business within the Group. The goodwill arising from the acquisition has been allocated to the manufacturing services CGU.

Fair value adjustments have been recognized for acquisition-related intangible assets, property, plant and equipment, inventories and related deferred tax.

Acquisition-related intangible assets of $39,965,000 relate to the valuation of the acquired ARTMS intellectual property. The useful economic life of the intellectual property has not been assessed at the acquisition date, as the intellectual property is not available for commercial use until regulatory approval has been obtained.

Acquisition costs of $455,000 have been charged to the statement of comprehensive income in the year relating to the acquisition of ARTMS.

ARTMS contributed $36,000 towards revenue and a net loss of $2,320,000 towards the Group's profit before tax attributable to equity holders of the parent for the period after the date of acquisition. As a preliminary assessment, had the acquisition of ARTMS been completed on the first day of the period, Group revenues would have been approximately $305,000 higher and Group profit before tax attributable to equity holders of the parent would have been approximately $2,477,000 lower.

10.3. QSAM Biosciences, Inc.

On May 3, 2024, Telix completed the acquisition of QSAM Biosciences, Inc. (QSAM) and its lead investigational drug Samarium-153-DOTMP (^{153}Sm-DOTMP). QSAM is developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer.

The upfront purchase price was $61,196,000 of which $54,470,000 was paid to QSAM in equity through the issue of 3,671,120 fully paid ordinary Telix shares and $6,726,000 paid in cash. 66,011 Telix shares were held back against any adjustments required to be made post completion. These shares were issued in July.

A further US$90,000,000 in Contingent Value Rights, or performance rights, is payable in cash and/or in ordinary shares, upon achievement of certain clinical or commercial milestones.

The Group has determined that substantially all of the fair value of the gross assets acquired is concentrated in a single asset or a group of similar assets. The Group has applied the optional concentration of fair value test in IFRS 3 Business Combinations and concluded that the components acquired will be treated as an asset acquisition.

The performance rights have been recognized as an equity settled share based payment at a fair value of $67,943,000 which has been included in the fair value of intellectual property. Each milestone has a fixed dollar amount which can be settled either in cash or shares. The fair value of the performance rights was determined based on management's assessment of the likelihood of each milestone being reached against the fixed dollar amount for that milestone. The likelihood of the milestones being attained are considered non-vesting conditions as there are no further services or obligations of the counterparty, thus being reflected in the fair value.

The fair values of identifiable assets on acquisition are outlined below:

Consideration	Fair value A$'000
Cash paid	6,726
Equity issued	54,470
Performance rights issued	67,943
Total consideration	**129,139**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	18
Trade and other receivables	52
Intellectual property	129,907
Trade and other payables	(838)
Total identifiable assets and liabilities	**129,139**

Acquisition costs of $5,863,000 have been capitalized to the intellectual property recognized, as the costs were directly attributable to preparing the intellectual property for its intended use.

11. Trade and other payables

	June 30, 2024	December 31, 2023
	A$'000	A$'000
Trade creditors	22,302	32,837
Accruals	51,878	37,895
Other creditors	5,678	6,738
Accrued royalties	1,846	3,205
Payroll liabilities	2,008	899
Government rebates payable	565	130
Total trade and other payables	**84,277**	**81,704**

12. Contingent consideration

	ANMI	TheraPharm	Optimal Tracers	IsoTherapeutics	ARTMS	Total
	A$'000	A$'000	A$'000	A$'000	A$'000	A$'000
Balance at January 1, 2024	**90,493**	**2,178**	**83**	**—**	**—**	**92,754**
Remeasurement of contingent consideration	3,071	—	—	—	—	3,071
Unwind of discount	6,631	144	—	—	717	7,492
Charged to profit or loss	**9,702**	**144**	**—**	**—**	**717**	**10,563**
Exchange differences	1,919	(12)	4	(144)	(362)	1,405
Acquisition of business	—	—	—	7,662	37,672	45,334
Amounts adjusted to intangible assets	—	170	—	—	—	170
Payments for contingent consideration	—	—	(49)	—	—	(49)
Balance at June 30, 2024	**102,114**	**2,480**	**38**	**7,518**	**38,027**	**150,177**
Current	102,114	—	38	7,518	—	109,670
Non-current	—	2,480	—	—	38,027	40,507
Total contingent consideration	**102,114**	**2,480**	**38**	**7,518**	**38,027**	**150,177**
Balance at January 1, 2023	**62,541**	**1,690**	**—**	**—**	**—**	**41,910**
Remeasurement of contingent consideration	34,275	—	—	—	—	34,275
Unwind of discount	11,033	278	83	—	—	11,394
Charged to profit or loss	**45,308**	**278**	**83**	**—**	**—**	**45,669**
Exchange differences	410	(279)	(46)	—	—	4,201
Acquisition of business	—	—	718	—	—	718
Amounts adjusted to intangible assets	—	489	(672)	—	—	256
Payments for contingent consideration	(17,766)	—	—	—	—	—
Balance at December 31, 2023	**90,493**	**2,178**	**83**	**—**	**—**	**92,754**
Current	37,070	—	83	—	—	37,153
Non-current	53,423	2,178	—	—	—	55,601
Total contingent consideration	**90,493**	**2,178**	**83**	**—**	**—**	**92,754**

12.1. Telix Innovations (formerly ANMI)

The Group acquired Telix Innovations on 24 December 2018. The Group is liable for future variable payments which are calculated based on the percentage of net sales for five years following the achievement of market authorization of Illuccix (TLX591-CDx). The percentage of net sales varies depending on the net sales achieved

in the United States and the rest of the world. The Group also holds an option to buy-out the remaining future variable payments in the third year following the achievement of market authorization, if specified sales thresholds are met.

As at the consolidated statement of financial position date, the Group has remeasured the contingent consideration to its fair value. The remeasurement is as a result of changes to the key assumptions such as the risk adjusted post-tax discount rate, expected sales volumes and net sales price per unit.

The contingent consideration liability has been valued using a discounted cash flow model that utilizes certain unobservable Level 3 inputs. These key assumptions include risk adjusted post-tax discount rate of 13.0% (December 31, 2023: 15.0%), expected sales volume over the forecast period and net sales price per unit.

Refer to the Group's 2023 financial statements for further quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable.

12.2. IsoTherapeutics

The Group acquired IsoTherapeutics on April 9, 2024. The Group is liable for $7,662,000 which is payable in cash for performance-related milestone payments that are subject to meeting milestone conditions within 12 months of closing.

The contingent consideration liability has not been discounted as it is due within 12 months.

12.3. ARTMS

Telix acquired ARTMS on April 11, 2024. Part of the consideration for the acquisition was in the form of future payments contingent on certain milestones. These are:

Milestone	Amount (US$)
Approval by the FDA and subsequent direct incorporation of the ARTMS Technology into the U.S. Telix Illuccix approved product labels	$4,500,000
Upon completion of the installation and acceptance of a target number of ARTMS QIS systems in commercial radiopharmacy sites in the United States	$5,000,000
Upon achieving cumulative Net Sales from consumables	$5,000,000
Upon achieving cumulative annual Net Sales from sales of ARTMS Products and consumables	$5,000,000
Upon achieving a cumulative total target Net Sales from ARTMS Products, inclusive of QIS installations, processing systems, QUANTM targets and consumable Net Sales	$5,000,000

In addition to the above, the contingent consideration includes future royalty payments for a low single to low double- digit percentage of net sales of ARTMS products or Telix products.

The contingent consideration liability has been valued using a discounted cash flow model that utilizes certain unobservable Level 3 inputs. These key assumptions include risk adjusted post-tax discount rate at acquisition of 15.0%, FDA approval dates, expected sales volume over the forecast period and net sales price per unit.

The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	June 30, 2024
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase in the post-tax discount rate would decrease the contingent consideration by 0.9% and a 0.5% decrease in the post-tax discount rate would increase the contingent consideration by 0.9%.

Unobservable input	Methodology	June 30, 2024
Expected sales volumes - ARTMS and Telix products	This is determined through assumptions on target market population, penetration and growth rates in the United States and Europe.	A 10.0% increase in the sales volumes would increase the contingent consideration by 10.0% and a 10.0% decrease in sales volumes would decrease the contingent consideration by 10.0%.
Net sales price per unit	The net sales price per unit is estimated based on comparable products currently in the market.	A 10.0% increase in the net sales price per unit would increase the contingent consideration by 10.0% to 21.0% across the different royalties and a 10.0% decrease in net sales price per unit would decrease the contingent consideration by 10.0% to 21.0% across the different royalties.

13. Contractual maturities of financial liabilities

As at June 30, 2024, the contractual maturities of the Group's non-derivative financial instrument liabilities are outlined below. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid. The tables include both interest and principal cash flows disclosed as remaining contractual maturities and therefore these totals may differ from their carrying amount in the consolidated statement of financial position.

As at June 30, 2024	1-6 months A$'000	6-12 months A$'000	1-5 years A$'000	Over 5 years A$'000	Total contractual cash flows A$'000	Carrying amount of liabilities A$'000
Non-derivatives						
Trade and other payables	84,277	—	—	—	84,277	84,277
Borrowings	1,095	1,095	8,763	5,705	16,658	11,852
Lease liabilities	1,492	1,469	8,497	538	11,996	10,291
Government grant liability	372	752	1,675	678	3,477	3,014
Contingent consideration	39,836	75,774	52,382	2,359	170,351	150,177
Total financial liabilities	**127,072**	**79,090**	**71,317**	**9,280**	**286,759**	**259,611**

As at December 31, 2023, the contractual maturities of the Group's non-derivative financial liabilities were as follows:

As at December 31, 2023	1-6 months A$'000	6-12 months A$'000	1-5 years A$'000	Over 5 years A$'000	Total contractual cash flows A$'000	Carrying amount of liabilities A$'000
Non-derivatives						
Trade and other payables	81,704	—	—	—	81,704	81,704
Borrowings	1,105	1,105	8,839	6,859	17,908	9,173
Lease liabilities	1,044	1,057	6,744	1,264	10,109	8,272
Government grant liability	376	577	3,169	593	4,715	2,664
Contingent consideration	—	38,382	65,229	2,352	105,963	92,754
Total financial liabilities	**84,229**	**41,121**	**83,981**	**11,068**	**220,399**	**194,567**

14. Equity

14.1. Share capital

	June 30, 2024	December 31, 2023	June 30, 2024	December 31, 2023
	Number '000	Number '000	A$'000	A$'000
Opening balance	**323,727**	**316,343**	**446,268**	**370,972**
Shares issued through the exercise of share options and warrants[1]	441	3,879	6,148	42,572
Shares issued for Dedicaid[2]	—	207	—	1,829
Shares issued for Lightpoint[3]	—	3,298	—	30,895
Shares issued for IsoTherapeutics[4]	718	—	8,912	—
Shares issued for ARTMS[5]	5,675	—	71,610	—
Shares issued for QSAM[6]	3,671	—	54,470	—
Closing balance	**334,232**	**323,727**	**587,408**	**446,268**

1. Options exercised during the half-year through the employee Equity Incentive Plan resulted in 441,373 (December 31, 2023: 3,878,633) shares being issued for a total value of $6,148,000 (December 31, 2023: $42,572,000).
2. On April 27, 2023, the Group completed the acquisition of Dedicaid. The consideration for the acquisition comprised an upfront payment of $1,829,000 (€1,100,000) in Telix shares at a fair value of A$8.73 per share (207,207 Telix shares).
3. On November 1, 2023, the Group completed the acquisition of Lightpoint through the issue of 3,298,000 fully paid ordinary Telix shares at $9.3659 per share.
4. On April 9, 2024, the Group completed the acquisition of IsoTherapeutics. The consideration included the issue of 717,587 fully paid ordinary Telix shares at A$12.42 per share.
5. On April 11, 2024, the Group completed the acquisition of ARTMS. The consideration included the issue of 5,674,365 fully paid ordinary Telix shares at A$12.62 per share.
6. On May 3, 2024, the Group completed the acquisition of QSAM. The purchase price included the issue of 3,671,120 fully paid ordinary Telix shares at A$14.80 per share.

The weighted average ordinary shares for the period January 1, 2024 to June 30, 2024 is 327,726,673 (December 31, 2023: 319,180,783). The Company does not have a limited amount of authorized capital.

14.2. Share-based payments reserve

	June 30, 2024	December 31, 2023	June 30, 2024	December 31, 2023
	Number '000	Number '000	A$'000	A$'000
Opening balance	**14,601**	**11,736**	**35,446**	**9,321**
EIP options issued	3,715	6,689	9,941	8,786
Performance Rights issued[1]	4,284	2,524	67,943	21,278
Options exercised	(520)	(4,524)	(507)	(3,939)
Options lapsed	(1,495)	(1,824)	—	—
Closing balance	**20,585**	**14,601**	**112,823**	**35,446**

1. Relates to the acquisition of QSAM in the current period and Lightpoint in the prior year.

15. Commitments and contingent liabilities

15.1. Commitments

At June 30, 2024, the Group had commitments against existing R&D costs and capital commitments relating to the construction of the Brussels South radiopharmaceutical production facility. R&D commitments in future years are estimated based on the contractual obligations included within agreements entered into by the Group. These R&D contracts have typical termination provisions to limit the commitment to the time and materials expended at termination, the orderly close out of activities or up to an approved work order amount.

	Due < 1 year A$'000	Due > 1 year A$'000
June 30, 2024		
Capital commitments[1]	22,407	35,191
R&D commitments	24,446	23,259
	46,853	**58,450**
December 31, 2023		
Capital commitments	16,572	40,000
R&D commitments	28,112	20,403
	44,684	**60,403**

1. Includes the three year supply of Ytterbium-176 isotope.

15.2. Contingent liabilities and contingent assets

Refer to the Group's 2023 financial statements for further details of existing agreements that could give rise to contingent liabilities. The Group has entered into a number of agreements with other third parties pertaining to intellectual property. Contingent liabilities may arise in the future if certain events or developments occur in relation to these agreements and as of June 30, 2024 we have assessed the likelihood of these contingent liabilities arising to be remote.

16. Related party transactions

16.1. Transactions with other related parties

In March 2024, the Group entered into an agreement to purchase the QDOSE dosimetry software platform from ABX-CRO. QDOSE is a software platform designed to enable reliable estimation of patient-specific dosimetry for both therapeutic and diagnostic radiopharmaceuticals. We agreed to pay ABX-CRO upfront cash consideration of €1,200,000, a share of profits generated from QDOSE sales and a referral fee on deals referred from or initiated by ABX-CRO over a two-year period from acquisition.

Dr. Andreas Kluge, Non-Executive Director, is the principal owner and Geschäftsführer (Managing Director) of ABX- CRO, a clinical research organization (CRO) that specializes in radiopharmaceutical product development. QDOSE was independently valued as part of the acquisition negotiation process to ensure the proposed consideration was at an arms' length basis.

17. Events occurring after the reporting period

On July 30, 2024, the Group completed the issue of $650,000,000 in convertible bonds maturing in 2029. The convertible bonds are convertible into fully paid ordinary shares in Telix Pharmaceuticals Limited. The initial conversion price of the convertible bonds is $24.78 per share, subject to anti-dilution adjustments set out in the final terms and conditions of the convertible bonds. The convertible bonds will bear interest at a rate of 2.375 per cent per annum. Interest will be payable quarterly in arrears on October 30, January 30, April 30 and July 30 in each year, beginning on October 30, 2024. The convertible bonds will mature on or about July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms. The convertible bonds are listed on the Singapore Exchange Securities Trading Limited (SGX-ST).

The net proceeds of approximately $635,000,000, after transaction costs, are intended to provide funding to bring forward proposed investment in order to accelerate key clinical development programs across the Company's theranostic portfolio. This includes label-expansion studies to expand the market opportunity across Telix's

portfolio of diagnostic imaging agents and funding the pivotal trials for kidney and brain cancer therapy programs. In addition, the funding will provide financial flexibility for Telix to explore opportunities and potentially pursue strategically significant M&A transactions and continued investment in global supply chain and manufacturing capabilities.

From the end of the reporting period to the date of issuance of these interim consolidated financial statements, there were no other matters or circumstances which have significantly affected, or may significantly affect, the operations of the Group, the results of those operations or the state of affairs of the Group.

18. Events subsequent to original issuance of financial statements (Unaudited)

Stock Purchase Agreement with RLS (USA) Inc.

On September 20, 2024, Telix entered into a conditional agreement to acquire RLS (USA) Inc. The purchase price for the potential acquisition consists of:

- US$230.0 million upfront consideration, payable in cash at closing of the acquisition, which will be adjusted for transaction expenses, cash and cash equivalents (net of restricted cash), debt and debt equivalents and working capital, and
- further milestone payments of up to US$20.0 million in the aggregate, payable in cash upon the achievement of certain commercial milestones related to the demonstration of accretive financial and operational performance during the four-quarters following closing.

Telix expects to fund the purchase price and related transaction costs from existing cash reserves. The acquisition is expected to close in the first quarter of 2025. The closing of the acquisition is subject to various conditions including regulatory approvals, RLS shareholder approval, license transfer approvals and certain-third party consents. Either party may terminate the acquisition agreement if the acquisition has not been consummated by February 17, 2025.

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form 20-F of Telix Pharmaceuticals Limited of our report dated September 13, 2024 relating to the financial statements of Telix Pharmaceuticals Limited, which appears in this Registration Statement. We also consent to the reference to us under the heading “Statement by Experts” in such Registration Statement.

/s/ PricewaterhouseCoopers
Melbourne, Australia
October 29, 2024