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

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

Filed in the month of February 2025 for the period ended December 31, 2024

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Silviu Itescu
Chief Executive Officer and Executive Director
Level 38
55 Collins Street
Melbourne 3000
Australia
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

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REPORT ON FORM 6-K
FOR THE SIX MONTHS ENDED DECEMBER 2024

Incorporation by Reference

This Report on Form 6-K (excluding Exhibit 99.1) is hereby incorporated by reference in:

- the Registration Statement on Form F-3 (No. 333-267175) that we filed with the U.S. Securities and Exchange Commission ("SEC") on August 31, 2022;
- the Post-Effective Amendment No. 1 to the Registration Statement on Form F-3 (No. 333-262301) that we filed with the SEC on December 20, 2022;
- the Registration Statement on Form F-3 (No. 333-268890) that we filed with the SEC on December 20, 2022;
- the Registration Statement on Form F-3 (No. 333-270814) that we filed with SEC on March 24, 2023;
- the Registration Statement on Form F-3 (No. 333-272029) that we filed with SEC on May 18, 2023;
- the Registration Statement on Form F-3 (No. 333-283799) that we filed with the SEC on December 13, 2024, as amended;
- the Registration Statement on Form F-3 (No. 333-284705) that we filed with the SEC on February 5, 2025, as amended; and
- the registration statements on (i) Form S-8 (File No. 333-210935) filed with the SEC on April 26, 2016, (ii) Form S-8 (File No. 333-220988) filed with the SEC on October 17, 2017, (iii) Form S-8 (File No. 333-240107) filed with the SEC on July 27, 2020, (iv) Form S-8 (File No. 333-261863) filed with the SEC on December 23, 2021, and (v) Form S-8 (File No. 333-267663) filed with the SEC on September 30, 2022.

This Form 6-K shall be deemed to be a part of such registration statements from the date on which this Report is furnished to the SEC, to the extent not superseded by documents or reports subsequently filed or furnished.

Foreword

The Board of Directors of Mesoblast Limited (ABN 68 109 431 870) has resolved to submit the following report of Mesoblast Limited and its subsidiaries for the six months ended December 31, 2024 in compliance with the provisions of the Corporations Act 2001.

Directors of Mesoblast Limited in office at any time during or since the end of the six months ended December 31, 2024 were:

Name	Position
Silviu Itescu	Executive Director
Eric Rose	Executive Director
Jane Bell	Chair of Board
William M Burns	Non-executive Director, Vice Chairman, Chair of the Nomination and Remuneration Committee
Philip Facchina	Non-executive Director, Chair of Audit and Risk Committee
Philip Krause	Non-executive Director
Joseph Swedish[(1)]	Non-executive Director

1. Mr. Joseph Swedish retired effective November 15, 2024.

Currency Presentation and Certain Defined Terms

In this Report on Form 6-K, references to "U.S." or "United States" are to the United States of America, its territories and its possessions. References to "US$" or "$" or "U.S. dollars" are to the legal currency of the United States, references to "€" or "Euro" are to the legal currency of the European Union, references to "S$" or "SGD" or "Singapore dollars" are to the legal currency of Singapore and references to "A$" or "Australian Dollars" are to the legal currency of Australia. Our financial statements are presented in U.S. dollars and are prepared in accordance with the International Financial Reporting Standards as issued by the International Accounting Standards Board, or "IFRS". References to a particular "fiscal" year are to our fiscal year ended June 30 of such year.

All references to "we", "us", "our", "Mesoblast" or "the Group" shall mean Mesoblast Limited (ABN 68 109 431 870) and its subsidiaries. We own or have rights to trademarks and trade names that we use in connection with the operation of our business, including our corporate name, logos, product names and website names. Other trademarks and trade names appearing in this Report are the property of their respective owners.

Forward-Looking Statements

This Report on Form 6-K includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, "believe", "expect", "anticipate", "estimate", "intend", "plan", "target", "likely", "will", "would", "could", "should", "may", "goal", "objective" and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs;
- our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials;
- our ability to advance our manufacturing capabilities;
- the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any;
- our ability to take advantage of the potential benefits of the 21st Century Cures Act;
- the impact that any future pandemic and other geopolitical instability could have on business operations;
- the commercialization of our product candidates, if approved;
- regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies;
- the potential for our product candidates, if they are approved, to be withdrawn from the market due to patient adverse events or deaths;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations;
- our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to obtain additional financing;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our financial performance;
- developments relating to our competitors and our industry;
- the pricing and reimbursement of our product candidates, if approved;
- general economic conditions; and
- other risks and uncertainties, including those listed under the caption "Risk Factors" included elsewhere in this Report on Form 6-K.

You should read thoroughly this Report on Form 6-K and the documents that we refer to herein with the understanding that our actual future results may be materially different from and/or worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Other sections of this Report on Form 6-K include additional factors which could adversely impact our business and financial performance. Moreover, we operate in an evolving environment. New risk factors 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 any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this Report on Form 6-K relate only to events or information as of the date on which the statements are made in this Report on Form 6-K. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Condensed Consolidated Income Statement
(unaudited)

(in U.S. dollars, in thousands, except per share amount)	Note	Six Months Ended December 31, 2024	2023
Revenue	3	3,156	3,388
Research & development		(20,649)	(12,647)
Manufacturing commercialization	6(d)(iii)	14,740	(6,746)
Management and administration		(17,188)	(11,482)
Fair value remeasurement of contingent consideration	3	(4,303)	(337)
Fair value remeasurement of warrant liability	3	(11,978)	4,434
Other operating income and expenses	3	(673)	1,068
Finance costs	3	(10,827)	(10,319)
Loss before income tax	3	**(47,722)**	**(32,641)**
Income tax benefit/(expense)	4	(212)	102
Loss attributable to the owners of Mesoblast Limited		**(47,934)**	**(32,539)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**
Basic - losses per share	10	(4.20)	(3.72)
Diluted - losses per share	10	(4.20)	(3.72)

The above consolidated income statement should be read in conjunction with the accompanying Notes.

Condensed Consolidated Statement of Comprehensive Income
(unaudited)

(in U.S. dollars, in thousands)	Note	Six Months Ended December 31, 2024	2023
Loss for the period		**(47,934)**	**(32,539)**
Other comprehensive (loss)/income			
Items that may be reclassified to profit and loss			
Exchange differences on translation of foreign operations		(113)	1,164
Items that will not be reclassified to profit and loss			
Financial assets at fair value through other comprehensive income		194	(931)
Other comprehensive (loss)/income for the period, net of tax		**81**	**233**
Total comprehensive losses attributable to the owners of Mesoblast Limited		**(47,853)**	**(32,306)**

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying Notes.

Condensed Consolidated Statement of Changes in Equity
For the six months ended December 31, 2024 and 2023
(unaudited)

(in U.S. dollars, in thousands)	Note	Issued Capital	Share Option Reserve	Investment Revaluation Reserve	Foreign Currency Translation Reserve	Warrant Reserve	(Accumulated losses)	Total
Balance as of July 1, 2023		**1,249,123**	**101,367**	**(543)**	**(40,273)**	**12,969**	**(820,805)**	**501,838**
Loss for the period		—	—	—	—	—	(32,539)	(32,539)
Other comprehensive income/ (loss)		—	—	(931)	1,164	—	—	233
Total comprehensive profit/(loss) for the period		**—**	**—**	**(931)**	**1,164**	**—**	**(32,539)**	**(32,306)**
Transactions with owners in their capacity as owners:								
Contributions of equity net of transaction costs		37,106	—	—	—	—	—	37,106
		37,106	**—**	**—**	**—**	**—**	**—**	**37,106**
Tax credited / (debited) to equity		—	(102)					(102)
Transfer of exercised options		—	—	—	—	—	—	—
Fair value of share-based payments		—	2,195	—	—	—	—	2,195
		—	**2,093**	**—**	**—**	**—**	**—**	**2,093**
Balance as of December 31, 2023	8(a)	**1,286,229**	**103,460**	**(1,474)**	**(39,109)**	**12,969**	**(853,344)**	**508,731**
Balance as of July 1, 2024		**1,310,813**	**106,842**	**(1,286)**	**(40,222)**	**12,969**	**(908,761)**	**480,355**
Loss for the period		—	—	—	—	—	(47,934)	(47,934)
Other comprehensive income/ (loss)		—	—	194	(113)	—	—	81
Total comprehensive profit/(loss) for the period		**—**	**—**	**194**	**(113)**	**—**	**(47,934)**	**(47,853)**
Transactions with owners in their capacity as owners:								
Contributions of equity net of transaction costs		2,231	—	—	—	—	—	2,231
Contributions of equity for unissued ordinary shares, net of transaction costs		3,550	—	—	—	—	—	3,550
		5,781	**—**	**—**	**—**	**—**	**—**	**5,781**
Tax credited / (debited) to equity		—	212	—	—	—	—	212
Transfer of exercised options		3,613	(3,613)	—	—	—	—	—
Fair value of share-based payments		—	22,767	—	—	—	—	22,767
		3,613	**19,366**	**—**	**—**	**—**	**—**	**22,979**
Balance as of December 31, 2024	8(a)	**1,320,207**	**126,208**	**(1,092)**	**(40,335)**	**12,969**	**(956,695)**	**461,262**

The above consolidated statement of changes in equity should be read in conjunction with the accompanying Notes.

Condensed Consolidated Balance Sheet
(unaudited)

(in U.S. dollars, in thousands)	Note	As of December 31, 2024	As of June 30, 2024
Assets			
Current Assets			
Cash & cash equivalents	5(a)	38,029	62,960
Trade & other receivables	5(b)	2,996	20,952
Prepayments	5(b)	4,460	2,551
Inventory	6(d)	24,194	—
Total Current Assets		**69,679**	**86,463**
Non-Current Assets			
Property, plant and equipment		1,004	1,106
Right-of-use assets		5,215	2,732
Financial assets at fair value through other comprehensive income		1,208	1,014
Other non-current assets		1,333	2,102
Intangible assets	6(a)	574,879	575,736
Total Non-Current Assets		**583,639**	**582,690**
Total Assets		**653,318**	**669,153**
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	11,860	7,070
Provisions	6(b)	27,567	45,038
Borrowings	5(d)	17,505	13,862
Lease liabilities		2,381	2,626
Warrant liability	5(e)	13,437	4,647
Total Current Liabilities		**72,750**	**73,243**
Non-Current Liabilities			
Provisions	6(b)	10,581	10,620
Borrowings	5(d)	101,475	100,483
Lease liabilities		4,750	1,952
Deferred consideration		2,500	2,500
Total Non-Current Liabilities		**119,306**	**115,555**
Total Liabilities		**192,056**	**188,798**
Net Assets		**461,262**	**480,355**
Equity			
Issued Capital	8(a)	1,320,207	1,310,813
Reserves		97,750	78,303
(Accumulated losses)		(956,695)	(908,761)
Total Equity		**461,262**	**480,355**

The above consolidated balance sheet should be read in conjunction with the accompanying Notes.

Condensed Consolidated Statement of Cash Flows
(unaudited)

(in U.S. dollars, in thousands)	Note	Six Months Ended December 31, 2024	2023
Cash flows from operating activities			
Commercialization revenue received		3,063	3,971
Government grants and tax incentives and credits received		2	2,565
Payments to suppliers and employees (inclusive of goods and services tax)		(24,159)	(33,994)
Interest received		441	887
Income taxes paid		(2)	(1)
Net cash (outflows) in operating activities	7(b)	**(20,655)**	**(26,572)**
Cash flows from investing activities			
Payments for property, plant and equipment		(106)	(194)
Receipts from investment in sublease		124	116
Payments for intellectual property		—	(10)
Receipt of security deposits		609	—
Net cash inflows/(outflows) in investing activities		**627**	**(88)**
Cash flows from financing activities			
Repayment of borrowings		(2,608)	—
Payment of transaction costs from borrowings		(644)	(540)
Interest and other costs of finance paid		(2,720)	(2,845)
Proceeds from exercise of options		1,341	—
Proceeds from exercise of warrants		1,362	—
Proceeds from issue of shares		—	39,708
Payments for share issue costs		(24)	(2,578)
Payments for lease liabilities		(971)	(2,145)
Net cash (outflows)/inflows by financing activities		**(4,264)**	**31,600**
Net (decrease)/increase in cash and cash equivalents		(24,292)	4,940
Cash and cash equivalents at beginning of period		62,960	71,318
Foreign exchange (losses)/gains on the translation of foreign bank accounts		(639)	1,296
Cash and cash equivalents at end of period	7(a)	**38,029**	**77,554**

The above consolidated statement of cash flows should be read in conjunction with the accompanying Notes.

Notes to Condensed Consolidated Financial Statements
(unaudited)

Mesoblast Limited (the "Company") and its subsidiaries (the "Group") are primarily engaged in the development of regenerative medicine products. The Company's primary proprietary regenerative medicine technology platform is based on specialized cells known as mesenchymal lineage adult stem cells. The Company was formed in 2004 as an Australian company and has been listed on the Australian Securities Exchange (the "ASX") since 2004. In November 2015, the Company listed in the United States of America ("U.S.") on the Nasdaq Global Select Market ("Nasdaq") and from this date has been dual-listed in Australia and the U.S.

These financial statements are presented in U.S. dollars ("$" or "USD" or "US$"), unless otherwise noted, including certain amounts that are presented in Australian dollars ("AUD" or "A$") and Singapore dollars ("SGD" or "S$").

1. Basis of preparation

Mesoblast Limited is a for-profit entity for the purpose of preparing the financial statements. The condensed consolidated financial statements of Mesoblast Limited and its subsidiaries have been prepared in accordance with International Accounting Standard IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board ("IASB"), and are unaudited. These condensed interim financial statements do not include all of the notes and disclosures required by International Financial Reporting Standards, as issued by the IASB, for annual consolidated financial statements and should therefore be read in conjunction with our annual report on Form 20-F for the year ended June 30, 2024. In the opinion of management, the interim financial data includes all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the results for the interim periods.

The financial statements cover Mesoblast Limited and its subsidiaries. The financial statements were authorized for issue by the board of directors on February 27, 2025. The directors have the power to amend and reissue the financial statements.

(i) Going concern

As of December 31, 2024, the Group held total cash reserves of $38.0 million. In January 2025, the Group announced completion of a global private placement primarily to existing major US, UK and Australian shareholders raising an additional $161.0 million after approval of Ryoncil® (remestemcel-L) for the treatment of SR-aGvHD in children 2 months and older. The Group continues its focus on maintaining tight control of net cash usage for operating activities, which were $20.7 million for the six months ended December 31, 2024, a reduction of 22% compared to the prior period.

The Group has cash reserves to execute the US commercial launch activities of RYONCIL, to commence life cycle extension of the FDA approved product in children and adults, and continue its clinical development pipeline. In conjunction with existing cash reserves, the proceeds from the January 2025 private placement and future revenue from sales of RYONCIL, the Group has sufficient cash to meet its forecast expenditure over at least the next twelve months.

(ii) Historical cost convention

These financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through other comprehensive income, financial assets and liabilities (including derivative instruments) at fair value through profit or loss, certain classes of property, plant and equipment and investment property.

(iii) New and amended standards adopted by the Group

The amendment to IAS 1 "Presentation of Financial Statements" was effective for Mesoblast from July 1, 2024, to improve the information an entity provides in its financial statements about long-term liabilities with covenants where the entity's right to defer settlement of those liabilities for at least twelve months after the reporting period is subject to the entity's complying with conditions specified in the loan arrangement. These amendments to the accounting policy have been adopted and there has been no material impact to the Group.

There were no other new or amended standards adopted by the Group in the six months ended December 31, 2024. These interim financial statements follow the same accounting policies as compared to the June 30, 2024 consolidated financial statements and related notes as filed with the Australian Securities Exchange and the Securities and Exchange Commission.

(iv) New accounting standards and interpretations not yet adopted by the Group

In April 2024, IFRS 18, "Presentation and Disclosure in Financial Statements" was issued to achieve comparability of the financial performance of similar entities. The standard, which replaces IAS 1 "Presentation of Financial Statements", impacts the presentation of primary financial statements and notes, including the statement of earnings where companies will be required to present separate categories of income and expense for operating, investing, and financing activities with prescribed subtotals for each new category. The standard will also require management-defined performance measures to be explained and included in a separate note within the consolidated financial statements. The standard is effective for annual reporting periods beginning on or after January 1, 2027, including interim financial statements, and requires retrospective application. The Group is currently assessing the impact of the new standard.

There were no new accounting standards and interpretations not yet adopted by the Group for the December 31, 2024 reporting period that are expected to materially impact the Group.

(v) Use of estimates

The preparation of these condensed consolidated financial statements requires the Group to make estimates and judgments that affect the reported amounts of assets, liabilities, income and expenses and related disclosures. On an ongoing basis, the Group evaluates its significant accounting policies and estimates. Estimates are based on historical experience and on various market-specific and other relevant assumptions that the Group believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

(vi) Impact of pandemics and geopolitical or economic instability and climate events

Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to pandemics, geopolitical and/or economic instability or the impact climate events could have on the Group's significant accounting estimates. The Group does not expect these areas to have a material impact on the Group's significant accounting estimates.

2. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was affected by the following event during the six months ended December 31, 2024.

- In July 2024, the Group resubmitted its Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") for approval of RYONCIL for the treatment of pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGvHD"). In December 2024, the FDA approved Mesoblast's RYONCIL for the treatment of SR-aGvHD in children 2 months and older. This is the first FDA-approved mesenchymal stromal cell ("MSC") therapy. Assumptions associated with SR-aGvHD are included within the impairment assessment of Osiris MSC products within intangible assets, contingent consideration, pre-launch inventory and the NovaQuest borrowings on the consolidated balance sheet and forecast cash usage.
- In August 2024, the compensation structure for short-term incentives were revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled the Group to avoid a $6.7 million cash payment of short-term incentives. Refer to Note 6(b)(*i*) for further discussion. The options granted in lieu of cash resulted in a $8.3 million increase in share-based payment expenses within the six months ended December 31, 2024.
- In August 2024, the Company announced that the consolidated shareholder class action, filed in the Federal Court of Australia in 2022, had been settled subject to Federal Court approval which was subsequently obtained on December 13, 2024. The settlement (inclusive of interest and costs) was fully funded by the insurer and includes no admission of liability. As a result, in December 2024, the Group reversed the provision for litigation settlement in the consolidated balance sheet (inclusive of interest and costs), refer to Note 6(b). Given the settlement has been funded entirely by Mesoblast's insurers, the Group also reversed the insurance asset within trade and other receivables in the consolidated balance sheet on settlement in December 2024, refer to Note 5(b).

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Six Months Ended December 31, 2024	2023
Revenue			
Commercialization revenue		3,156	3,388
Total Revenue		**3,156**	**3,388**
Clinical trial and research & development		**(3,266)**	**(2,045)**
Manufacturing production & development	6(d)(iii)	**16,654**	**(5,484)**
Employee benefits			
Salaries and employee benefits		(10,139)	(10,096)
Defined contribution superannuation expenses		(199)	(199)
Equity settled share-based payment transactions[(1)]		(15,172)	(2,195)
Total Employee benefits		**(25,510)**	**(12,490)**
Depreciation and amortization of non-current assets			
Plant and equipment depreciation		(171)	(281)
Right of use asset amortization		(1,006)	(1,420)
Intellectual property amortization		(906)	(742)
Total Depreciation and amortization of non-current assets		**(2,083)**	**(2,443)**
Other Management & administration expenses			
Overheads & administration		(4,183)	(4,594)
Consultancy		(848)	(1,285)
Legal and other professional fees		(2,440)	(1,124)
Intellectual property expenses (excluding the amount amortized above)		(1,421)	(1,410)
Total Other Management & administration expenses		**(8,892)**	**(8,413)**
Fair value remeasurement of contingent consideration			
Remeasurement of contingent consideration	5(e)(iii)	(4,303)	(337)
Total Fair value remeasurement of contingent consideration		**(4,303)**	**(337)**
Fair value remeasurement of warrant liability			
Remeasurement of warrant liability	5(e)(vi)	(11,978)	4,434
Total Fair value remeasurement of warrant liability		**(11,978)**	**4,434**
Other operating income and expenses			
Interest revenue		435	903
Foreign exchange (losses)/gains		(630)	165
Foreign withholding tax paid		(480)	—
Government grant income		2	—
Total Other operating income and expenses		**(673)**	**1,068**
Finance (costs)/gains			
Remeasurement of borrowing arrangements		(31)	(120)
Facility Fee		(106)	—
Interest expense		(10,690)	(10,199)
Total Finance costs		**(10,827)**	**(10,319)**
Total loss before income tax		**(47,722)**	**(32,641)**

(1) Share-based payment transactions

In August 2024, the compensation structure for short-term incentives was revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled the Group to avoid a $6.7 million cash payment of short-term incentives. The options granted in lieu of cash resulted in a $8.3 million increase in share-based payment expenses. For the six months ended December 31, 2024 and 2023, the share-based payment transactions have been reflected in the Consolidated Income Statement functional expense categories as follows:

	Six Months Ended December 31,	
(in U.S. dollars)	**2024**	**2023**
Research and development	8,180,398	1,104,007
Manufacturing and commercialization	661,392	48,064
Management and administration	6,330,095	1,043,365
Equity settled share-based payment transactions	**15,171,885**	**2,195,436**

Revenue recognition

Grünenthal arrangement

In September 2019, the Group entered into a strategic partnership with Grünenthal for the development and commercialization in Europe and Latin America of the Group's allogeneic mesenchymal precursor cell ("MPC") product, MPC-06-ID, receiving exclusive rights to the Phase 3 allogeneic product candidate for the treatment of low back pain due to degenerative disc disease.

The Group received a non-refundable upfront payment of $15.0 million in October 2019, on signing of the contract with Grünenthal. The Group received a milestone payment in December 2019 of $2.5 million in relation to meeting a milestone event as part of the strategic partnership with Grünenthal.

In June 2022, the Group amended the strategic partnership with Grünenthal and is eligible to receive payments up to US$112.5 million prior to product launch, inclusive of US$17.5 million already received, if certain clinical and regulatory milestones are satisfied and reimbursement targets are achieved. Cumulative milestone payments could reach US$1 billion depending on the final outcome of Phase 3 studies and patient adoption. The Group will also receive tiered double-digit royalties on product sales as per the agreement.

The $2.5 million milestone payment received in December 2019 from Grünenthal was considered deferred consideration as of December 31, 2024, as the performance obligation has not been met. For the six months ended December 31, 2024 and 2023, respectively, no milestone revenue was recognized in relation to this strategic partnership with Grünenthal.

Tasly arrangement

In July 2018, the Group entered into a strategic alliance with Tasly Pharmaceutical Group ("Tasly") for the development, manufacture and commercialization in China of the Group's allogeneic mesenchymal precursor cell ("MPC") products, MPC-150-IM and MPC-25-IC. Tasly received all exclusive rights for MPC-150-IM and MPC-25-IC in China and Tasly will fund all development, manufacturing and commercialization activities in China.

The Group received a $20.0 million up-front technology access fee from Tasly upon closing of this strategic alliance in October 2018. The Group recognized $10.0 million from this $20.0 million up-front technology access fee at closing in October 2018 and the remaining $10.0 million was recognized in revenue in February 2020. The Group is also entitled to receive $25.0 million on product regulatory approvals in China, double-digit escalating royalties on net product sales and up to six escalating milestone payments when the product candidates reach certain sales thresholds in China.

For the six months ended December 31, 2024 and 2023, respectively, no revenue was recognized in relation to this strategic alliance with Tasly.

TiGenix arrangement

In December 2017, the Group entered into a patent license agreement with TiGenix NV (“TiGenix”), now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”), which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell (“MSC") product, Alofisel® a registered trademark of TiGenix, previously known as Cx601, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the agreement, the Group received a $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment, a further payment of $5.9 million (€5.0 million) before withholding tax 12 months after the patent license agreement date, and a further $1.2 million (€1.0 million) product regulatory milestone payment in the year ended June 30, 2022. The Group is entitled to further payments up to €9.0 million when Takeda reaches certain product regulatory milestones. Additionally, the Group receives single digit royalties on net sales of Alofisel®.

For the six months ended December 31, 2024 and 2023, the Group earned $0.1 million and $0.2 million, respectively, of royalty income on sales of Alofisel® in Europe by our licensee Takeda.

For the six months ended December 31, 2024 and 2023, respectively, no milestone revenue was recognized in relation to the Group's patent license agreement with Takeda.

JCR arrangement

In October 2013, the Group acquired all of the culture-expanded, MSC-based assets from Osiris Therapeutics, Inc. These assets included assumption of a collaboration agreement with JCR, a research and development oriented pharmaceutical company in Japan. Revenue recognized under this agreement is limited to the amount of cash received or for which the Group is entitled, as JCR has the right to terminate the agreement at any time.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. Under the JCR Agreement, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. With respect to the First JCR Field, the Group are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties in the twenties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, the Group are entitled to an approximately 50% profit share. The Group expanded our partnership with JCR in Japan for two new indications: for wound healing in patients with Epidermolysis Bullosa (“EB”) in October 2018, and for neonatal hypoxic ischemic encephalopathy (“HIE”), a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. The Group will receive royalties on TEMCELL product sales for licensed indications, if and when JCR begins selling TEMCELL for such indications in Japan. The Group applies the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognizes royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the six months ended December 31, 2024, the Group recognized $3.0 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $3.2 million for the six months ended December 31, 2023. These amounts were recorded in revenue as there are no further performance obligations required in regard to these items.

4. Income tax benefit/(expense)

(in U.S. dollars, in thousands)	Six Months Ended December 31, 2024	2023
Income tax (benefit)/expense		
Current tax		
Current tax	—	—
Total current tax (benefit)/expense	—	—
Deferred tax		
(Increase)/decrease in deferred tax assets	364	22
(Decrease)/increase in deferred tax liabilities	(152)	(124)
Total deferred tax (benefit)/expense	**212**	**(102)**
Income tax (benefit)/expense	**212**	**(102)**

Deferred tax assets have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities.

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized. Deferred tax assets are offset against taxable temporary differences (deferred tax liabilities) when the deferred tax balances relate to the same tax jurisdiction in accordance with our accounting policy.

Deferred taxes are measured at the rate in which they are expected to settle within the respective jurisdictions, which can change based on factors such as new legislation or timing of utilization and reversal of associated assets and liabilities.

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Deferred tax assets not brought to account		
Unused tax losses		
Potential tax benefit at local tax rates [(1)]	131,993	140,129
Other temporary differences		
Potential tax benefit at local tax rates	8,524	14,204
Other tax credits		
Potential tax benefit at local tax rates	3,220	3,220
	143,737	**157,553**

(1) In December 2024, there was a change in the expected tax rate applicable on unused tax losses in Singapore for the years 2018-2020. For the tax years 2018-2020, the Singapore tax losses have been revalued from the statutory rate of 17% to the concessionary tax rate applicable under the Singapore tax incentives granted by the Singapore Economic Development Board.

5. Financial assets and liabilities

This note provides information about the Group's financial instruments, including:

- an overview of all financial instruments held by the Group;
- specific information about each type of financial instrument;
- accounting policies; and
- information used to determine the fair value of the instruments, including judgments and estimation uncertainty involved.

The Group holds the following financial instruments:

Financial assets (in U.S. dollars, in thousands)	Notes	Assets at FVOCI[1]	Assets at FVTPL[2]	Assets at amortized cost	Total
As of December 31, 2024					
Cash & cash equivalents	5(a)	—	—	38,029	38,029
Trade & other receivables	5(b)	—	—	2,996	2,996
Financial assets at fair value through other comprehensive income		1,208	—	—	1,208
Other non-current assets		—	—	1,333	1,333
		1,208	**—**	**42,358**	**43,566**
As of June 30, 2024					
Cash & cash equivalents	5(a)	—	—	62,960	62,960
Trade & other receivables	5(b)	—	—	20,952	20,952
Financial assets at fair value through other comprehensive income		1,014	—	—	1,014
Other non-current assets		—	—	2,102	2,102
		1,014	**—**	**86,014**	**87,028**

(1) Fair value through other comprehensive income

(2) Fair value through profit or loss

Financial liabilities (in U.S. dollars, in thousands)	Notes	Liabilities at FVOCI[1]	Liabilities at FVTPL[2]	Liabilities at amortized cost	Total
As of December 31, 2024					
Trade and other payables	5(c)	—	—	11,860	11,860
Borrowings	5(d)	—	—	118,980	118,980
Contingent consideration	5(e)(iii)	—	31,195	—	31,195
Warrant liability	5(e)(vi)	—	13,437	—	13,437
		—	**44,632**	**130,840**	**175,472**
As of June 30, 2024					
Trade and other payables	5(c)	—	—	7,070	7,070
Borrowings	5(d)	—	—	114,345	114,345
Contingent consideration	5(e)(iii)	—	26,892	—	26,892
Warrant liability	5(e)(vi)	—	4,647	—	4,647
		—	**31,539**	**121,415**	**152,954**

(1) Fair value through other comprehensive income

(2) Fair value through profit or loss

The Group's exposure to various risks associated with the financial instruments is discussed in Note 9. The maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets mentioned above.

a. Cash and cash equivalents

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Cash at bank	37,656	62,563
Deposits at call[(1)]	373	397
	38,029	**62,960**

(1) As of December 31, 2024 and June 30, 2024, interest-bearing deposits at call include amounts of $0.4 million and $0.4 million, respectively, held as security and restricted for use.

(i) Classification as cash equivalents

Term deposits are presented as cash equivalents if they have a maturity of three months or less from the date of acquisition.

b. Trade and other receivables and prepayments

(i) Trade and other receivables

(in U.S. dollars, in thousands)	Notes	As of December 31, 2024	As of June 30, 2024
Trade debtors		1,463	1,403
Tax incentives recoverable [(1)]		802	854
Foreign withholding tax recoverable		47	471
Net investment in sublease		225	224
Interest receivables		2	23
Other recoverable taxes (Goods and services tax and value-added tax)		457	423
Other asset	13	—	17,554
Trade and other receivables		**2,996**	**20,952**

(1) Research and development tax incentive

The Group's research and development activities are eligible under the Australian government's Innovation Australia Research and Development Tax Incentive program for research and development activities conducted in relation to qualifying research that meets the regulatory criteria. Management has assessed these activities and expenditures to determine which costs are likely to be eligible under the incentive scheme. The Group assesses, on an annual basis, the quantum of previous research and development tax claims and on-going eligibility to claim this tax incentive in Australia. The tax incentives recoverable as of December 31, 2024 pertains to an estimate for the year ended June 30, 2024.

(ii) Prepayments

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Clinical trial research and development expenditure	367	391
Prepaid insurance and subscriptions	2,736	1,775
Other	1,357	385
Prepayments	**4,460**	**2,551**

(iii) Classification as trade and other receivables

Trade receivables and other receivables represent the principal amounts due at balance date less, where applicable, any provision for expected credit losses. The Group uses the simplified approach to measuring expected credit losses, which uses a lifetime expected credit loss allowance. Debts which are known to be uncollectible are written off in the consolidated income statement. All trade receivables and other receivables are recognized at the value of the amounts receivable, as they are due for settlement within 60 days and therefore do not require remeasurement.

(iv) Fair values of trade and other receivables

Due to the short-term nature of the current receivables, their carrying amount is assumed to be the same as their fair value.

(v) Impairment and risk exposure

Information about the impairment of trade and other receivables, their credit quality and the Group's exposure to credit risk, foreign currency risk and interest rate risk can be found in Note 9.

c. Trade and other payables

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Trade payables and other payables	11,860	7,070
Trade and other payables	**11,860**	**7,070**

The carrying amounts of trade and other payables are assumed to be the same as their fair values, due to their short-term nature.

d. Borrowings

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Borrowings		
Secured liabilities:		
Borrowing arrangements	81,919	81,919
Less: transaction costs	(10,479)	(9,833)
Amortization of carrying amount, net of payments made	47,540	42,259
	118,980	**114,345**

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Borrowings		
Current		
Borrowings - NovaQuest	3,721	1,869
Borrowings - Oaktree	13,784	11,993
	17,505	**13,862**
Non-current		
Borrowings - NovaQuest	68,673	64,562
Borrowings - Oaktree	32,802	35,921
	101,475	**100,483**
	118,980	**114,345**

(i) Borrowing arrangements

Funds associated with Oaktree Capital Management, L.P. ("Oaktree")

In November 2021, the Group entered into a five-year senior debt facility provided by funds associated with Oaktree. The facility had a three-year interest only period, at a fixed rate of 9.75% per annum, after which time the principal balance amortizes 5% per quarter beginning December 2024 and a final payment is due no later than November 2026. The facility also allowed the Group to make quarterly payments of interest at a rate of 8.0% per annum for the first two years, and the unpaid interest portion (1.75% per annum) has been added to the outstanding loan balance and currently accrues further interest at a fixed rate of 9.75% per annum. The principal balance at the end of the three-year interest only period was $52.2 million, which amortizes at 5% per quarter beginning December 2024. The outstanding loan balance as of December 31, 2024 is $49.6 million.

On November 19, 2021, Oaktree were also granted warrants to purchase 1,769,669 American Depositary Shares ("ADSs") at US$7.26 per ADS, a 15% premium to the 30-day VWAP. The Group determined that an obligation to issue the warrants arose from the time the debt facility was signed; consequently, a liability for the warrants was recognized in November 2021. The warrants were legally issued on January 11, 2022 and may be exercised within 7 years of issuance. On the issuance date of the Oaktree facility and the warrants, the warrants were initially measured at fair value and the Oaktree borrowing liability measured as the difference between the $60.0 million received from the Oaktree facility and the fair value of the warrants. In December 2022, the Group amended the terms of the loan agreement with Oaktree and in connection with the loan amendment, Oaktree was granted warrants to purchase 455,000 ADSs at $3.70 per ADS, a 15% premium to the 30-day VWAP. The Group determined that an obligation to issue the warrants arose from the time the first amendment to the loan agreement was signed; consequently, a liability for the warrants was recognized in December 2022. The warrants were legally issued on March 8, 2023 and had an exercise term of 7 years from the date of issuance.

On January 5, 2024, the ratio under Mesoblast's American Depository Receipt ("ADR") program was changed from 5 ordinary shares representing 1 ADS (5:1 ratio) to a new ratio of 10 ordinary shares representing 1 ADS (10:1 ratio). As a result of this ratio change and as a result of completing the pro-rata accelerated non-renounceable rights issue in December 2023, the number and exercise price for the warrants was adjusted in accordance with the terms of these warrants. The warrants issued in November 2021 changed from 1,769,669 ADSs at US$7.26 per ADS to 884,838 ADSs at US$14.36 per

ADS. The warrants issued in December 2022 changed from 455,000 ADSs at US$3.70 per ADS to 227,502 ADSs at US$7.24 per ADS.

In December 2024 Oaktree exercised 188,122 ADS warrants that were issued in December 2022. Refer to Note 5(e)(vi) for more details on warrants issued.

In the six months ended December 31, 2024, the Group recognized a loss of $0.1 million in the Income Statement as remeasurement of borrowing arrangements within finance costs in relation to the adjustment of the carrying amount of the financial liability to reflect the revised estimated future cash flows from the credit facility. In the six months ended December 31, 2023 the Group recognized a minimal loss in the Income Statement as remeasurement of borrowing arrangements within finance costs.

The Group has pledged substantially all of its assets as collateral under the loan facility with Oaktree.

NovaQuest Capital Management, L.L.C.

On June 29, 2018, the Group entered into an eight-year loan and security agreement with NovaQuest drawing $30.0 million of the principal in July 2018. The loan term included an interest only period of approximately four years through until July 8, 2022. All interest and principal payments (i.e. the amortization period) are deferred until the earlier of loan maturity or from after the first commercial sale of RYONCIL for the treatment in pediatric patients with SR-aGVHD in the United States and other geographies excluding Asia ("RYONCIL for pediatric SR-aGVHD"). Principal is repayable in equal quarterly instalments over the amortization period of the loan and is subject to the payment cap described below. The loan has a fixed interest rate of 15% per annum. If there are no net sales of RYONCIL for pediatric SR-aGVHD, the loan is only repayable at maturity. The Group can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge.

Following approval and first commercial sales, repayments commence based on a percentage of net sales and are limited by a payment cap which is equal to the principal due for the next 12 months, plus accumulated unpaid principal and accrued unpaid interest. During the four-year period commencing July 8, 2022, principal amortizes in equal quarterly instalments payable only after approval and first commercial sales. If in any quarterly period, 25% of net sales of RYONCIL for pediatric SR-aGVHD exceed the annual payment cap, the Group will pay the payment cap and an additional portion of excess sales which will be used towards the prepayment amount in the event there is an early prepayment of the loan. If in any quarterly period 25% of net sales of RYONCIL for pediatric SR-aGVHD is less than the annual payment cap, then the payment is limited to 25% of net sales of RYONCIL for pediatric SR-aGVHD. Any unpaid interest will be added to the principal amounts owing and shall accrue further interest. At maturity date, any unpaid loan balances are repaid.

Because of this relationship of net sales and repayments, changes in our estimated net sales may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. The adjustment is recognized in the Income Statement as remeasurement of borrowing arrangements within finance costs in the period the revision is made.

In the six months ended December 31, 2024 and 2023, the Group recognized a gain of $0.1 million and a loss of $0.1 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows as a net result of changes to the key assumptions in development timelines.

The Group recognizes a liability as current based on repayments linked to estimates of sales of RYONCIL. However, if sales of RYONCIL are higher than estimated, actual repayments will exceed this amount, subject to the annual payment cap described above.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group's fixed rate loan with the senior creditor, Oaktree. The Group have pledged a portion of our assets relating to the SR-aGVHD product candidate as collateral under the loan facility with NovaQuest.

(ii) Compliance with loan covenants

Our loan facilities with Oaktree and NovaQuest contain a number of covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. The Group has an operating objective to at all times maintain unrestricted cash reserves in excess of six months liquidity. The objective aligns with our loan and security agreement with Oaktree where the Group is currently obliged to maintain a minimum unrestricted cash balance of $13.0 million, which reduces at a proportionate rate with each quarterly repayment of principal.

The Group has complied with the financial and other restrictive covenants of its borrowing facilities during the six months ended December 31, 2024 and as of June 30, 2024.

(iii) Net Debt Reconciliation

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Cash and cash equivalents	38,029	62,960
Borrowings	(118,980)	(114,345)
Lease liabilities	(7,131)	(4,578)
Warrant liability	(13,437)	(4,647)
Net Debt[(1)]	**(101,519)**	**(60,610)**
Cash and cash equivalents	38,029	62,960
Gross debt - fixed interest rates	(126,111)	(118,923)
Gross debt - variable interest rates	—	—
Warrant liability	(13,437)	(4,647)
Net Debt[(1)]	**(101,519)**	**(60,610)**

(1) Net debt amount includes leases and borrowing arrangements.

	Liabilities from financing activities				Other assets	
(in U.S. dollars, in thousands)	Borrowings	Leases	Warrant liability	Sub-total	Cash and cash equivalents	Total
Net Debt as at June 30, 2024	(114,345)	(4,578)	(4,647)	(123,570)	62,960	(60,610)
Cash Flows[(1)]	5,880	1,063	—	6,943	(24,292)	(17,349)
Remeasurement adjustments	(31)	—	(11,978)	(12,009)	—	(12,009)
Other Changes[(2)]	(10,484)	(1,107)	—	(11,591)	—	(11,591)
Exercise of warrants	—	—	3,188	3,188	—	3,188
Acquisition – leases	—	(2,564)	—	(2,564)	—	(2,564)
Foreign exchange adjustments	—	55	—	55	(639)	(584)
Net Debt as at December 31, 2024	**(118,980)**	**(7,131)**	**(13,437)**	**(139,548)**	**38,029**	**(101,519)**

(1) Cash flows include the payments of borrowings, lease liabilities, interest and debt transaction costs which are presented as financing cash flows in the statement of cash flows.

(2) Other changes include modification of leases and accrued interest expenses for borrowings and leases.

(iv) Fair values of borrowing arrangements

The carrying amount of the borrowings at amortized cost in accordance with our accounting policy is a reasonable approximation of fair value.

e. Recognized fair value measurement

(i) Fair value hierarchy

The following table presents the Group's financial assets and financial liabilities measured and recognized at fair value as of December 31, 2024 and June 30, 2024 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of December 31, 2024 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector		—	—	1,208	1,208
Total Financial Assets		**—**	**—**	**1,208**	**1,208**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(e)(iii)	—	—	31,195	31,195
Warrant liabilities	5(e)(vi)	—	—	13,437	13,437
Total Financial Liabilities		**—**	**—**	**44,632**	**44,632**

As of June 30, 2024 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector		—	—	1,014	1,014
Total Financial Assets		**—**	**—**	**1,014**	**1,014**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(e)(iii)	—	—	26,892	26,892
Warrant liabilities	5(e)(vi)	—	—	4,647	4,647
Total Financial Liabilities		**—**	**—**	**31,539**	**31,539**

There were no transfers between any of the levels for recurring fair value measurements during the period.

The Group’s policy is to recognize transfers into and transfers out of fair value hierarchy levels as at the end of the reporting period.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, trading and financial assets at fair value through other comprehensive income securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price. These instruments are included in level 1.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) 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. This is the case for provisions (contingent consideration), equity securities (unlisted) and warrant liabilities.

(ii) Valuation techniques used.

The Group did not hold any level 1 and level 2 financial instruments as at December 31, 2024 or June 30, 2024.

The Group's level 3 assets consists of an investment in unlisted equity securities in the biotechnology sector. Level 3 assets were 100% of total assets measured at fair value as at December 31, 2024 and June 30, 2024. The Group's level 3 liabilities consist of a contingent consideration provision related to the acquisition of the MSC assets and warrant liabilities related to the warrants granted to Oaktree as part of the debt facility. Level 3 liabilities were 100% of total liabilities measured at fair value as at December 31, 2024 and June 30, 2024. The Group used discounted cash flow analysis to determine the fair value measurements of contingent consideration and used the Black-Scholes valuation method to determine the fair value of warrant liabilities. Refer to Note 5(e)(vi) for the fair value measurement and movements in warrant liability for the period ended December 31, 2024 and June 30, 2024.

(iii) Fair value measurements using significant unobservable inputs (level 3)

The following table presents the changes in the contingent consideration balances within the level 3 instruments for the six months ended December 31, 2024 and the year ended June 30, 2024.

(in U.S. dollars, in thousands)	Contingent consideration provision
Opening balance - July 1, 2023	17,199
Reclassification during the period	—
Charged/(credited) to consolidated income statement:	
Remeasurement[(1)]	9,693
Closing balance - June 30, 2024	**26,892**
Opening balance - July 1, 2024	26,892
Charged/(credited) to consolidated income statement:	
Remeasurement[(2)]	4,303
Closing balance - December 31, 2024[(3)]	**31,195**

(1) In the year ended June 30, 2024 a loss of $9.7 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This remeasurement was a net result of changing key assumptions of the contingent consideration valuation, such as probability of success, developmental timelines and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

(2) In the six months ended December 31, 2024 a $4.3 million loss was recognized on the remeasurement of contingent consideration pertaining to the acquisition of the MSC assets. This remeasurement was a net result of changing key assumptions of the contingent consideration valuation such as probability of success, development timelines and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration including the impact of receiving FDA approval for RYONCIL in the treatment of children with SR-aGVHD in December 2024.

(3) In January 2025, as discussed in Note 11, the Group issued 10,228,239 ordinary shares to Osiris as payment for a $20.0 million milestone following the FDA approval of RYONCIL in the United States.

(iv) Valuation inputs and relationship to fair

The following table summarizes the quantitative information about the significant unobservable inputs used in level 3 fair value measurements:

(in U.S. dollars, in thousands, except percent data)					Range of inputs (weighted average)		
Description	**Fair value as of December 31, 2024**	**Fair value as of June 30, 2024**	**Valuation technique**	**Unobservable inputs[1]**	**Six Months Ended December 31, 2024**	**Year Ended June 30, 2024**	**Relationship of unobservable inputs to fair value**
Contingent consideration provision	31,195	26,892	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Six months ended December 31, 2024: A change in the discount rate by 0.5% would have no impact to the fair value. Year ended 30 June, 2024: A change in the discount rate by 0.5% would have no impact to the fair value.
				Expected unit sales price	Various	Various	Six months ended December 31, 2024: A change in the price assumptions by 10% would increase/decrease the fair value by 0.1%. Year ended 30 June, 2024: A change in the price assumptions by 10% would increase/decrease the fair value by 0.1%.
				Expected sales volumes	Various	Various	Six months ended December 31, 2024: A change in the volume assumptions by 10% would increase/decrease the fair value by 0.1%. Year ended 30 June, 2024: A change in the volume assumptions by 10% would increase/decrease the fair value by 0.1%.
				Probability of success and payment	Various	Various	Six months ended December 31, 2024: A change in the probability of success and payment assumptions by 10% and 20% would increase/decrease the fair value by 3.6% and 7.2%, respectively. Year ended 30 June, 2024: A change in the probability of success and payment assumptions by 10% and 20% would increase/decrease the fair value by 10.0% and 20.1%, respectively.

(1) There were no significant inter-relationships between unobservable inputs that materially affect fair values.

(v) Valuation processes

In connection with the acquisition of the MSC assets on October 11, 2013 (the “acquisition date”), an independent valuation of the contingent consideration was carried out by an independent valuer.

For the six months ended December 31, 2024 and the year ended June 30, 2024, the Group has adopted a process to value contingent consideration internally. This valuation has been completed by the Group’s internal valuation team and reviewed by the interim Chief Financial Officer (the "CFO"). The valuation team is responsible for the valuation model. The valuation team also manages a process to continually refine the key assumptions within the model. This is done with input from the relevant business units. The key assumptions in the model have been clearly defined and the responsibility for refining those assumptions has been assigned to the most relevant business units. For each indication we determine the probability of success based on the current development status within each jurisdiction and payment provisions within the agreement. Cash flows relevant to each jurisdiction are discounted appropriately based on the discount rate assumed. The remeasurement charged to the consolidated income statement in the six months ended December 31, 2024 was a net result of changing the key assumptions of the contingent consideration valuation such as development timelines and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent

consideration including the impact of receiving FDA approval for RYONCIL in the treatment of children with SR-aGVHD in December 2024.

The fair value of contingent consideration (in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets[(1)]	30,506	26,236
Fair value of royalty payments from commercialization of the intellectual property acquired	689	656
	31,195	**26,892**

(1) In January 2025, as discussed in Note 11, we issued 10,228,239 ordinary shares to Osiris as payment for a $20.0 million milestone following the FDA approval of RYONCIL in the United States.

The main level 3 inputs used by the Group are evaluated as follows:

Risk adjusted discount rate:	The 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, their size and number of projects) and the indicative rates of return required by suppliers of venture capital for investments with similar technical and commercial risks. This assumption is reviewed as part of the valuation process outlined above.
Expected unit sales prices:	Expected market sale price of the most comparable products currently available in the market place. This assumption is reviewed as part of the valuation process outlined above.
Expected sales volumes:	Expected sales volumes of the most comparable products currently available in the market place. This assumption is reviewed as part of the valuation process outlined above.
Probability of success and payment:	Expected cash flows used to measure contingent consideration are risk adjusted for the probability of successful development of products and payment provisions within the agreement. This assumption is reviewed as part of the valuation process outlined above.

(vi) Warrant liability

(in U.S. dollars, in thousands) **Warrant liability**	As of December 31, 2024	As of June 30, 2024
Opening balance	4,647	5,426
Remeasurement of warrant liability	11,978	(779)
Exercise of warrants	(3,188)	—
Closing Balance	**13,437**	**4,647**

On November 19, 2021, in connection with the $60.0 million drawdown of the Oaktree debt, Oaktree were granted the right to warrants to purchase 1,769,669 ADSs at $7.26 per ADS, a 15% premium to the 30-day VWAP. Given that Oaktree received an unconditional right to the warrants on November 19, 2021, this date has been determined as the measurement date. The warrants instruments were issued on January 11, 2022, following the required administrative process, and these warrants may be exercised within 7 years of issuance of the warrant instruments. The warrants do not confer any rights to dividends or a right to participate in a new issue without exercising the warrant.

On December 22, 2022, the Group amended the terms of the loan agreement with Oaktree and in connection with the loan amendment, Oaktree was granted warrants to purchase 455,000 ADSs at $3.70 per ADS, a 15% premium to the 30-day VWAP. We determined that an obligation to issue the warrants has arisen from the time the first amendment to the loan agreement was signed; consequently, a liability for the warrants has been recognized in December 2022. The warrants were legally issued on March 8, 2023 and may be exercised within 7 years of issuance.

On January 5, 2024, the ratio under Mesoblast's ADR program was changed from 5 ordinary shares representing 1 ADS (5:1 ratio) to a new ratio of 10 ordinary shares representing 1 ADS (10:1 ratio). As a result of this ratio change and as a result of completing the pro-rata accelerated non-renounceable rights issue in December 2023, the number and exercise price for the warrants was adjusted in accordance with the terms of these warrants. The warrants issued in November 2021 changed from 1,769,669 ADSs at US$7.26 per ADS to 884,838 ADSs at US$14.36 per ADS. The warrants issued in December 2022 changed from 455,000 ADSs at US$3.70 per ADS to 227,502 ADSs at US$7.24 per ADS.

The exercise price of the warrants will be received in U.S. dollars, which is different to Mesoblast Limited’s functional currency of Australian dollars which gives rise to variability in the cash flow. As a result, the warrants are classified as a financial liability in accordance with *IAS32 Financial Instruments: Presentation*. The financial liability is recorded in warrant liability at fair value at grant date and subsequently remeasured at each reporting period with changes being recorded in the Income Statement as remeasurement of warrant liability. The warrant liabilities are considered level 3 liabilities as the determination of fair value includes various assumptions about the share prices and historical volatility as inputs.

On December 31, 2024, Oaktree exercised 188,122 ADS warrants that were issued in December 2022. The Group received $1.4 million of proceeds in relation to the exercise price of the warrants at US$7.24 per ADS, which was recognized within cash and cash equivalents in December 2024. On the exercise date of December 31, 2024, the fair value of $3.2 million relating to the warrants exercised was transferred from the warrant liability to share capital within the equity statement. Subsequent to the balance sheet date, Oaktree exercised the remaining 39,380 ADS warrants that were issued in December 2022. On January 3, 2025, the Group formally issued 2,275,020 ordinary shares to Oaktree relating to the exercise of these ADS warrants.

As at December 31, 2024, and June 30, 2024 the fair value of the warrant liability was $13.4 million and $4.6 million, respectively. During the six months ended December 31, 2024, a remeasurement loss of $12.0 million was recognized on the remeasurement of warrant liability. During the six months ended December 31, 2023, a remeasurement gain of $4.4 million was recognized on the remeasurement of warrant liability.

(vii) Fair value of warrants

The warrants granted are not traded in an active market and therefore the fair value has been estimated by using the Black-Scholes valuation method based on the following assumptions. Key terms of the warrants are included below. The following assumptions were based on observable market conditions that existed at the issue date and as of December 31, 2024.

(in U.S. dollars, except percent data and as otherwise noted) Assumption	As of December 31, 2024	As of June 30, 2024	Rationale
Share Price	$19.80	$6.81	Closing share price on valuation date from external market source
Exercise Price	$7.24 to $14.36	$7.24 to $14.36	As per subscription agreement
Expected Term	4 to 6 years	5 to 6 years	As per subscription agreement
Dividend Yield	0%	0%	Based on Company's nil dividend history
Expected Volatility	92.19%	91.91%	Based on historical volatility data for the Company
Risk Free Interest Rate	4.48%	4.38%	Based on the closing U.S treasury issued 7 year bonds on valuation date
Fair value per warrant	$14.4322 to $16.9444	$3.9352 to $5.1211	Determined using Black-Scholes valuation model with the inputs above
Fair value	$13,437,429	$4,647,075	Fair value of 924,218 warrants of $13,437,429 as of December 31, 2024 and fair value of 1,112,340 warrants of $4,647,075 as of June 30, 2024.

6. Non-financial assets and liabilities

a. Intangible assets

(in U.S. dollars, in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Current marketed products	Total
Year Ended June 30, 2024					
Opening net book amount	134,453	1,618	427,779	13,333	577,183
Additions	—	37	—	—	37
Exchange differences	—	1	—	—	1
Amortization charge	—	(30)	—	(1,455)	(1,485)
Closing net book amount	**134,453**	**1,626**	**427,779**	**11,878**	**575,736**
As of June 30, 2024					
Cost	134,453	3,032	489,698	24,000	651,183
Accumulated amortization	—	(1,406)	—	(12,122)	(13,528)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,626**	**427,779**	**11,878**	**575,736**
Six Months Ended December 31, 2024					
Opening net book amount	134,453	1,626	427,779	11,878	575,736
Additions	—	50	—	—	50
Reclassification[(1)]	—	—	(102,698)	102,698	—
Exchange differences	—	—	—	—	—
Amortization charge	—	(12)	—	(895)	(907)
Closing net book amount	**134,453**	**1,664**	**325,081**	**113,681**	**574,879**
As of December 31, 2024					
Cost	134,453	3,054	387,000	126,697	651,204
Accumulated amortization	—	(1,390)	—	(13,016)	(14,406)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,664**	**325,081**	**113,681**	**574,879**

(1) The Group reclassified $102.7 million from in-process research and development ("IPRD") acquired to current marketed products upon receiving FDA approval for RYONCIL for the treatment of pediatric SR-aGVHD in December 2024. As a result of this reclassification, the asset is now being amortized on a straight line basis over its useful life through to expected patent expiry which is 22 years.

(i) Carrying value of in-process research and development acquired by product

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Cardiovascular products[1]	254,351	254,351
Intravenous products for metabolic diseases and inflammatory/immunologic conditions[2]	70,730	70,730
MSC products[3]	—	102,698
	325,081	**427,779**

(1) Includes MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction

(2) Includes MPC-300-IV for the treatment of biologic-refractory rheumatoid arthritis and diabetic nephropathy

(3) Includes the treatment of SR-aGVHD and Crohn's disease. In December 2024, the carrying value of in-process research and development acquired relating to MSC products was reclassified to currently marketed products on FDA approval of RYONCIL for the treatment of pediatric SR-aGVHD in December 2024.

For all products included within the above balances, the underlying currency of each item recorded is US$.

(ii) Significant estimate: Impairment of goodwill and assets with an indefinite useful life

The Group tests annually, or more frequently if events or changes in circumstances indicate that they might be impaired, whether goodwill and its assets with indefinite useful lives have suffered any impairment in accordance with its accounting policy stated in Note 23(j) in the Form 20-F for the year ended June 30, 2024. The recoverable amounts of these assets and cash-generating units have been determined based on fair value less costs to dispose calculations, which require the use of market-participant assumptions that are based on development strategies using external data sources as well as past experience. The full annual impairment assessment was performed at March 31, 2024 and no impairment of the in-process research and development and goodwill was identified.

In December 2024, the FDA approved RYONCIL for the treatment of pediatric SR-aGVHD, and as a result the Group reclassified the carrying value relating to MSC products from in-process research and development to currently marketed products. The Group completed an impairment assessment on its MSC products intangible asset as at December 31, 2024 as a result of the change from indefinite-lived in-process research and development to finite-lived currently marketed product. The assumptions used in the impairment assessment were updated from the March 31, 2024 impairment assessment and included changes to the probability of success, product pricing and development timelines. The impairment assessment on the MSC products intangible asset has been determined based on fair value less costs to dispose calculations as at December 31, 2024 and no impairment of the MSC products intangible asset was identified.

(iii) Impairment tests for goodwill and intangible assets with an indefinite useful life

In-process research and development acquired is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form (see Note 23(p)(iii) in the Form 20-F for the year ended June 30, 2024). The intangible asset's life will remain indefinite until such time it is completed and commercialized or impaired. The carrying value of in-process research and development is a separate asset which has been subject to impairment testing at the cash generating unit level, which has been determined to be at the product level.

On acquisition, goodwill was not able to be allocated to the cash generating unit ("CGU") level or to a group of CGU given the synergies of the underlying research and development. For the purpose of impairment testing, goodwill is monitored by management at the operating segment level. The Group is managed as one operating segment, being the development of cell technology platform for commercialization.

The recoverable amount of both goodwill and in-process research and development was assessed as of March 31, 2024 based on the fair value less costs to dispose. As a result of the FDA approved RYONCIL for the treatment of pediatric SR-aGVHD in December 2024, an impairment assessment was performed over the Group's MSC products intangible asset as of December 31, 2024 based on fair value less costs to dispose. No impairment was identified as a result of these impairment assessments.

Management assessed the remaining in-process research and development assets for indicators of impairment as at December 31, 2024 including considering events up to the date of the approval of the financial statements. No impairment indicators as at December 31, 2024 were identified.

(iv) Key assumptions used for fair value less costs to dispose calculations

In determining the fair value less costs to dispose the Group has given consideration to the following internal and external indicators:

- discounted expected future cash flows of programs valued by the Group's internal valuation team and reviewed by the interim CFO. The valuation team also manages a process to continually refine the key assumptions within the model. This is done with input from the relevant business units. The key assumptions in the model have been clearly defined and the responsibility for refining those assumptions has been assigned to the most relevant business units. When determining key assumptions, the business units refer to both external sources and past experience as appropriate. The valuation is considered to be level 3 in the fair value hierarchy due to unobservable inputs used in the valuation;
- the scientific results and progress of the trials since acquisition;
- the market capitalization of the Group on the ASX (ASX:MSB); and
- the valuation of the Group's assets from an independent valuation. An independent valuation was obtained for all assets at March 31, 2024 and for the MSC products intangible asset and goodwill an impairment assessment was performed at December 31, 2024 as a result of the FDA approved RYONCIL for the treatment of pediatric SR-aGVHD in December 2024.

Costs of disposal were assumed to be immaterial.

Discounted cash-flows used a real post-tax discount rate range of 13.8% to 15.5%, and include estimated real cash inflows and outflows for each program through to expected patent expiry which ranges from 8 to 24 years.

In relation to cash outflows consideration has been given to cost of goods sold, selling costs and clinical trial schedules including estimates of numbers of patients and per patient costs. Associated expenses such as regulatory fees and patent maintenance have been included as well as any further preclinical development if applicable.

In relation to cash inflows consideration has been given to product pricing, market population and penetration, sales rebates and discounts, launch timings and probability of success in the relevant applicable markets.

There are no standard growth rates applied, other than our estimates of market penetration which increase initially, plateau and then decline.

The assessment of the recoverable amount of each product has been made in accordance with the discounted cash-flow assumptions outlined above. The assessments showed that the recoverable amount of each product exceeds the carrying amount and therefore there is no impairment.

The assessment of goodwill showed the recoverable amount of the Group's operating segment, including goodwill and remaining in-process research and development, exceeds carrying amounts, and therefore there is no impairment.

(v) Impact of possible changes in key assumptions

The Group has considered and assessed reasonably possible changes in the key assumptions and has not identified any instances that could cause the carrying amount of our intangible assets to exceed its recoverable amount.

Whilst there is no impairment, the key sensitivities in the valuation are dependent on the continued successful development of our technology platforms. If the Group is unable to successfully develop our technology platforms, an impairment of the carrying amount of our intangible assets may result.

b. Provisions

(in U.S. dollars, in thousands)	Notes	As of December 31, 2024 Current	Non-current	Total	As of June 30, 2024 Current	Non-current	Total
Contingent consideration[(1)]		20,625	10,570	31,195	16,298	10,594	26,892
Employee benefits		3,192	11	3,203	7,436	26	7,462
Provision for license agreements		3,750	—	3,750	3,750	—	3,750
Provision for litigation settlements	13	—	—	—	17,554	—	17,554
		27,567	**10,581**	**38,148**	**45,038**	**10,620**	**55,658**

(1) The classification of contingent consideration as current represents the expected payments within the next 12 months based on current development timelines. In January 2025, as discussed in Note 11, we issued 10,228,239 ordinary shares to Osiris as payment for a $20.0 million milestone following the FDA approval of RYONCIL in the United States.

(i) Information about individual provisions and significant estimates

Contingent consideration

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements pertaining to the acquired MSC assets from Osiris. Further disclosures can be found in Note 5(e)(iii).

Employee benefits

The provision for employee benefits relates to the Group's liability for annual leave, short term incentives and long service leave.

Employee benefits include accrued annual leave. As at December 31, 2024 and June 30, 2024, the entire amount of the annual leave accrual was $1.1 million and $1.2 million respectively, and is presented as current, since the Group does not have an unconditional right to defer settlement for any of these obligations.

Employee benefits include a provision for the Group's liability for short term incentives. As at December 31, 2024 and June 30, 2024, the provision for short term incentives was $1.4 million and $5.4 million, respectively, and the provision as of June 30, 2024 of $5.4 million included $2.4 million and $3.0 million relating to the entitlements for the years ended June 30, 2024 and 2023, respectively, given that the conditions of achievement of the short term incentive for the years ended June 30, 2024 and 2023 were modified to make it dependent on Mesoblast achieving FDA marketing authorization. In August, 2024, the compensation structure for short-term incentives were revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled the Group to avoid a $6.7 million cash payment of short-term incentives. The options granted in lieu of cash resulted in a $5.4 million reduction in the provision for short term incentives relating to the entitlements for the year ended June 30, 2024 and 2023.

(ii) Movements

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements. Refer to Note 5(e)(iii) for movements in contingent consideration for the period ended December 31, 2024 and June 30, 2024.

c. Deferred tax balances

(i) Deferred tax balances

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	79,301	74,602
Other temporary differences	8,292	13,143
Total deferred tax assets	**87,593**	**87,745**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	87,593	87,745
Total deferred tax liabilities	**87,593**	**87,745**
Net deferred tax liabilities	**—**	**—**

(ii) Movements

(in U.S. dollars, in thousands)	Tax losses[(1)] (DTA)	Other temporary differences[(1)] (DTA)	Intangible assets (DTL)	Total (DTL)
As of June 30, 2023	**76,020**	**11,972**	**(87,992)**	**—**
Charged/(credited) to:				
- profit or loss	(1,227)	1,171	247	**191**
- directly to equity	(191)	—	—	**(191)**
As of June 30, 2024	**74,602**	**13,143**	**(87,745)**	**—**
Charged/(credited) to:				
- profit or loss	4,487	(4,851)	152	**(212)**
- directly to equity	212	—	—	**212**
As of December 31, 2024	**79,301**	**8,292**	**(87,593)**	**—**

(1) Deferred tax assets are netted against deferred tax liabilities

d. Inventories and other current assets

(i) Inventories

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Current Assets		
Raw materials	946	—
Work in progress	—	—
Finished goods	23,248	—
	24,194	—

(ii) Assigning costs to inventories

Inventories are included in the financial statements at the lower of cost (including raw materials, direct labor, other direct costs and related production overheads) and net realizable value. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product in accordance with IAS 2 *Inventories*. Before that point, a provision is made against the carrying value to its recoverable amount in accordance with IAS 2 *Inventories*; the provision is then reversed at the point when a high probability of regulatory approval is determined.

The Group considers a number of factors in determining the probability of the product candidate realizing future economic benefit, including the product candidate's current status in the regulatory approval process, results from the related pivotal clinical trial, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, the market need, historical experience, as well as potential impediments to the approval process such as product safety or efficacy, commercialization and market trends.

When a provision is made against the carrying value of pre-launch inventory the costs are recognized within Manufacturing Commercialization expenses. When the high probability threshold is met, the provision is reversed through Manufacturing Commercialization expenses.

Where it is determined that the pre-launch inventory will be used within a clinical trial, that amount is removed from the cost of pre-launch inventory.

As of June 30, 2024, all inventory costs were fully provided for and recognized within Manufacturing Commercialization expenses. In December 2024, the FDA approved Mesoblast's RYONCIL for the treatment of SR-aGvHD in children 2 months and older. As a result of the FDA approval in December 2024, the Group determined that there is a high probability of the product candidate realizing future economic benefit, and therefore the provision against the carrying value of pre-launch inventory was reversed through Manufacturing Commercialization expenses.

As of December 31, 2024, there was $24.7 million of inventory recognized on the balance sheet, of which $0.5 million was provided for as obsolete stock, compared with $19.2 million at June 30, 2024, which was fully provided for.

(iii) Amounts recognized in profit or loss

As of December 31, 2024, the Group recognized inventory of $24.2 million on the balance sheet, which had been fully provided for and recognized within Manufacturing Commercialization expenses previously. As a result of the FDA approval of Mesoblast's RYONCIL in December 2024, in the six months ended December 31, 2024 a corresponding reversal was recorded within Manufacturing Commercialization expenses as the provision against the carrying value of inventory was reversed.

7. Cash flow information

(in U.S. dollars, in thousands) (a) Reconciliation of cash and cash equivalents	As of December 31, 2024	As of June 30, 2024
Cash at bank	37,656	62,563
Deposits at call	373	397
	38,029	**62,960**

(in U.S. dollars, in thousands)	Six Months Ended December 31,	
(b) Reconciliation of net cash flows used in operations with loss after income tax	**2024**	**2023**
Loss for the period	(47,934)	(32,539)
Add/(deduct) net loss for non-cash items as follows:		
Depreciation and amortization	2,081	2,443
Foreign exchange (gains)/losses	616	(159)
Finance costs	10,790	10,319
Remeasurement of contingent consideration	4,303	337
Remeasurement of warrant liabilities	11,978	(4,434)
Restructure of short term incentive	6,711	—
Equity settled share-based payment	15,172	2,195
Deferred tax expense/(benefit)	212	(102)
Adjustment for pre-launch inventory	(24,194)	—
Change in operating assets and liabilities:		
Decrease/(increase) in trade and other receivables	17,567	2,084
Decrease/(increase) in prepayments	(1,198)	(131)
Decrease/(increase) in tax incentive recoverable	424	1,094
Increase/(decrease) in trade and other payables	4,710	(9,500)
Increase/(decrease) in provisions	(21,893)	1,821
Net cash outflows used in operations	**(20,655)**	**(26,572)**

8. Equity

a. Contributed equity

(i) Share capital

	As of December 31,			
	2024	**2023**	**2024**	**2023**
	Shares No.		**(U.S. dollars, in thousands)**	
Contributed equity				
(i) Share capital				
Ordinary shares	1,154,023,928	1,015,342,237	1,320,207	1,286,229
Less: Treasury Shares	(1,579,499)	(542,903)	—	—
Total Contributed Equity	**1,152,444,429**	**1,014,799,334**	**1,320,207**	**1,286,229**

(ii) Movements in ordinary share capital

	Six Months Ended December 31,		Six Months Ended December 31,	
	2024	2023	2024	2023
	Shares No.		(U.S. dollars, in thousands)	
Opening balance	1,141,784,114	814,204,825	1,310,813	1,249,123
Issues of ordinary shares during the period				
Exercise of share options[(1)]	—	—	1,341	—
Transfer to employee share trust[(1)]	7,200,000	—	—	—
Placement of shares under a share placement agreement[(2)]	5,039,814	—	1,000	—
Placement of shares under a share placement agreement[(3)]	—	201,137,412	—	39,708
Transaction costs arising on share issue	—	—	(110)	(2,602)
Total contributions of equity during the period	12,239,814	201,137,412	2,231	37,106
Unissued ordinary shares during the period				
Placement of shares under a share placement agreement[(2)]	—	—	(1,000)	—
Exercise of warrants[(4)]	—	—	4,550	—
Total contributions of unissued equity during the period	—	—	3,550	—
Total contributions of equity during the period	12,239,814	201,137,412	5,781	37,106
Share options reserve transferred to equity on exercise of options	—	—	3,613	—
Ending balance	**1,154,023,928**	**1,015,342,237**	**1,320,207**	**1,286,229**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Option Plan. Unpaid shares are issued to the share trust to enable future option exercises to be settled. On exercise of options, the proceeds of the exercise are recorded in ordinary share capital in Mesoblast Limited and the exercise is settled by transfer of the shares from the share trust to the employee.

(2) In March 2024, Dr. Eric Rose, the Company's Chief Medical Offer and a director of Mesoblast, subscribed for 5,039,814 shares in Mesoblast Limited at A$0.30 per share, subject to shareholder approval which was received in November 2024. The shares remained in unissued capital until the shares were issued in December 2024.

(3) During the six months ended December 31, 2023, 201,137,412 shares were issued in a 1 for 4 pro-rata accelerated non-renounceable entitlement offer of new fully paid ordinary shares in Mesoblast Limited to existing shareholders in Australia and certain other countries together with an institutional placement of new fully paid ordinary shares in Mesoblast Limited, at A$0.30 per share.

(4) On December 31, 2024, Oaktree exercised 188,122 ADS warrants that were issued in December 2022. The Group received $1.4 million of proceeds in relation to the exercise price of the warrants at US$7.24 per ADS, which was recognized within cash and cash equivalents in December 2024. On the exercise date of December 31, 2024, the fair value of $3.2 million relating to the warrants exercised and the exercise price of $1.3 million were recognized as unissued capital within the equity statement and remained as unissued capital until the shares were formally issued. On January 3, 2025, the Group formally issued 1,881,220 ordinary shares to Oaktree in relation to the exercise of these ADS warrants.

(iii) Movements of shares in share trust

	Six Months Ended December 31,		Six Months Ended December 31,	
	2024	2023	2024	2023
	Shares No.		(U.S. dollars, in thousands)	
Opening balance	542,903	542,903	—	—
Movement of shares in share trust				
Transfer to employee share trust[(1)]	7,200,000	—	—	—
Exercise of share options[(1)]	(6,163,404)	—	—	—
Ending balance	**1,579,499**	**542,903**	**—**	**—**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Option Plan. Unpaid shares are issued to the share trust to enable future option exercises to be settled. On exercise of options, the proceeds of the exercise are recorded in ordinary share capital in Mesoblast Limited and the exercise is settled by transfer of the shares from the share trust to the employee.

b. Warrant reserve

(in U.S. dollars, in thousands)	As of December 31,	As of June 30,
Warrant reserve	2024	2024
Opening balance	12,969	12,969
Movement during the period	—	—
Closing Balance	**12,969**	**12,969**

In March 2021, the Group completed a A$138.0 million (US$110.0 million) private placement of 60,109,290 new fully-paid ordinary shares at a price of A$2.30. As part of this placement, the Group also issued one warrant for every four ordinary shares issued in the placement, which resulted in a further 15,027,327 warrants issued. Each warrant has an exercise price of A$2.88 per share and a 7-year term. The Group has a right to compel exercise of the warrants at any time, subject to the price of the Group's ordinary shares trading at least A$4.32 for 45 consecutive days on the ASX. The warrants do not confer any rights to dividends or a right to participate in a new issue without exercising the warrant. As a result of completing the pro-rata accelerated non-renounceable rights issue in December 2023, the exercise price for the warrants was adjusted from A$2.88 per share to A$2.86 per share with effect from January 5, 2024.

The terms of the warrants include certain anti-dilution clauses, which adjust the exercise price or conversion ratio in the event of a rights issue or bonus issue. Management analyzed these clauses and determined the fixed-for-fixed requirement was still satisfied because the relative rights of shareholders and warrant holders were maintained. Therefore the warrants were classified as equity. The warrants were initially measured in equity at fair value, which was determined using a Monte Carlo simulation (refer to Note 7(b)(iv) in the Form 20-F for the year ended June 30, 2024 for more details), with the residual consideration being attributed to the ordinary shares issued in the same transaction. The warrants are not remeasured for subsequent changes in fair value.

9. Financial risk management

This note explains the Group's exposure to financial risks and how these risks could affect the Group's future financial performance. Current year profit and loss information has been included where relevant to add further context.

Risk	Exposure arising from	Measurement	Management
Market risk – currency risk	Future commercial transactions Recognized financial assets and liabilities not denominated in the functional currency of each entity within the Group	Cash flow forecasting Sensitivity analysis	The future cash flows of each currency are forecast and the quantum of cash reserves held for each currency are managed in line with future forecasted requirements. Cross currency swaps are undertaken as required.
Market risk – interest rate risk	Term deposits at fixed rates Cash deposits at variable rates	Sensitivity analysis	Vary length of term deposits, utilize interest bearing accounts and periodically review interest rates available to ensure we earn interest at market rates.
Market risk – price risk	Long-term borrowings	Sensitivity analysis	Forecasts of net sales of the product underlying the NovaQuest borrowing arrangement are updated on a quarterly basis to evaluate the impact on the carrying amount of the financial liability.
Market risk – share price risk	Warrant liability	Sensitivity analysis	The future exercise of warrants will not impact the Group's future cash flows significantly given the warrants will be paid in shares upon exercise. Therefore there are no significant cashflow risks associated with these warrants. The Group monitors the impact on profit or loss that share price movements have on the valuation of the warrant liability each period.
Credit risk	Cash and cash equivalents, and trade and other receivables and other non-current assets	Aging analysis Credit ratings	Transact primarily with the best risk rated banks available in each region giving consideration to the products required, the quantum of cash reserves held and future forecasted requirements.
Liquidity risk	Cash and cash equivalents, borrowings, trade payables, lease liabilities and contingent consideration	Rolling cash flow forecasts	Future cash flow requirements are forecasted and capital raising strategies are planned to ensure sufficient cash balances are maintained to meet the Group's future commitments.

a. Market risk

(i) Currency risk

The Group has foreign currency amounts owing relating to clinical, regulatory and overhead activities and foreign currency deposits held primarily in the Group's Australian based entity, whose functional currency is the A$. The Group also has foreign currency amounts owing in the Group's Swiss and Singapore based entities, whose functional currencies are the US$. The Group also has foreign currency amounts owing in various other non-US$ currencies in A$ and US$ functional currency entities in the Group relating to clinical, regulatory and overhead activities. These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on the Group's financial performance.

Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

As of December 31, 2024, the Group held 73% of its cash in US$, 26% in A$ and 1% in other currencies. As of June 30, 2024, the Group held 76% of its cash in US$, and 23% in A$ and 1% in other currencies.

(ii) Cash flow and fair value interest rate risk

The Group is exposed to interest rate movements which impacts interest income earned on its deposits and at call accounts. The interest rate risk is managed by spreading the maturity date of our deposits across various periods. The Group ensures that sufficient funds are available, in at call accounts, to meet the working capital requirements of the Group.

The deposits held which derive interest revenue are described in the table below, together with the maximum and minimum interest rates being earned as of December 31, 2024 and June 30, 2024. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

	As of December 31, 2024			As of June 30, 2024		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**US$**	**Low**	**High**	**US$**
Funds invested - US$	1.05%	1.05%	9,850	1.84%	1.84%	25,123
Rate increase by 10%	1.16%	1.16%	10	2.02%	2.02%	46
Rate decrease by 10%	0.95%	0.95%	(10)	1.66%	1.66%	(46)

	As of December 31, 2024			As of June 30, 2024		
(in Australian dollars, in thousands, except percent data)	**Low**	**High**	**A$**	**Low**	**High**	**A$**
Funds invested - A$	3.85%	4.91%	16,273	3.85%	4.86%	22,169
Rate increase by 10%	4.24%	5.40%	70	4.24%	5.35%	95
Rate decrease by 10%	3.47%	4.42%	(70)	3.47%	4.37%	(95)

(iii) Price risk

Price risk is the risk that future cash flows derived from financial instruments will be altered as a result of a market price movement, which is defined as movements other than foreign currency rates and interest rates. The Group is exposed to price risk which arises from long-term borrowings under its facility with NovaQuest, where the timing and amounts of principal and interest payments is dependent on net sales of RYONCIL for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of RYONCIL for the treatment of SR-aGVHD in pediatric patients in these territories increase/decrease, the timing and amount of principal and interest payments relating to this type of financing arrangement will also fluctuate, resulting in an adjustment to the carrying amount of the financial liability. The adjustment is recognized in the Consolidated Income Statement as remeasurement of borrowing arrangements within finance costs in the period the revision is made.

The exposure of the Group's borrowing to price rate changes are as follows:

	As of December 31, 2024		As of June 30, 2024	
(in U.S. dollars, in thousands, except percent data)	**Total**	**% of total borrowings**	**Total**	**% of total borrowings**
Financial liabilities				
Current borrowings				
Borrowings - NovaQuest	3,721	3%	336	0%
Non-current borrowings				
Borrowings - NovaQuest	68,673	58%	55,739	51%
	72,394	**61%**	**56,075**	**51%**

As at December 31, 2024, all other factors held constant, a +/- 20% increase/decrease in the forecast net sales of RYONCIL for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia would not have a significant impact on non-current borrowings and losses.

The Group is also exposed to price risk on contingent consideration provision balances, as expected unit revenues are a significant unobservable input used in the level 3 fair value measurements. As at December 31, 2024, all other factors held constant, the increase/decrease in price assumptions adopted in the fair value measurements of the contingent consideration provision are discussed in Note 5(e)(*iv*).

The Group does not consider it has any exposure to price risk other than those already described above.

(iv) Share price risk

The Group's exposure to share price risk arises from warrant liabilities held by the Group and classified in the statement of financial position at fair value through profit or loss. The future exercise of these warrants will not impact the Group's future cash flows significantly given the warrants will be paid in shares upon exercise, therefore there are no significant cashflow risks associated with these warrants. The Group monitors the impact on profit or loss that share price movements have on the valuation of the warrant liability each period.

The table below summarizes the impact of the increase/decrease of Mesoblast's share price on the Group's profit or loss during the period, based on the assumption that the share price had increased/decreased by 10% and 10% with all other variables held constant as of December 31, 2024 and June 30, 2024 respectively.

(in U.S. dollars, in thousands)	As of December 31, 2024	As of June 30, 2024
Financial liabilities		
Warrant liability	13,437	4,647
Impact on profit or (loss)		
Share price increase by 10% (2024: 10%)	(1,632)	(598)
Share price decrease by 10% (2024: 10%)	1,613	587

b. Credit risk

Credit risk is the risk that one party to a financial instrument will fail to discharge its obligation and cause financial loss to the other party. The maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets as mentioned in Note 5.

c. Liquidity risk

Liquidity risk is the risk that the Group will not be able to pay its debts as and when they fall due. Liquidity risk has been assessed in Note 1(i).

All financial liabilities, excluding contingent consideration, borrowings and lease liabilities held by the Group as of December 31, 2024 and June 30, 2024 mature within 6 months. Trade payables and contingent consideration held by the Group as of December 31, 2024 and June 30, 2024 are non-interest bearing. The total contractual cash flows associated with trade payables equate to the carrying amount disclosed within the financial statements.

As of December 31, 2024, the maturity profile of the anticipated future contractual cash flows on an undiscounted basis and removing probability adjustments as applicable for contingent consideration, and which therefore differs from the carrying value, is as follows:

(in U.S. dollars, in thousands)	Within 1 year	Between 1-2 years	Between 2-5 years	Over 5 years	Total contractual cash flows	Carrying amount
Borrowings[1][2]	(19,673)	(131,199)	—	—	(150,872)	(118,981)
Trade payables	11,860	—	—	—	11,860	(11,860)
Lease liabilities	(2,780)	(3,052)	(1,818)	(417)	(8,067)	(7,131)
Contingent consideration[3]	(6,247)	(720)			(6,967)	(689)
	(16,840)	**(134,971)**	**(1,818)**	**(417)**	**(154,046)**	**(138,661)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at December 31, 2024 without taking into account drawdowns of further tranches.

(2) In relation to the contractual maturities of the NovaQuest borrowings, there is variability in the maturity profile of the anticipated future contractual cash flows given the timing and amount of payments are calculated based on our estimated net sales of RYONCIL for the treatment of pediatric SR-aGVHD in the United States and other territories excluding Asia**.**

(3) In relation to the contractual maturities of the royalty payments related to contingent consideration, there is variability in the maturity profile of the anticipated future contractual cash flows given the timing and amount of payments are calculated based on our estimated net sales of RYONCIL for the treatment of children and adults with aGVHD. Product royalties will be payable in cash which will be funded from royalties received from net sales. With respect to future milestone payments, contingent consideration will be payable in cash or shares at our discretion. The carrying amount reflects the discounted and probability adjusted contractual balance related to royalty payments.

Purchase commitments

In December 2019, the Group commenced production under its manufacturing service agreement with Lonza for the supply of commercial product for the potential approval and launch of RYONCIL for the treatment of pediatric SR-aGVHD in the US market. This agreement contains lease and non-lease components. As of December 31, 2024, the agreement contains a minimum remaining financial commitment of the non-lease component of $11.6 million, payable until June 2026. The Group has accounted for the lease component within the agreement as a lease liability separately from the non-lease components. As of December 31, 2024, the lease component is $2.9 million on an undiscounted basis, as disclosed within the total contractual cash flows as lease liabilities in Note 9(c).

The Group have agreements with third parties related to contract manufacturing and other goods and services. As of December 31, 2024, the Group had $3.6 million of non-cancellable purchase commitments related to raw materials, manufacturing agreements and other goods and services (excluding those with Lonza). This amount represents our minimum contractual obligations, including termination fees. Certain agreements provide for termination rights subject to termination fees. Under such agreements, the Group are contractually obligated to make certain payments, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation.

The Group did not have any other purchase commitments as of December 31, 2024.

10. (Losses) per share

	Six Months Ended	
	December 31, 2024	December 31, 2023
	Cents	Cents
(Losses) per share		
(in cents)		
(a) Basic (losses) per share		
From continuing operations attributable to the ordinary equity holders of the company	(4.20)	(3.72)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(4.20)**	**(3.72)**
(b) Diluted (losses) per share		
From continuing operations attributable to the ordinary equity holders of the company	(4.20)	(3.72)
Total diluted (losses) per share attributable to the ordinary equity holders of the company	**(4.20)**	**(3.72)**
(c) (Losses) used in calculating (losses) per share		
(in U.S. dollars, in thousands)		
Basic (losses) per share		
(Losses) attributable to the ordinary equity holders of the company used in calculating basic (losses) per share:		
From continuing operations	(47,934)	(32,539)
Diluted (losses) per share		
(Losses) from continuing operations attributable to the ordinary equity holders of the company:		
Used in calculating basic (losses) per share	(47,934)	(32,539)
(Losses) attributable to the ordinary equity holders of the company used in calculating diluted losses per share	(47,934)	(32,539)

	Six Months Ended	
	December 31, 2024	December 31, 2023
	(In Shares)	(In Shares)
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	1,142,301,447	875,366,004
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	1,142,301,447	875,366,004

Options granted to employees and warrants are considered to be potential ordinary shares. These securities have been excluded from the determination of basic losses per share in the six months ended December 31, 2024 and 2023. Shares that may be paid as contingent consideration have also been excluded from basic losses per share. They have been excluded from the calculation of diluted losses per share because they are anti-dilutive for the six months ended December 31, 2024 and 2023.

The calculations for the six months ended December 31, 2023 have been adjusted to reflect the bonus element in the entitlement offer to existing eligible shareholders which completed in March 2024.

11. Events occurring after the reporting period

In January 2025, the Group completed a global private placement primarily to Mesoblast's existing major US, UK, and Australian shareholders raising $161.0 million at A$2.50 per share. In January 2025, proceeds of $161.0 million were received and recognized in cash and cash equivalents.

In January 2025, the Group issued 10,228,239 ordinary shares to Osiris as payment for a $20.0 million milestone within contingent consideration recognized on the balance sheet following the FDA approval of RYONCIL in the United States.

There were no other events that have occurred after December 31, 2024 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

12. Segment information

Operating segments are identified on the basis of whether the allocation of resources and/or the assessment of performance of a particular component of the Company's activities are regularly reviewed by the Company's chief operating decision maker as a separate operating segment. By these criteria, the activities of the Company are considered to be one segment being the development of adult stem cell technology platform for commercialization, and the segmental analysis is the same as the analysis for the Company as a whole. The chief operating decision maker (Chief Executive Officer) reviews the consolidated income statement, balance sheet, and statement of cash flows regularly to make decisions about the Company's resources and to assess overall performance.

In July 2024, the IASB published an IFRIC agenda decision clarifying certain requirements for segment disclosures in accordance with IFRS 8. Since the Company is operating as one segment, no impact is expected.

13. Legal proceedings

In August 2024, the Company announced that the consolidated shareholder class action, filed in the Federal Court of Australia in 2022, had been settled subject to Federal Court approval which was subsequently obtained on December 13, 2024. The settlement (inclusive of interest and costs) was fully funded by the insurer and includes no admission of liability. As a result, in December 2024, the Group reversed the provision for litigation settlement in the consolidated balance sheet (inclusive of interest and costs), refer to Note 6(b). Given the settlement has been funded entirely by Mesoblast's insurers, the Group also reversed the insurance asset within trade and other receivables in the consolidated balance sheet on settlement in December 2024, refer to Note 5(b).

Australian Disclosure Requirements

Directors' Declaration

In accordance with a resolution of directors of Mesoblast Limited,

In the director's opinion:

a) the financial statements and notes set out on pages 6 to 43 are in accordance with the *Corporations Act 2001,* including:

   i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements, and

   ii) giving a true and fair view of the consolidated entity's financial position as at December 31, 2024 and of its performance for the six months ended on that date, and

b) there are reasonable grounds to believe that the Group will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

/s/ Jane Bell	/s/ Silviu Itescu
Jane Bell	Silviu Itescu
Chair of Board	Chief Executive Officer

February 27, 2025
Melbourne

Preparation of interim financial statements

The Company has prepared the interim financial statements to conform to the requirements applicable in both Australia and the United States.

The Company has prepared the interim financial statements to conform to the requirements of IAS 34 *Interim Financial Reporting*. The Company has labelled the interim financial information "unaudited" because the interim financial information is not subject to an audit by our independent registered public accounting firm. The Appendix 4D, auditor's independence declaration and independent auditor's review report are included within this filing to meet the requirements of Australian laws and regulations and are not incorporated in any registration statement under the U.S. Securities Act of 1933.

The Company has prepared the interim financial statements to conform to the requirements of the *Corporations Act 2001* and AASB 134 Interim Financial Reporting. A review of the interim financial information has been performed by the Company's independent auditors to meet the requirements of Australian Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* and users should refer to the auditor's independence declaration and independent auditor's review report included within this filing.

Independent auditor's review report to the members of Mesoblast Limited

Report on the half-year financial report

Conclusion

We have reviewed the half-year financial report of Mesoblast Limited (the Company) and the entities it controlled during the half-year (together the Group), which comprises the Condensed consolidated balance sheet as at 31 December 2024, the Condensed consolidated statement of comprehensive income, Condensed consolidated statement of changes in equity, Condensed consolidated statement of cash flows and Condensed consolidated income statement for the half-year ended on that date, selected explanatory notes and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Mesoblast Limited does not comply with the *Corporations Act 2001* including:

1. giving a true and fair view of the Group's financial position as at 31 December 2024 and of its performance for the half-year ended on that date

2. complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report.

We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Responsibilities of the directors for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report, in accordance with Australian Accounting Standards and the *Corporations Act 2001*, including giving a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement whether due to fraud or error.

Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true

and fair view of the Group's financial position as at 31 December 2024 and of its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

PricewaterhouseCoopers

Jon Roberts
Partner

Melbourne
27 February 2025

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements included in this Report on Form 6-K. We present our condensed consolidated financial statements in U.S. dollars and in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, or IFRS, and Australian equivalent International Financial Reporting Standards, as issued by the Australian Accounting Standards Board.

For us and our subsidiaries that use a functional currency that is not U.S. dollars, the assets and liabilities have been translated at the closing exchange rate, while the income and expenses have been translated at the average exchange rate. The resulting exchange differences are recognized in our consolidated statement of comprehensive income. See note 23(d) in the notes to our consolidated financial statements and the related notes thereto included in our annual report on Form 20-F for the fiscal year ended June 30, 2024 ("Form 20-F"), filed with the Securities and Exchange Commission on August 29, 2024, for more information.

Our fiscal year ends each year on June 30. Reference to a year relates to the fiscal year, ended in June 30 of the year indicated, rather than the calendar year, unless indicated by a specific date.

Overview

Mesoblast is a world leader in developing allogeneic (off-the shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The therapies from our proprietary mesenchymal lineage cell therapy technology platform respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process. We have developed a range of products and late-stage product candidates derived from our first and second generation proprietary mesenchymal lineage cell therapy technology platforms.

Mesoblast's Ryoncil® (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months and older is the first FDA-approved mesenchymal stromal cell (MSC) therapy.

We are committed to developing additional cell therapies for distinct indications based on our remestemcel-L (RYONCIL) and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L (RYONCIL) is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L, our second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product candidate, is being developed for chronic heart failure with reduced ejection fraction (HFEF) and persistent inflammation, congenital heart disease, and chronic low back pain (CLBP). We have established commercial partnerships in Japan, Europe and China.

About **our intellectual property:** We have a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications are expected to provide commercial protection extending through to at least 2041 in major markets.

About **our manufacturing:** Our proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

On February 24, 2025, we appointed Dr. Gregory George MD PhD, our largest shareholder, to our Board of Directors.

On January 31, 2025, we provided an update on the progress of the U.S. commercial launch of RYONCIL for SR-aGvHD in pediatric patients 2 months and older and key upcoming milestones for our late-stage pipeline.

On January 14, 2025, we announced completion of a global private placement primarily to existing major US, UK, and Australian shareholders raising approximately US$160.0 million (A$260 million).

On December 19, 2024, we announced the FDA approved RYONCIL as the first mesenchymal stromal cell (MSC) therapy in the United States. RYONCIL is the only MSC therapy approved in the U.S. for any indication, and the only approved therapy for SR-aGvHD in children 2 months and older, including adolescents and teenagers.

On December 18, 2024, we announced Mesoblast's addition to the Nasdaq Biotechnology Index (Nasdaq: NBI) as part of the annual reconstitution of the 2024 Nasdaq index.

On December 5, 2024, we announced the U.S. FDA granted Revascor® (rexlemestrocel-L) Regenerative Medicine Advanced Therapy (RMAT) designation following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.

On December 3, 2024, we announced a key publication in the online issue of the prestigious peer-reviewed E*uropean Journal of Heart Failure (EJHF)*, which reports that a single intramyocardial injection of the Company's allogeneic cell therapy Revascor® (rexlemestrocel-L) results in improved survival in high-risk patients with ischemic heart failure and inflammation.

On August 21, 2024, we announced that the consolidated shareholder class action, filed in the Federal Court of Australia in 2022, has been resolved subject to Federal Court approval. The settlement (inclusive of interests and costs) will be funded entirely by Mesoblast's insurers and includes no admission of liability.

On July 23, 2024. we announced that the FDA has accepted our Biologics License Application ("BLA") resubmission for RYONCIL in the treatment of children with SR-aGVHD. The FDA considered the resubmission to be a complete response and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 7, 2025.

On July 22, 2024, we announced that the confirmatory Phase 3 trial of rexlemestrocel-L in patients with chronic low back pain ("CLBP") due to inflammatory degenerative disc disease of less than five years duration has commenced enrollment at multiple sites across the United States.

On July 9, 2024, we resubmitted our BLA for approval of RYONCIL in the treatment of children with SR-aGVHD.

In the period covered in this Report, no material cybersecurity incidents occurred.

Financial Overview

We have incurred significant losses since our inception. For the six months ended December 31, 2024, we had an accumulated deficit of $956.7 million. Our net loss for the six months ended December 31, 2024 was $47.9 million.

We anticipate that we may continue to incur significant losses for the foreseeable future. There can be no assurance that we will ever achieve or maintain profitability.

We expect our future capital requirements will continue as we:

- continue the research and clinical development of our product candidates;
- initiate and advance our product candidates into larger clinical studies;
- commercialize RYONCIL for pediatric SR-aGVHD in the United States following its approval by the FDA;
- seek regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical studies;
- establish collaborations with third parties for the development and commercialization of our product candidates, or otherwise build and maintain a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- further develop and implement our proprietary manufacturing processes and expand our manufacturing capabilities and resources for commercial production;
- seek coverage and reimbursement from third-party payors, including government and private payors for future products;
- make interest payments, principal repayments and other charges on our debt financing arrangements;

- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

We have our first approved product which will generate revenues from sales in the US market, however we expect to incur losses in the foreseeable future given our ongoing manufacturing commercialization and development and selling, general and administrative expenses for our approved product and research and development expenses for our other product candidates. Therefore, beyond the next twelve months we will need additional capital to fund our operations, which we may raise through equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. While we anticipate to generate revenue from the commercialization of RYONCIL for pediatric SR-aGVHD, we do not expect to generate significant revenue from other product sales unless and until we obtain additional regulatory approvals of and commercialize more of our other cell-based product candidates. For further discussion on our ability to continue as a going concern, see Note 1(i) in our accompanying financial statements.

Commercialization and Milestone Revenue. Commercialization and milestone revenue relates to upfront, royalty and milestone payments recognized under development and commercialization agreements; milestone payments, the receipt of which is dependent on certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products. Payment is generally due on standard terms of 30 to 60 days.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred consideration in our consolidated balance sheet, depending on the nature of the arrangement. Amounts expected to be recognized as revenue within the 12 months following the consolidated balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the consolidated balance sheet date are classified within non-current liabilities.

Research and Development. Research and development expenditure is recognized as an expense as incurred.

Our research and development expenses consist primarily of:

- third party costs comprising all external expenditure on our research and development programs such as fees paid to Contract Research Organizations (“CROs”) and on our pre-commercial activities, such as research pertaining to market access and pricing, brand marketing and initiation of trade and distribution contracts. Third party costs also comprise fees paid to consultants who perform research on our behalf and under our direction, rent and utility costs for our research and development facilities, and database analysis fees;
- third party costs under license and/or sub-license arrangements for the research and development, license, manufacture and/or commercialization of products and/or product candidates, such as payments for options to acquire rights to products and product candidates as well as contingent obligations under the agreements;
- product support costs consisting primarily of salaries and related overhead expenses for personnel in research and development and pre-commercial functions (for example wages, salaries and associated on costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires);
- intellectual property support costs comprising payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents; and
- amortization of currently marketed products on a straight-line basis over the life of the asset.

Our research and development expenses are not charged to specific products or programs, since the number of clinical and preclinical product candidates or development projects tends to vary from period to period and since internal resources are utilized across multiple products and programs over any given period of time. As a result, our management does not maintain and evaluate research and development costs by product or program. Acquired in-process research and development is capitalized as an asset and is not amortized but is subject to annual impairment review during the development phase. Upon completion of its development, the acquired in-process research and development amortization will commence.

Manufacturing Commercialization. Manufacturing commercialization expenditure is recognized as an expense as incurred. Our manufacturing commercialization expenses consist primarily of:

- salaries and related overhead expenses including share-based incentives for personnel in manufacturing functions;
- fees paid to our contract manufacturing organizations, which perform process development on our behalf and under our direction;
- costs related to laboratory supplies used in our manufacturing development efforts; and
- reversal of provisions against the carrying value of pre-launch inventory and obsolete stock, as a result of FDA approval of RYONCIL in December 2024.

Management and Administration. Management and administration expenses consist primarily of salaries and related costs including share-based incentives for directors and employees in corporate and administrative functions, including the executives of those areas. Other significant management and administration expenses include legal and professional services, rent and depreciation of leasehold improvements, insurance and information technology services.

Fair Value Remeasurement of Contingent Consideration. Remeasurement of contingent consideration pertains to the acquisition of the MSC assets from Osiris Therapeutics, Inc ("Osiris"). The fair value remeasurement of contingent consideration is recognized as a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, market growth, probability of success and payment, market penetration, product pricing and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

Fair Value Movement of Warrants. Remeasurement of warrants pertain to the warrants granted to Oaktree Capital Management, L.P ("Oaktree") in relation to the refinancing and amendment of our senior debt facility. The fair value movement of warrants is recognized when there is a change in the valuation assumptions such as share price, risk-free interest rates and volatility.

Other Operating Income and Expenses. Other operating income and expenses primarily comprise foreign exchange gains and losses.

Tax incentives comprise payments from the Australian government’s Innovation Australia Research and Development Tax Incentive program for research and development activities conducted in relation to our qualifying research that meets the regulatory criteria. The research and development tax incentive credit is available for our research and development activities in Australia. Eligible companies with an aggregated turnover of A$20.0 million or less can receive a refundable tax offset for a percentage of their research and development spending. Companies with an aggregated turnover of A$20.0 million or more are eligible for a non-refundable tax offset for a percentage of their research and development spending.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our foreign currency amounts in our Australian based entity, whose functional currency is the A$, and foreign currency amounts in our Switzerland and Singapore based entities, whose functional currencies are the US$, plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates.

Interest Revenue. Interest revenue is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable.

Finance Costs. Finance costs primarily consists of remeasurement of borrowing arrangements, interest expense in relation to finance lease charges, accrued interest expense and interest expense in relation to the amortization of transaction costs and other charges associated with the borrowings as represented in our consolidated balance sheet using the effective interest rate method over the period of initial recognition through maturity.

Remeasurement of borrowing arrangements recognized pertain to our loan and security agreements with NovaQuest Capital Management, L.L.C. (“NovaQuest”) and Oaktree. Remeasurement of borrowing arrangements is recognized when there is a modification of the borrowing arrangement with no significant change to the contractual cash flows of the borrowings at the remeasurement date or when there is a revision in the estimated future cash flows which is recorded as an

adjustment of the carrying amount of the financial liability. The carrying amount is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate.

Income Tax Benefit/Expense. Income tax benefit/expense consists of net changes in deferred tax assets and liabilities recognized on the balance sheet during the period.

Results of Operations

Comparison of Our Results for the Six Months Ended December 31, 2024 with the Six Months Ended December 31, 2023

The following table summarizes our results of operations for the six months ended December 31, 2024 and 2023, together with the changes in those items in dollars and as a percentage.

(in U.S. dollars, in thousands except per share information)	Year ended December 31, 2024	2023	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 3,156	$ 3,388	(232)	(7%)
Total revenue	**3,156**	**3,388**	**(232)**	**(7%)**
Research & development	(20,649)	(12,647)	(8,002)	63%
Manufacturing commercialization	14,740	(6,746)	21,486	NM
Management and administration	(17,188)	(11,482)	(5,706)	50%
Fair value remeasurement of contingent consideration	(4,303)	(337)	(3,966)	NM
Fair value movement of warrants	(11,978)	4,434	(16,412)	NM
Other operating income and expenses	(673)	1,068	(1,741)	(163%)
Finance costs	(10,827)	(10,319)	(508)	5%
Loss before income tax	**(47,722)**	**(32,641)**	**(15,081)**	**46%**
Income tax (expense)/benefit	(212)	102	(314)	NM
Loss attributable to the owners of Mesoblast Limited	**$ (47,934)**	**$ (32,539)**	**(15,395)**	**47%**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(4.20)	(3.72)	(0.48)	13%
Diluted - losses per share	(4.20)	(3.72)	(0.48)	13%

* NM = not meaningful.

Revenue

Revenues were $3.2 million for the six months ended December 31, 2024, compared with $3.4 million for the six months ended December 31, 2023, a decrease of $0.2 million. The following table shows the movement within revenue for the six months ended December 31, 2024 and 2023, together with the changes in those items.

(in U.S. dollars, in thousands)	Year ended December 31, 2024	2023	$ Change	% Change
Revenue:				
Commercialization revenue	3,156	3,388	(232)	(7%)
Revenue	**$ 3,156**	**$ 3,388**	**(232)**	**(7%)**

Commercialization revenue from royalty income earned on sales of TEMCELL in Japan and Alofisel® decreased by $0.2 million for the six months ended December 31, 2024. Royalty income on sales of TEMCELL in Japan by our licensee JCR were $3.1 million in the six months ended December 31, 2024 compared to $3.2 million in the six months ended December 31, 2023, a decrease of $0.1 million. Royalty income on sales of Alofisel® by our licensee Takeda decreased by $0.1 million in the six months ended December 31, 2024 compared with the six months ended December 31, 2023.

Research and development

Research and development expenses were $20.6 million for the six months ended December 31, 2024, compared with $12.6 million for the six months ended December 31, 2023, an increase of $8.0 million. The $8.0 million increase in research and development expenses was primarily due to an increase in product support costs.

	Year ended December 31,			
(in U.S. dollars, in thousands)	**2024**	**2023**	**$ Change**	**% Change**
Research and development:				
Third party costs	3,290	1,916	1,374	72%
Product support costs	15,032	8,601	6,431	75%
Intellectual property support costs	1,433	1,403	30	2%
Amortization of current marketed products	894	727	167	23%
Research and development	**$ 20,649**	**$ 12,647**	**8,002**	**63%**

Third party costs, which consist of all external expenditure on our research and development programs and pre-commercial activities, increased by $1.4 million in the six months ended December 31, 2024 compared with the six months ended December 31, 2023.

This $1.4 million increase was due to an increase in our third party costs due to the clinical advancement of our confirmatory Phase 3 clinical trial for the treatment of MPC-06-ID (CLBP) in the six months ended December 31, 2024. In the six months ended December 31, 2024, we also incurred costs of $0.6 million associated with our pre-commercial activities as we prepared for the launch of RYONCIL in the United States.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development and pre-commercial functions, have increased by $6.4 million, for the six months ended December 31, 2024 compared with the six months ended December 31, 2023. Within this $6.4 million increase, $6.9 million relates to an increase in product support costs for research and development functions and $0.5 million relates to a decrease in product support costs for pre-commercial functions.

The $6.9 million increase in product support costs for personnel in research and development functions is primarily due to an increase of $7.1 million in share-based payment expenses. In August 2024, the compensation structure for short-term incentives was revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled us to avoid a $4.1 million cash payment of short-term incentives. The options granted in lieu of cash resulted in a $5.1 million increase in share-based payment expenses.

The $0.5 million decrease in product support costs for personnel in pre-commercial functions is primarily due to a decrease of $0.2 million due to one-off restructuring costs in the six months ended December 31, 2023 compared with the six months ended December 31, 2024. There was also a decrease of $0.2 million in consulting expenses and $0.1 million in recruitment in the six months ended December 31, 2024 compared with the six months ended December 31, 2023.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and costs of renewing our granted patents. These costs have remained consistent in the six months ended December 31, 2024 compared with the six months ended December 31, 2023.

Amortization of current marketed products increased by $0.2 million in the six months ended December 31, 2024 compared with the six months ended December 31, 2023 due to the reclassification of RYONCIL from in-process research and development ("IPRD") acquired to current marketed products upon receiving FDA approval in December 2024.

Manufacturing commercialization

Manufacturing commercialization recognized income of $14.7 million for the six months ended December 31, 2024, compared with an expense of $6.7 million for the six months ended December 31, 2023, a decrease of $21.5 million. This decrease is primarily due to a decrease in platform technology costs.

	Year ended December 31,			
(in U.S. dollars, in thousands)	2024	2023	$ Change	% Change
Manufacturing commercialization:				
Platform technology	(16,634)	5,633	(22,267)	NM
Manufacturing support costs	1,894	1,113	781	70%
Manufacturing commercialization	**$ (14,740)**	**$ 6,746**	**(21,486)**	**NM**

* NM = not meaningful

Platform technology costs decreased by $22.3 million for the six months ended December 31, 2024 compared with six months ended December 31, 2023. These costs consist of fees paid to our contract manufacturing organizations, potency assay work that supported the aGVHD BLA resubmission, process development of our proprietary technology that facilitates the increase in yields necessary for the long-term commercial supply of our product candidates and next generation manufacturing processes to reduce labor, drive down cost of goods and improve manufacturing efficiencies in our MPC and MSC based products. The decrease is primarily due to a reversal of $23.0 million in relation to the provision against the carrying value of pre-launch inventory as a result of FDA approval of RYONCIL for pediatric SR-aGVHD during the six months ended December 31, 2024.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions increased by $0.8 million in the six months ended December 31, 2024 compared with the six months ended December 31, 2023 primarily due to an increase of $0.6 million in share-based payment expenses. In August 2024, the compensation structure for short-term incentives was revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled us to avoid a $0.6 million cash payment of short-term incentives. The options granted in lieu of cash resulted in a $0.2 million increase in share-based payment expenses.

Management and administration

Management and administration expenses were $17.2 million for the six months ended December 31, 2024, compared with $11.5 million for the six months ended December 31, 2023, an increase of $5.7 million. This increase was primarily due to an increase in labor and associated expenses and legal and professional fees.

	Year ended December 31,			
(in U.S. dollars, in thousands)	2024	2023	$ Change	% Change
Management and administration:				
Labor and associated expenses	9,644	4,405	5,239	119%
Corporate overheads	5,072	5,916	(844)	(14%)
Legal and professional fees	2,472	1,161	1,311	113%
Management and administration	**$ 17,188**	**$ 11,482**	**5,706**	**50%**

Labor and associated expenses increased by $5.2 million from $4.4 million for the six months ended December 31, 2023 to $9.6 million for the six months ended December 31, 2024. This increase is primarily due to an increase of $5.2 million in share-based payment expenses. In August 2024, the compensation structure for short-term incentives was revised providing all employees with the choice to elect into receiving an option grant in lieu of cash payment of their short-term

incentive entitlements pertaining to the years ended June 30, 2023 and 2024. This revised structure enabled us to avoid a $2.0 million cash payment of short-term incentives. The options granted in lieu of cash resulted in a $3.0 million increase in share-based payment expenses.

Corporate overhead expenses decreased by $0.8 million from $5.9 million for the six months ended December 31, 2023 to $5.1 million for the six months ended December 31, 2024 primarily due to a decrease in depreciation and insurance premiums.

Legal and professional fees increased by $1.3 million for the six months ended December 31, 2024 compared with the six months ended December 31, 2023 due to a one-off expense incurred following the FDA approval of RYONCIL for pediatric SR-aGVHD during the six months ended December 31, 2024.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration recognized a $4.3 million loss for the six months ended December 31, 2024 compared with a $0.3 million loss for the six months ended December 31, 2023. The $4.3 million loss for the six months ended December 31, 2024 was due to the remeasurement of contingent consideration pertaining to the acquisition of the MSC assets. This loss was a net result of changing the key assumptions of the contingent consideration valuation such as probability of success, development timelines and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration including the impact of receiving FDA approval for RYONCIL in the treatment of children with SR-aGVHD in December 2024.

The $0.3 million loss for the six months ended December 31, 2023 was due to the remeasurement of contingent consideration pertaining to the acquisition of the MSC assets. This loss was a net result of changing the key assumptions of the contingent consideration valuation such as development timelines and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

With respect to future milestone payments, contingent consideration will be payable in cash or shares at our discretion. With respect to commercialization, product royalties will be payable in cash which will be funded from royalties received from net sales.

Fair value movement of warrants

Fair value movement of warrants was a $12.0 million loss for the six months ended December 31, 2024 compared with a $4.4 million gain for the six months ended December 31, 2023. This $12.0 million loss for the six months ended December 31, 2024 is a net result of changes to the key valuation inputs of the warrants, primarily the movement in the share price, with other factors such as risk-free interest rates and volatility.

Other operating income and expenses

In relation to other operating income and expenses, we recognized a loss of $0.7 million for the six months ended December 31, 2024, compared with an income of $1.1 million for the six months ended December 31, 2023, a decrease in income of $1.7 million. The following table shows movements within other operating income and expenses for the six months ended December 31, 2024 and 2023, together with the changes in those items:

	Year ended December 31,			
(in U.S. dollars, in thousands)	**2024**	**2023**	**$ Change**	**% Change**
Other operating income and expenses:				
Interest income	(435)	(903)	468	(52%)
Foreign exchange losses/(gains) (net)	630	(165)	795	NM
Foreign withholding tax	480	—	480	NM
Government grant revenue	(2)	—	(2)	NM
Other operating (income) and expenses	**$ 673**	**$ (1,068)**	**1,741**	**(163%)**

* NM = not meaningful.

The $0.5 million decrease in interest income for the six months ended December 31, 2024 compared with the six months ended December 31, 2023 was primarily driven by lower interest rates on US$ cash deposits and us retaining lower cash reserves in the six months ended December 31, 2024, when compared to the six months ended December 31, 2023.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors. In the six months ended December 31, 2024, we recognized a foreign exchange loss of $0.6 million, primarily due to movements in exchange rates on US$ liabilities held in Mesoblast Limited, whose functional currency is the A$, as the A$ depreciated against the US$. In the six months ended December 31, 2023, we recognized a foreign exchange gain of $0.2 million.

In the six months ended December 31, 2024, we recognized $0.5 million of foreign withholding tax expenses primarily related to the write-off of foreign withholding tax receivable based on management's assessment of the likelihood of recovery. There was no foreign withholding tax recognized in the six months ended December 31, 2023.

Finance costs

(in U.S. dollars, in thousands)	Year ended December 31, 2024	2023	$ Change	% Change
Finance costs:				
Remeasurement of borrowing arrangements	31	120	(89)	(74%)
Facility fee	106	—	106	NM
Interest expense	10,690	10,199	491	5%
Finance costs	**$ 10,827**	**$ 10,319**	**508**	**5%**

* NM = not meaningful

In the six months ended December 31, 2024, we recognized a minimal loss for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our credit facilities with NovaQuest and Oaktree, a decrease in losses of $0.1 million as compared with a $0.1 million loss for the six months ended December 31, 2023.

Within the loss in the six months ended December 31, 2024, in relation to our existing credit facility with NovaQuest, we recognized a $0.1 million gain for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows as a net result of changes to the key assumption in development timelines, a decrease in losses of $0.2 million as compared with a $0.1 million loss recognized for the six months ended December 31, 2023.

Also within the loss in the six months ended December 31, 2024, in relation to our existing credit facility with Oaktree, we recognized a $0.1 million loss for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows, an increase in losses of $0.1 million as compared with a minimal loss for the six months ended December 31, 2023.

In the six months ended December 31, 2024, we recognized $0.1 million for facility fees. There was no facility fees in the six months ended December 31, 2023.

Interest expense increased by $0.5 million from $10.2 million for the six months ended December 31, 2023 to $10.7 million for the six months ended December 31, 2024.

In the six months ended December 31, 2024, in relation to our loan and security agreement with Oaktree, we recognized $4.4 million of interest expense, a decrease of $0.4 million as compared with $4.8 million for the six months ended December 31, 2023. Within this $4.4 million recognized in the six months ended December 31, 2024, $2.6 million was recognized with regards to interest expense paid and a further $1.8 million of interest expense was recognized with regard to the amortization of transaction costs incurred on the outstanding loan principal for the six months ended December 31, 2024 using the effective interest rate method over the period of initial recognition through maturity.

In the six months ended December 31, 2024, in relation to our loan and security agreement with NovaQuest, we recognized $6.0 million of interest expense, an increase of $0.9 million as compared with $5.1 million for the six months

ended December 31, 2023. Interest expense relating to the NovaQuest loan is accrued on the loan principal balance and all interest payments are deferred until the earlier of loan maturity or from after the first commercial sale of our allogeneic product candidate RYONCIL for the treatment of pediatric patients with SR-aGVHD in the United States and other geographies excluding Asia.

In line with IFRS 16 *Leases*, we also recognized interest expenses of $0.2 million in relation to lease charges for the six months ended December 31, 2024 and 2023, respectively.

Loss after income tax

(in U.S. dollars, in thousands)	Year ended December 31, 2024	2023	$ Change	% Change
Loss before income tax	(47,722)	(32,641)	(15,081)	46%
Income tax (expense)/benefit	(212)	102	(314)	NM
Loss after income tax	**$ (47,934)**	**$ (32,539)**	**(15,395)**	**47%**

* NM = not meaningful

Loss before income tax was $47.7 million for the six months ended December 31, 2024 compared with $32.6 million for the six months ended December 31, 2023, an increase in the loss by $15.1 million. This increase is the net effect of the changes in revenues and expenses that have been discussed above.

A non-cash income tax expense of $0.2 million was recognized in the six months ended December 31, 2024, in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

A non-cash income tax benefit of $0.1 million was recognized in the six months ended December 31, 2023 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

Liquidity and Capital Resources

Sources of liquidity

We held total cash reserves of $38.0 million as of December 31, 2024. In January 2025, we announced completion of a global private placement primarily to existing major US, UK and Australian shareholders raising an additional $161.0 million after approval of RYONCIL for the treatment of SR-aGvHD in children 2 months and older. We continue our focus on maintaining tight control of net cash usage for operating activities, which were $20.7 million for the six months ended December 31, 2024, a reduction of 22% compared to the prior period.

We have cash reserves to execute the US commercial launch activities of RYONCIL, to commence life cycle extension of the FDA approved product in children and adults, and continue our clinical development pipeline. In conjunction with existing cash reserves, the proceeds from the January 2025 private placement and future revenue from sales of RYONCIL, we have sufficient cash to meet our forecast expenditure over at least the next twelve months.

Our primary sources of liquidity have historically been equity raisings, upfront and milestone payments from strategic license agreements, and borrowings under our loan agreements. We also expect net sales to become a source of liquidity. While in the long-term we expect to be able to complete transactions, draw upon these facilities and achieve approval of our product candidates to provide liquidity as needed, there can be no assurance as to whether we will be successful or, if successful, what the terms or proceeds may be.

Cash flows

(in U.S. dollars, in thousands)	Year ended December 31, 2024	2023	$ Change	% Change
Cash Flow Data:				
Net cash (outflows) in operating activities	(20,655)	(26,572)	5,917	(22%)
Net cash inflows/(outflows) in investing activities	627	(88)	715	NM
Net cash (outflows)/inflows by financing activities	(4,264)	31,600	(35,864)	(113%)
Net (decrease)/increase in cash and cash equivalents	**(24,292)**	**4,940**	**(29,232)**	**NM**

Net cash outflows in operating activities

Net cash outflows for operating activities were $20.7 million for the six months ended December 31, 2024, compared with $26.6 million for the six months ended December 31, 2023, a decrease of $5.9 million. The decrease of $5.9 million is due to a decrease in cash outflows of $9.8 million and a decrease in cash inflows of $3.9 million in the six months ended December 31, 2024, compared with the six months ended December 31, 2023.

The $3.9 million decrease of inflows comprised: inflows from royalty income earned on sales of TEMCELL in Japan and Alofisel® decreased by $0.9 million during the six months ended December 31, 2024, compared with the six months ended December 31, 2023; received $2.6 million of receipts for research and development tax incentive during the six months ended December 31, 2023, compared to minimal receipts in the six months ended December 31, 2024; and inflows from interest receipts decreased by $0.4 million in the six months ended December 31, 2024, compared with the six months ended December 31, 2023.

Outflows for payments to suppliers and employees decreased by $9.8 million from $34.0 million for the six months ended December 31, 2023 to $24.2 million for the six months ended December 31, 2024, primarily due to a decrease in payments in relation to manufacturing commercialization and product manufacturing and operating costs.

Net cash inflows in investing activities

Net cash inflows for investing activities increased by $0.7 million in the six months ended December 31, 2024, compared with the six months ended December 31, 2023 primarily due to proceeds from rental deposits of $0.6 million which was released to us in the six months ended December 31, 2024 as we relocated our New York office.

Net cash outflows in financing activities

Net cash outflows for financing activities decreased by $35.9 million for the six months ended December 31, 2024, compared with the six months ended December 31, 2023. The decrease of $35.9 million is due to a decrease in cash inflows of $37.0 million and a decrease in cash outflows of $1.1 million in the six months ended December 31, 2024 compared with the six months ended December 31, 2023.

The $37.0 million decrease in inflows comprised: $39.7 million of proceeds received from an institutional placement and entitlement offer during the six months ended December 31, 2023, compared with $Nil for the six months ended December 31, 2024; received $1.3 million in receipts from employee share option exercises during the six months ended December 31, 2024, compared with $Nil for the six months ended December 31, 2023; received $1.4 million of proceeds from warrant exercises during the six months ended December 31, 2024, compared with $Nil for the six months ended December 31, 2023.

The $1.1 million decrease in outflows comprised: payments of $2.7 million and $2.8 million for interest and other costs of finance during the six months ended December 31, 2024 and 2023, respectively; payments of $1.0 million and $2.1 million for lease liabilities during the six months ended December 31, 2024 and 2023, respectively; payments of $2.6 million for capital raising costs in the six months ended December 31, 2023, compared to minimal payments for the six months ended December 31, 2024; payments of $0.6 million and $0.5 million for borrowings costs in the six months ended December 31, 2024 and 2023, respectively; principal repayment of $2.6 million to reduce debt under our five-year facility with Oaktree during the six months ended December 31, 2024, compared with $Nil for the six months ended December 31, 2023.

Operating Capital Requirements

We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. While we anticipate to generate revenue from the commercialization of RYONCIL for pediatric SR-aGHVD, we do not expect to generate significant revenue from other product sales unless and until we obtain additional regulatory approvals of and commercialize more of our other cell-based product candidates. We anticipate that we will continue to incur losses for the foreseeable future as we continue the development of, and seek additional regulatory approvals for our cell-based product candidates, and begin to commercialize any approved products, including RYONCIL for pediatric SR-aGVHD, either directly ourselves or through a collaborator or partner. We are subject to all of the risks inherent in the development of new cell-based products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We have our first approved product which will generate revenues from sales in the US market, however we expect to incur losses in the foreseeable future given our ongoing manufacturing commercialization and development and selling, general and administrative expenses for our approved product and research and development expenses for our other product candidates. Therefore, beyond the next twelve months we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our ordinary shares. If we incur further indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Borrowings

For a description of our borrowing arrangements, refer to Note 5(d) in the notes to our condensed consolidated financial statements.

Contractual Obligations and Commitments

Contractual commitments

Purchase commitments means an agreement to purchase goods or services that is enforceable and legally binding that specifies all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Purchase obligations are not recognized as liabilities at December 31, 2024. For a description of our contractual commitments, refer to Note 9(c) in the notes to our condensed consolidated financial statements.

Lease and sub-lease commitments

We lease various offices under non-cancellable leases expiring within 1 to 6 years. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated. We subleased a portion of our office in Melbourne Australia under a non-cancellable lease expiring within 2 years. We also lease a manufacturing suite under a manufacturing services agreement with Lonza for the supply of commercial product for the launch of RYONCIL for the treatment of pediatric SR-aGVHD in the US market expiring within 2 years from December 31, 2024.

Contingent liabilities

We acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with our use of the Medvet IP, on completion of certain milestones we will be obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to $2.2 million, and single-digit royalties on net sales of

products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) single-digit royalties on net sales of the specified products for applications outside the specified fields.

We have 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 December 31, 2024 we have assessed that the probability of outflows is remote.

Capital commitments

We did not have any commitments for future capital expenditure outstanding as of December 31, 2024.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, other than the purchase commitments and contingent liabilities as mentioned above.

Certain Differences Between IFRS and U.S. GAAP

IFRS differs from U.S. GAAP in certain respects. Management has not assessed the materiality of differences between IFRS and GAAP. Our significant accounting policies are described in Note 23 to our consolidated financial statements and the related notes thereto included in our Form 20-F.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to interest rate risk, share price risk, price risk and foreign currency exchange risk. We make use of sensitivity analyses which are inherently limited in estimating actual losses in fair value that can occur from changes in market conditions. For additional information, refer to Note 9 in the notes to our condensed consolidated financial statements.

Events subsequent to balance date

In January 2025, we completed a global private placement primarily to our existing major US, UK, and Australian shareholders raising $161.0 million at A$2.50 per share. In January 2025, proceeds of $161.0 million were received and recognized in cash and cash equivalents.

In January 2025, we issued 10,228,239 ordinary shares to Osiris as payment for a $20.0 million milestone within contingent consideration recognized on the balance sheet following the FDA approval of RYONCIL in the United States.

There have not been any other events subsequent to the balance date, not otherwise disclosed in this report, which significantly affected or may significantly affect our operations, our results of our operations or our state of affairs in subsequent financial periods.

Rounding of amounts

Our company is of a kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, issued by the Australian Securities and Investments Commission, relating to the 'rounding off' of amounts in the financial and directors' reports. Unless mentioned otherwise, amounts within this report have been rounded off in accordance with that Legislative Instrument to the nearest thousand dollars, or in certain cases, to the nearest dollar.

Directors' resolution

This report is made in accordance with a resolution of the directors on February 27, 2025.

Corporate Governance

Under Nasdaq Stock Market Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the Nasdaq Stock Market Rules. For example, we may follow home country practice with regard to certain corporate governance requirements, such as the composition of the board of directors and quorum requirements applicable to shareholders' meetings. In addition, we may follow home country practice instead of the Nasdaq Stock Market Rules requirement to hold executive sessions and to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions or private placements of securities. Further, we may follow home country practice instead of the Nasdaq Stock Market Rules requirement to obtain shareholder approval prior to the establishment or amendment of certain share option, purchase or other compensation plans. A foreign private issuer that elects to follow a home country practice instead of any Nasdaq rule must submit to Nasdaq, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. We submitted such a written statement to Nasdaq.

Other than as set forth below, we currently intend to comply with the corporate governance listing standards in the Nasdaq Stock Market Rules to the extent possible under Australian law. However, we may choose to change such practices to follow home country practice in the future.

The Nasdaq Stock Market Rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least 33 1/3% of the outstanding shares of the company's common voting stock. We follow our home country practice, rather than complying with this rule. Consistent with Australian law, our constitution does not require a quorum of at least 33 1/3% of the issued voting shares of Mesoblast for any general meeting of its shareholders. Our constitution provides that a quorum for a general meeting of our shareholders constitutes two shareholders present in person, by proxy, by attorney, or, where the shareholders is a body corporate, by representative. This provision and our practice of holding meetings with this quorum are not prohibited by the ASX Listing Rules or any other Australian law.

In addition, we may follow home country practice instead of Nasdaq Rule 5635(d), which requires a company to obtain shareholder approval for an issuance of securities (other than a public offering) that equals of 20% or more of the outstanding voting power in the company before such issuance. This Nasdaq rule is inconsistent with an ASX Listing Rule that provides a company cannot issue a number of securities over any rolling 12-month period exceeding 15% of the outstanding capital of the company without approval of shareholders but subject to certain exceptions such as pro-rata offers of securities to all shareholders.

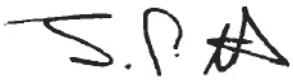
Auditor's Independence Declaration

As lead auditor for the review of Mesoblast Limited for the half-year ended 31 December 2024, I declare that to the best of my knowledge and belief, there have been:

(a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and

(b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Mesoblast Limited and the entities it controlled during the period.



Jon Roberts
Partner
PricewaterhouseCoopers

Melbourne
27 February 2025

RISK FACTORS

You should carefully consider the risks described below and all other information contained in this Report on Form 6-K before making an investment decision. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our ADSs could decline, and you may lose part or all of your investment. This Report on Form 6-K also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in this Report on Form 6-K.

Risks Related to Our Financial Position and Capital Requirements

We have incurred operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a single product, Ryoncil® (remestemcel-L), approved only in the United States for treatment of steroid-refractory acute graft-versus-host disease in pediatric patients of 2 months of age and older which we are in the process of commercializing. We have not yet generated significant revenues. We have incurred net losses during most of our fiscal periods since our inception. Our net loss for the six months ended December 31, 2024 was $47.9 million. As of December 31, 2024, we have an accumulated deficit of $956.7 million since our inception. We do not know whether or when we will become profitable. Our losses have resulted principally from costs incurred in clinical development and manufacturing activities.

We anticipate that our expenses will increase as we progress commercialization, including the scaling up of our manufacturing activities and for infrastructure and logistics necessary to support the RYONCIL product launch and potential further product launches. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To achieve and maintain profitability, we must successfully develop our product candidates, obtain regulatory approval, and manufacture, market and sell those products for which we obtain regulatory approval. Our future revenue will depend upon the size of any markets in which our products receive approval, and our ability to achieve and maintain sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. We may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our company could cause you to lose part or all of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, either alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not currently generate revenues from product sales (other than licensing revenue from sales of TEMCELL® HS. Inj. ("TEMCELL"), a registered trademark of JCR Pharmaceuticals Co., Ltd. ("JCR"), by JCR in Japan, and royalty revenue from net sales of Alofisel® a registered trademark of TiGenix NV ("TiGenix"), previously known as Cx601, an adipose-derived mesenchymal stromal cell product developed by TiGenix, now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") and approved for marketing in the EU and Japan), and we may never generate product sales. Our ability to generate future revenues from product sales depends heavily on our success in a number of areas, including:

- completing research, preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for RYONCIL and our product candidates for which we complete clinical studies;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our RYONCIL product in the United States and our product candidates, if approved;
- launching and commercializing our RYONCIL product in the United States and our product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing commercial and distribution capabilities necessary to effectively seek and

maintain market access and ensure compliance with legal and regulatory requirements relating to interactions with healthcare providers, healthcare organizations and government agencies;

- obtaining market acceptance of our RYONCIL product in the United States and our product candidates, if approved, as viable treatment options;
- addressing competing technological and market developments;
- obtaining and sustaining an adequate level of reimbursement from payors;
- identifying and validating new cell therapy product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how and trademarks;
- attracting, hiring and retaining qualified personnel; and
- implementing additional internal systems and infrastructure, as needed.

We anticipate incurring significant costs associated with commercializing and distributing RYONCIL and any further approved product candidate. Our expenses could increase beyond expectations if we are required by the United States Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), or other regulatory agencies, to perform clinical and other studies in addition to those that we currently anticipate. We may not become profitable and may need to obtain additional funding to continue operations.

We may require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital or establish and maintain strategic partnerships to provide funding support for our development programs could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. As of December 31, 2024, our cash and cash equivalents were $38.0 million. In January 2025, we announced completion of a global private placement primarily to existing major US, UK and Australian shareholders raising $161.0 million in proceeds. Subject to us achieving successful regulatory approval, we expect an increase in our total expenses and an increase our cumulative operating losses for the foreseeable future in connection with our planned research and development, manufacturing commercialization and selling, general and administrative expenses as we progress commercialization. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. We anticipate that our expenses will increase if and as we:

- continue the research and clinical development of our product candidates, including MPC-150-IM (Class II-IV Chronic Heart Failure ("CHF")), MPC-06-ID (Chronic Low Back Pain ("CLBP")), remestemcel-L (RYONCIL) and MPC-300-IV (inflammatory conditions) product candidates;
- progress commercialization of remestemcel-L, or RYONCIL, for pediatric SR-aGVHD in the United States;
- seek to identify, assess, acquire, and/or develop other and combination product candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical studies and identify and apply for regulatory designations to facilitate development and ultimate commercialization of our products;
- establish and maintain collaborations and strategic partnerships with third parties for the development and commercialization of our product candidates, or otherwise build and maintain a sales, marketing and distribution infrastructure and/or external logistics to commercialize RYONCIL in the United States and any other products for which we may obtain marketing approval;
- further develop and implement our proprietary manufacturing processes in both planar technology and our bioreactor programs, and expand our manufacturing capabilities and resources for commercial production;
- seek coverage and reimbursement from third-party payors, including government and private payors for RYONCIL and future products;
- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology;
- seek to maintain, protect and expand our intellectual property portfolio;

- seek to attract and retain skilled personnel; and
- develop and maintain the compliance and other infrastructure necessary to support product commercialization and distribution.

If we were to experience any delays or encounter issues with any of the above, including clinical holds, failed studies, inconclusive or complex results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above. Further, the net operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder or as a holder of the ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to do so at an earlier stage than would otherwise be ideal and/or may have to limit valuable rights to our intellectual property, technologies, product candidates or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize RYONCIL in the United States and our product candidates.

As of December 31, 2024, we held total cash reserves of $38.0 million. In January 2025, we announced completion of a global private placement primarily to existing major US, UK and Australian shareholders raising an additional $161.0 million after approval of RYONCIL for the treatment of SR-aGvHD in children 2 months and older. We continue our focus on maintaining tight control of net cash usage for operating activities, which were $20.7 million for the six months ended December 31, 2024, a reduction of 22% compared to the prior period. We have cash reserves to execute the US commercial launch activities of RYONCIL, to commence life cycle extension of the FDA approved product in children and adults, and continue our clinical development pipeline. In conjunction with existing cash reserves, the proceeds from the January 2025 private placement and future revenue from sales of RYONCIL, we have sufficient cash to meet our forecast expenditure over at least the next twelve months. If we are unable to obtain adequate funding or partnerships beyond the 12-month period we may not be able to continue as a going concern, and our shareholders and holders of the ADSs may lose some or all of their investment in Mesoblast. See Note 1(i) of our accompanying financial statements.

The terms of our loan facilities with funds associated with Oaktree Capital Management, L.P. ("Oaktree") and NovaQuest Capital Management, L.L.C. ("NovaQuest") could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.

On November 19, 2021, we entered into a loan agreement and guaranty with Oaktree, with a secured five-year senior debt facility. The principal balance at the end of the three-year interest only period was $52.2 million, which amortizes at 5% per quarter beginning December 2024. The outstanding loan balance as of December 31, 2024 is $49.6 million. On June 29, 2018, we entered into a loan and security agreement with NovaQuest for a non-dilutive, eight-year term credit facility, repayable from net sales of RYONCIL in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD"), in the United States and other geographies excluding Asia, and we drew $30.0 million on closing. Our loan facilities with Oaktree and NovaQuest contain a number of covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. Under the terms of our Oaktree agreement the minimum unrestricted cash balance we need to maintain is $13.0 million and reduces at a proportionate rate with each quarterly repayment of principal. Our ability to comply with the various covenants under the agreements may be affected by events beyond our control, and we may not be able to continue to meet the covenants. Upon the occurrence of an event of default, Oaktree or NovaQuest could elect to declare all amounts outstanding under the loan facility to be immediately due and payable and terminate all commitments to extend further credit. If Oaktree or NovaQuest accelerates the repayment, we may not have sufficient funds to repay our existing debt. If we were unable to repay the owed amounts, Oaktree or NovaQuest could proceed against the collateral granted to it to secure such indebtedness. We have pledged substantially all of our assets as collateral under the loan facility with Oaktree, and a portion of our assets relating to the SR-aGVHD product as collateral under the loan facility with NovaQuest.

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

Historically, a substantial portion of our operating expenses has been denominated in U.S. dollars and our main currency requirements are U.S. dollars, Australian dollars and Singapore dollars. Approximately 73% of our cash and cash equivalents as of December 31, 2024 were denominated in U.S. dollars, 26% were denominated in Australian dollars and 1% were denominated in other currencies. Because we have multiple functional currencies across different jurisdictions, changes in the exchange rate between these currencies and the foreign currencies of the transactions recorded in our accounts could materially impact our reported results of operations and distort period-to-period comparisons. For example, where a portion of our research and clinical trials are undertaken in Australia, payment will be made in Australian dollar currency, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the U.S. dollar.

More specifically, 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. 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.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our RYONCIL product in the United States and our product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Risks Related to Clinical Development and Regulatory Review and Approval of Our Product Candidates

Our product candidates are based on our novel mesenchymal lineage cell technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. RYONCIL, approved in December 2024, became the first mesenchymal stromal cell (MSC) therapy approved by FDA for any indication.

Other than with respect to sales of products by our licensees, we have not commercially marketed, distributed or sold any products. The success of our business depends on our ability to develop and commercialize our RYONCIL product in the United States and our product candidates, if approved. We have concentrated our product research and development efforts on our mesenchymal lineage cell platform, a novel type of cell therapy. Our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future related to our mesenchymal lineage cell platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring these processes to collaborators, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer to develop than for other, better known or extensively studied pharmaceutical or other product candidates. In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

We may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies.

We must conduct extensive testing of our product candidates to demonstrate their safety and efficacy, including both preclinical animal testing and evaluation in human clinical trials, before we can obtain regulatory approval to market and sell them. Conducting such testing is a lengthy, time-consuming, and expensive process and there is a high rate of failure.

Our current and completed preclinical and clinical results for our product candidates are not necessarily predictive of the results of our ongoing or future clinical trials. Promising results in preclinical studies of a product candidate may not be predictive of similar results in humans during clinical trials, and successful results from early human clinical trials of a product candidate may not be replicated in later and larger human clinical trials or in clinical trials for different indications. If the results of our or our collaborators' ongoing or future clinical trials are negative or inconclusive with respect to the efficacy of our product candidates, or if these trials do not meet the clinical endpoints with statistical significance, or if there are safety concerns or adverse events associated with our product candidates, we or our collaborators may be prevented or delayed in obtaining marketing approval for our product candidates.

Even if ongoing or future clinical studies meet the clinical endpoints with statistical significance, the FDA or other regulatory agencies may still find the data insufficient to support marketing approval based on other factors.

We may encounter substantial delays in our clinical studies, including as a result of disruptive events beyond our control, including pandemics.

We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve our expected clinical milestones. A failure can occur at any stage of testing. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include:

- problems which may arise as a result of our transition of research and development programs from licensors or previous sponsors;
- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays by us or our collaborators in reaching a consensus with regulatory agencies on trial design;
- changes in trial design;
- inability to identify, recruit and train suitable clinical investigators;
- inability to add new clinical trial sites;
- delays in reaching agreement on acceptable terms for the performance of the trials with contract research organizations ("CROs"), and clinical trial sites;
- delays in obtaining required Institutional Review Board ("IRB"), approval at each clinical trial site;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials and delays in accruing medical events necessary to complete any events-driven trial;
- imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites;
- failure by CROs, other third parties or us or our collaborators to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices ("cGCP"), or applicable regulatory guidelines in other countries;
- delays in testing, validation, manufacturing and delivery of a product candidate to clinical trial sites;
- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate efficacy;
- occurrence of serious adverse events in clinical trials that are associated with a product candidates and that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or

- disagreements between us and the FDA or other regulatory agencies regarding a clinical trial design, protocol amendments, or interpreting the data from our clinical trials.

In addition, our ongoing clinical trials may be affected by delays caused by disruptive events outside our control, such as delays in monitoring and data collection as a result of geopolitical instability, significant climate events and pandemics, including due to prioritization of hospital resources, travel restrictions, and the inability to access sites for patient monitoring. In addition, some patients may be unable to comply with clinical trial protocols if quarantines or stay at home orders impede patient movement or interrupt health services.

Delays, including delays caused by the above factors, can be costly and could negatively affect our or our collaborators' ability to complete clinical trials for our product candidates. If we or our collaborators are not able to successfully complete clinical trials or are not able to do so in a timely and cost-effective manner, we will not be able to obtain regulatory approval and/or will not be able to commercialize our product candidates and our commercial partnering opportunities will be harmed.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our cell therapy trials because of negative publicity from adverse events in the biotechnology or cell therapy industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval for our product candidates may be delayed. Additionally, we or our collaborators generally will have to run multi-site and potentially multi-national trials, which can be time consuming, expensive and require close coordination and supervision. If we have difficulty enrolling a sufficient number of patients or otherwise conducting clinical trials as planned, we or our collaborators may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

If there are delays in accumulating the required number of trial subjects or, in trials where clinical events are a primary endpoint, if the events needed to assess performance of our clinical candidates do not accrue at the anticipated rate, there may be delays in completing the trial. These delays could result in increased costs, delays in advancing development of our product candidates, including delays in testing the effectiveness, or even termination of the clinical trials altogether.

Patient enrollment and completion of clinical trials are affected by factors including:

- size of the patient population, particularly in orphan diseases;
- severity of the disease under investigation;
- design of the trial protocol;
- eligibility criteria for the particular trial;
- perceived risks and benefits of the product candidate being tested;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians and level and effectiveness of study site recruitment efforts; and
- ability to monitor patients adequately during and after treatment.

Once enrolled, patients may choose to discontinue their participation at any time during the trial, for any reason. Participants also may be terminated from the study at the initiative of the investigator, for example if they experience serious adverse clinical events or do not follow the study directions. If we are unable to maintain an adequate number of patients in our clinical trials, we may be required to delay or terminate an ongoing clinical trial, which would have an adverse effect on our business.

We may conduct multinational clinical trials, which present additional and unique risks.

We plan to seek initial marketing approval for our product candidates in the United States and in select non-U.S. jurisdictions such as Europe, Japan and Canada. Conducting trials on a multinational basis requires collaboration with foreign medical institutions and healthcare providers. Our ability to successfully initiate, enroll and complete a clinical trial in multiple countries is subject to numerous risks unique to conducting business internationally, including:

- difficulty in establishing or managing relationships with physicians, sites and CROs;
- standards within different jurisdictions for conducting clinical trials and recruiting patients;
- our ability to effectively interface with non-US regulatory authorities;
- our inability to identify or reach acceptable agreements with qualified local consultants, physicians and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments, and anti-corruption/anti-bribery laws;
- differing genotypes, average body weights and other patient profiles within and across countries from our donor profile may impact the optimal dosing or may otherwise impact the results of our clinical trials; and
- global events like geopolitical instability, climate events and pandemics limiting our ability to commence and conduct studies, including recruiting patients.

The complexity of conducting multinational clinical trials could negatively affect our or our collaborators' ability to complete trials as intended which could have an adverse effect on our business.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, or limit the scope of any approved indication or market acceptance.

Participants in clinical trials of our investigational cell therapy products may experience adverse reactions or other undesirable side effects. While some of these can be anticipated, others may be unexpected. We cannot predict the frequency, duration, or severity of adverse reactions or undesirable side effects that may occur during clinical investigation of our product candidates. If any of our product candidates, prior to or after any approval for commercial sale, cause serious adverse events or are associated with other safety risks, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend (e.g., through a clinical hold) or terminate clinical trials;
- regulatory authorities may deny regulatory approval of our product candidates;
- regulators may restrict the indications or patient populations for which a product candidate is approved;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a risk evaluation and mitigation strategy ("REMS"), in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS than any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- patient recruitment into our clinical trials may suffer;
- our relationships with our collaborators may suffer;
- we could be required to provide compensation to subjects for their injuries, e.g., if we are sued and found to be liable or if required by the laws of the relevant jurisdiction or by the policies of the clinical site; or
- our reputation may suffer.

There can be no assurance that adverse events associated with our product candidates will not be observed, in such settings where no prior adverse events have occurred. As is typical in clinical development, we have a program of ongoing toxicology studies in animals for our clinical-stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. In addition, regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial for any of our product candidates, the commercial prospects for that product as well as our other product candidates may be harmed and our ability to generate product revenue from these product candidates may be delayed or eliminated. Furthermore, any of these events could prevent us or our collaborators from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these product candidates either by us or by our collaborators.

Several of our product candidates are being evaluated for the treatment of patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to our product candidates.

We are developing MPC-150-IM, which will focus on patients with heart failure with reduced ejection fraction associated with ischemic and/or diabetic etiology, and remestemcel-L (RYONCIL), which focuses on SR-aGVHD for adults. The patients who receive our product candidates are very ill due to their underlying diseases.

Generally, patients remain at high risk following their treatment with our product candidates and may more easily acquire infections or other common complications during the treatment period, which can be serious and life threatening. As a result, it is likely that we will observe severe adverse outcomes in patients during our Phase 3 and other trials for these product candidates, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to our product candidates, our ability to obtain regulatory approval for the applicable product candidate may be adversely impacted and our business could be materially harmed. Should studies of a candidate product result in regulatory approval, any association with a significant number of study subject deaths could limit the commercial potential of an approved product candidate, or negatively impact the medical community's willingness to use our product with patients.

The requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time-consuming, and unpredictable. If we or our collaborators are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.

The regulatory approval process is expensive and the time and resources required to obtain approval from the FDA or other regulatory authorities in other jurisdictions to sell any product candidate is uncertain and approval may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the discretion of the regulatory authorities. For example, governing legislation, approval policies, regulations, regulatory policies, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Further, regulatory requirements governing cell therapy products in particular have changed and may continue to change in the future. For example, in December 2016, the 21st Century Cures Act ("Cures Act") was signed into law in the United States. This law is designed to advance medical innovation, and includes a number of provisions that may impact our product development programs. For example, the Cures Act establishes a new "regenerative medicine advanced therapy" designation ("RMAT"), and creates a pathway for increased interaction with FDA for the development of products which obtain designations. Although the FDA issued guidance documents in 2019, it remains unclear how and when the FDA will fully implement all deliverables under the Cures Act.

Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in

obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to successfully complete our ongoing and future clinical trials of product candidates;
- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe, pure, and potent for any or all of a product candidate's proposed indications;
- we may be unable to demonstrate that a product candidate's benefits outweigh the risk associated with the product candidate;
- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- a decision by the FDA, other regulatory authorities or us to suspend or terminate a clinical trial at any time;
- the data collected from clinical trials of our product candidates may be inconclusive or may not be sufficient to support the submission of a Biologics License Application ("BLA"), or other submission or to obtain regulatory approval in the United States or elsewhere;
- our third party manufacturers of supplies needed for manufacturing product candidates may fail to satisfy FDA or other regulatory requirements and may not pass inspections that may be required by FDA or other regulatory authorities;
- the failure to comply with applicable regulatory requirements following approval of any of our product candidates may result in the refusal by the FDA or similar foreign regulatory agency to approve a pending BLA or supplement to a BLA submitted by us for other indications or new product candidates; and
- the approval policies or regulations of the FDA or other regulatory authorities outside of the United States may significantly change in a manner rendering our clinical data insufficient for approval.

We or our collaborators may gain regulatory approval for any of our product candidates in some but not all of the territories available and any future approvals may be for some but not all of the target indications, limiting their commercial potential. Regulatory requirements and timing of product approvals vary from country to country and some jurisdictions may require additional testing beyond what is required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval.

Our drug candidates may not benefit from an expedited approval path for cellular medicines designated as Regenerative Medicine Advanced Therapies (RMATs) under the 21st Century Cures Act.

In 2017, the FDA granted RMAT designation for our novel mesenchymal precursor cell ("MPC") therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices. The FDA granted RMAT designation for our novel MPC therapy in the treatment of chronic lower back pain due to degenerative disc disease. While the Cures Act offers several potential benefits to drugs designated as RMATs, including eligibility for increased agency support and advice during development, priority review on filing, a potential pathway for accelerated or full approval based on surrogate or intermediate endpoints, and the potential to use patient registry data and other sources of real world evidence for post approval confirmatory studies, there is no assurance that any of these potential benefits will either apply to any or all of our drug candidates or, if applicable, accelerate marketing approval. RMAT designation does not change the evidentiary standards of safety and effectiveness needed for marketing approval.

Furthermore, there is no certainty as to whether any of our product candidates that have not yet received RMAT designation under the Cures Act will receive such designation under the Cures Act. Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our products or product candidates meets the criteria for RMAT designation, the FDA may disagree. Additionally, for any product candidate that receives RMAT designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The

FDA may withdraw RMAT designation if it believes that the product no longer meets the qualifying criteria for designation.

Even if we obtain regulatory approval for our product candidates, our products will be subject to ongoing regulatory scrutiny.

RYONCIL and any future product candidates that are approved in the United States or in other jurisdictions will continue to be subject to ongoing regulatory requirements relating to the quality, identity, strength, purity, safety, efficacy, testing, manufacturing, marketing, advertising, promotion, distribution, sale, storage, packaging, pricing, import or export, record-keeping and submission of safety and other post-market information for all approved product candidates. In the United States, this includes both federal and state requirements. In particular, as a condition of approval of a BLA, the FDA may require a REMS, to ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Moreover, regulatory approval may require substantial post-approval (Phase 4) testing and surveillance to monitor the drug's safety or efficacy. Delays in the REMS approval process could result in delays in the BLA approval process. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize our product candidates, and dramatically reduce their market potential thereby adversely impacting our business, results of operations and financial condition. Post-approval study requirements could add additional burdens, and failure to timely complete such studies, or adverse findings from those studies, could adversely affect our ability to continue marketing the product.

Any failure to comply with ongoing regulatory requirements, including post-marketing requirements and commitments as well as post-approval discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may significantly and adversely affect our ability to generate revenue from our product candidates, and may result in, among other things:

- restrictions on the marketing or manufacturing of the product candidates, withdrawal of the product candidates from the market, or voluntary or mandatory product recalls;
- suspension or withdrawal of regulatory approval;
- costly regulatory inspections;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of BLAs;
- restrictions on our operations;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties by FDA or other regulatory bodies.

If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our business and our operating results will be adversely affected.

The FDA's policies, or that of the applicable regulatory bodies in other jurisdictions, may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are not able to maintain regulatory compliance, are slow or unable to adopt new requirements or policies, or effect changes to existing requirements, we or our collaborators may no longer be able to lawfully market our product, and we may not achieve or sustain profitability, which would adversely affect our business.

Ethical and other concerns surrounding the use of embryonic stem cell-based therapy may negatively affect regulatory approval or public perception of our non-embryonic stem cell product candidates, which could reduce demand for our products or depress our share price.

The use of embryonic stem cells ("ESCs"), for research and therapy has been the subject of considerable public debate, with many people voicing ethical, legal and social concerns related to their collection and use. Our cells are not ESCs, which have been the predominant focus of this public debate and concern in the United States and elsewhere. However, the distinction between ESCs and non-ESCs, such as our mesenchymal lineage cells, may be misunderstood by the public. Negative public attitudes toward cell therapy and publicity and harm from cell therapy usage clinically by others could also result in greater governmental regulation of cell therapies, which could harm our business. The improper use of cells could give rise to ethical and social commentary adverse to us, which could harm the market demand for new products and depress the price of our ordinary shares and ADSs. Ongoing lack of understanding of the difference between ESCs and non-ESCs could negatively impact the public's perception of our company and product candidates and could negatively impact us.

Additional government-imposed restrictions on, or concerns regarding possible government regulation of, the use of cell therapies in research, development and commercialization could also cause an adverse effect on us by harming our ability to establish important partnerships or collaborations, delaying or preventing the development of certain product candidates, and causing a decrease in the price of our ordinary shares and ADSs, or by otherwise making it more difficult for us to raise additional capital. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Also, existing and potential government regulation of cell therapies may lead researchers to leave the field of cell therapy research altogether in order to assure that their careers will not be impeded by restrictions on their work. This may make it difficult for us to find and retain qualified scientific personnel.

Orphan drug designation may not ensure that we will benefit from market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting (1) a patient population of fewer than 200,000 in the United States, (2) a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States, or (3) an "orphan subset" of a patient population greater than 200,000 in the United States. In the European Union ("EU"), the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 10,000 persons in the EU. Currently, this designation provides market exclusivity in the United States and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is "clinically superior" to the original orphan drug.

Our remestemcel-L product candidate has received orphan drug designation for the treatment of aGVHD by the FDA and EMA, and our CHF product candidate, rexlemestrocel-L has received orphan drug designation from the FDA for both the prevention of post-implantation mucosal bleeding in end-stage CHF patients who require a left ventricular assist device ("LVAD") and children with hypoplastic left heart syndrome ("HLHS"). If we seek orphan drug designations for other product candidates in other indications, we may fail to receive such orphan drug designations and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

We may face competition from biosimilars due to changes in the regulatory environment.

In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar", or biosimilar, to or "interchangeable" with an

FDA-approved innovator (original) biological product. This pathway could allow competitors to reference data from innovator biological products already approved after 12 years from the time of approval. For several years the annual budget requests of President Obama's administration included proposals to cut this 12-year period of exclusivity down to seven years. Those proposals were not adopted by Congress. In the United States, it is unclear if a similar change will be pursued in the future. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data from biological products already approved, but will not be able to get on the market until ten years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars causing the price for our products and our potential market share to suffer, resulting in lower product sales.

Risks Related to Collaborators

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely and cost-effective manner or at all, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party entities, including CROs, academic institutions, hospitals and other third-party collaborators, to monitor, support, conduct and/or oversee preclinical and clinical studies of our current and future product candidates. We rely on these parties for execution of our nonclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of these third-parties fail to comply with the applicable protocol, legal, regulatory, and scientific standards, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative parties or do so on commercially reasonable terms. In addition, these parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical studies may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Third parties may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with these third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

Our existing product development and/or commercialization arrangements, and any that we may enter into in the future, may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We are a party to, and continue to seek additional, collaboration arrangements with biopharmaceutical companies for the development and/or commercialization of our current and future product candidates. We may enter into new arrangements on a selective basis depending on the merits of retaining certain development and commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for RYONCIL or our product candidates, both in the United States and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate

collaborators. Any failure to meet our clinical milestones with respect to an unpartnered product candidate would make finding a collaborator more difficult. Moreover, collaboration arrangements are complex, costly and time consuming to negotiate, document and implement, and we cannot guarantee that we can successfully maintain such relationships or that the terms of such arrangements will be favorable to us. If we fail to establish and implement collaboration or other alternative arrangements, the value of our business and operating results will be adversely affected.

We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. The terms of any collaboration or other arrangements that we may establish may not be favorable to us. The management of collaborations may take significant time and resources that distract our management from other matters.

Our ability to successfully collaborate with any existing or future collaborators may be impaired by multiple factors including:

- a collaborator may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaborator may cease development in therapeutic areas which are the subject of our strategic alliances;
- a collaborator may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payments tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaborator may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaborator concerning the research or development of a product candidate or commercialization of a product resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- the results of our clinical trials may not match our collaborators' expectations, even if statistically significant;
- a collaborator may not adequately protect or enforce the intellectual property rights associated with a product or product candidate; and
- a collaborator may use our proprietary information or intellectual property in such a way as to invite litigation from a third party.

Any such activities by our current or future collaborators could adversely affect us financially and could harm our business reputation.

Risks Related to Our Manufacturing and Supply Chain

We have no experience manufacturing RYONCIL or our product candidates at a commercial scale. We may not be able to manufacture RYONCIL or our product candidates in quantities sufficient for development and commercialization, or for any current or future commercial demand for RYONCIL or our product candidates.

We have manufactured clinical and commercial quantities of our mesenchymal lineage cell product candidates in manufacturing facilities owned by Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd. (collectively referred to as "Lonza"). In 2023, FDA conducted a pre-license inspection of the manufacturing process of RYONCIL which did not result in the issuance of a Form 483 and there were no observed concerns. Following approval of RYONCIL, the process is subject to continued surveillance inspections, typically on a 3 year cycle, to ensure ongoing compliance with Good Manufacturing Practices.

The production of any biopharmaceutical, particularly cell-based therapies, involves complex processes and protocols. We cannot provide assurance that such production efforts will enable us to manufacture RYONCIL or our product candidates in the quantities and with the quality needed and in a timely manner for clinical trials, regulatory approval(s), and/or any resulting commercialization.

If we are unable to do so, our clinical trials and commercialization efforts, if any, may not proceed in a timely fashion and our business will be adversely affected. We may be required to manufacture the product in large quantities to meet demand for RYONCIL and any of our product candidates that may be approved for commercialization and marketing. Producing product in commercial quantities requires developing and adhering to complex manufacturing processes that are different from the manufacture of a product in smaller quantities for clinical trials, including adherence to additional and more demanding regulatory standards. Although we believe that we have developed processes and protocols that will enable us to consistently manufacture commercial-scale quantities of product, we cannot provide assurance that such processes and protocols will enable us to manufacture RYONCIL or our product candidates in quantities that may be required for commercialization of the product with yields and at costs that will be commercially attractive. If we are unable to establish or maintain commercial manufacture of the product or are unable to do so at costs that we currently anticipate, our business will be adversely affected.

We are focusing on the introduction of novel manufacturing approaches with the potential to result in efficiency and yield improvements to our current process. Certain of these novel approaches include modifying the media used in cell production. Another approach includes the development of 3-dimensional ("3D") bioreactor-based production for mesenchymal lineage cells. There is no guarantee that we will successfully complete either of these processes or meet all applicable regulatory requirements. This may be due to multiple factors, including the failure to produce sufficient quantities and the inability to produce cells that are equivalent in physical and therapeutic properties as compared to the products produced using our current manufacturing processes. In the event our transition to these improved manufacturing processes is unsuccessful, we may not be able to produce certain of our products in a cost-efficient manner and our business may be adversely affected.

Global events may adversely impact the manufacturing and commercialization of RYONCIL, and other product candidates.

On October 17, 2019, we announced that we had entered into a manufacturing service agreement with Lonza Bioscience Singapore Pte. Ltd. for the supply of commercial product for the launch of RYONCIL. We currently also manufacture our other product candidates with Lonza Singapore.

Due to the after-effects of the COVID-19 pandemic, and recent geopolitical instability, countries in which we have operations, including Singapore, have experienced some challenges in the ability of our suppliers and contractors to source, supply or acquire raw materials or components needed for our manufacturing process and supply chain. As a result, the manufacturing and commercialization of RYONCIL and other product candidates could be adversely affected if those impacts and impacts from other disruptive events such as significant climate and geopolitical events are experienced, with potential for increased costs.

We rely on contract manufacturers to supply and manufacture RYONCIL and our product candidates. Our business could be harmed if Lonza fails to provide us with sufficient quantities of RYONCIL or these product candidates or fails to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our mesenchymal lineage cell product candidates for use in the conduct of our clinical trials, and we currently lack the internal resources and the capability to manufacture RYONCIL or any of our product candidates on a clinical or commercial scale. As a result, we currently depend on Lonza to manufacture RYONCIL and our mesenchymal lineage cell product candidates. Relying on Lonza to manufacture RYONCIL and our mesenchymal lineage cell product candidates entails risks, and Lonza may:

- cease or reduce production or deliveries, raise prices or renegotiate terms;
- be unable to meet any product specifications and quality requirements consistently;
- delay or be unable to procure or expand sufficient manufacturing capacity, which may harm our reputation or frustrate our customers;
- not have the capacity sufficient to support the scale-up of manufacturing for RYONCIL or our product candidates;

- have manufacturing and product quality issues related to scale-up of manufacturing;
- experience costs and validation of new equipment facilities requirement for scale-up that it will pass on to us;
- fail to comply with cGMP and similar international standards;
- lose its manufacturing facility in Singapore, stored inventory or laboratory facilities through fire or other causes, or other loss of materials necessary to manufacture our product candidates;
- experience disruptions to its operations by conditions unrelated to our business or operations, including the bankruptcy or interruptions of its suppliers;
- experience carrier disruptions or increased costs that it will pass on to us;
- fail to secure adequate supplies of essential ingredients in our manufacturing process;
- experience failure of third parties involved in the transportation, storage or distribution of our products, including the failure to deliver supplies it uses for the manufacture of RYONCIL and our product candidates under specified storage conditions and in a timely manner;
- terminate agreements with us; and
- appropriate or misuse our trade secrets and other proprietary information.

Any of these events could lead to delays in the development of our product candidates, including delays in our clinical trials, or failure to obtain regulatory approval for our product candidates, or it could impact our ability to successfully commercialize RYONCIL, our current product candidates or any future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure or total or partial suspension of production.

In addition, the lead time needed to establish a relationship with a new manufacturer can be lengthy and expensive, and we may experience delays in meeting demand in the event we must switch to a new manufacturer. We are expanding our manufacturing collaborations in order to meet future demand and to provide back-up manufacturing options, which also involves risk and requires significant time and resources. Our future collaborators may need to expand their facilities or alter the facilities to meet future demand and changes in regulations. These activities may lead to delays, interruptions to supply, or may prove to be more costly than anticipated. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to manufacture or commercialize RYONCIL or our product candidates in a profitable manner.

We have implemented a business model under which we control the manufacture, supply and distribution of RYONCIL and our product candidates, including but not exclusively, through our product suppliers, including Lonza. There can be no assurance as to whether we and our suppliers will be able to scale-up the manufacturing processes and implement technological improvements in a manner that will allow the manufacture of RYONCIL or our product candidates in a cost effective manner. Our or our collaborators' inability to sell RYONCIL or our product candidates at a price that exceeds our cost of manufacture by an amount that is profitable for us will have a material adverse result on the results of our operations and our financial condition.

Collaborators' ability to identify, test and verify new donor tissue in order to create new master cell banks involves many risks.

The initial stage of manufacturing involves obtaining mesenchymal lineage cell-containing bone marrow from donors, for which we currently rely on our suppliers. Mesenchymal lineage cells are isolated from each donor's bone marrow and expanded to create a master cell bank. Each individual master cell bank comes from a single donor. A single master cell bank can source many production runs, which in turn can produce up to thousands of doses of a given product, depending on the dose level. The process of identifying new donor tissue, testing and verifying its validity in order to create new master cell banks and validating such cell bank with the FDA and other regulatory agencies is time consuming, costly and prone to the many risks involved with creating living cell products. There could be consistency or quality control issues with any new master cell bank. Although we believe we and our collaborators have the necessary know-how and processes to enable us to create master cell banks with consistent quality and within the timeframe necessary to meet projected demand and we have begun doing so, we cannot be certain that we or our collaborators will be able to successfully do so, and any failure or delays in creating new master cell banks may have a material adverse impact on our

business, results of operations, financial conditions and growth prospects and could result in our inability to continue operations.

We and our collaborators depend on a limited number of suppliers for RYONCIL's and our product candidates' materials, equipment or supplies and components required to manufacture RYONCIL and our product candidates. The loss of these suppliers, or their failure to provide quality supplies on a timely basis, could cause delays in our current and future capacity and adversely affect our business.

We and our collaborators depend on a limited number of suppliers for the materials, equipment and components required to manufacture RYONCIL and our product candidates, as well as various "devices" or "carriers" for some of our programs (e.g., the catheter for use with MPC-150-IM, and the hyaluronic acid used for chronic lower back pain). The main consumable used in our manufacturing process is our media, which currently is sourced from fetal bovine serum ("FBS"). This material comes from limited sources, and as a result is expensive. Consequently, we or our collaborators may not be able to obtain sufficient quantities of RYONCIL or our product candidates or other critical materials equipment and components in the future, at affordable prices or at all. A delay or interruption by our suppliers may also harm our business, and operating results. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we or our collaborators may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our and our collaborators' dependence on single-source suppliers exposes us to numerous risks, including the following:

- our or our collaborators' suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- our or our collaborators' suppliers may not be able to source materials, equipment or supplies and components required to manufacture RYONCIL or our product candidates as a result of the after-effects of the COVID-19 pandemic or geopolitical and/or economic instability adversely or the impact of climate events affecting the supply chain;
- we or our collaborators may be unable to locate suitable replacement suppliers on acceptable terms or on a timely basis, or at all; and
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

We and our collaborators and Lonza are subject to significant regulation with respect to manufacturing RYONCIL and our product candidates. The Lonza manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing manufacturers, including Lonza, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with current international Good Manufacturing Practice and other international regulatory requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product and product candidates. We, our collaborators, or suppliers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to current Good Laboratory Practice and current Good Manufacturing Practice regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Other than RYONCIL, Lonza and other suppliers have never produced a commercially approved cellular therapeutic product and therefore have not yet obtained the requisite regulatory authority approvals to do so.

Before we can begin commercial manufacture of our product candidates for sale in the United States, we must obtain FDA regulatory approval for the product in addition to the approval of the processes and quality systems associated with the manufacturing of such product, which requires a successful FDA inspection of the facility handling the manufacturing of our product, including the manufacturing facilities. The novel nature of our product and product candidates creates significant challenges in regards to manufacturing. For example, the U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of tissue, including those incorporated in federal Good

Tissue Practice regulations. We may not be able to identify or develop sources for the cells necessary for our product candidates that comply with these laws and regulations.

In addition, the regulatory authorities may, at any time before or after product approval, audit or inspect a manufacturing facility involved with the preparation of our product and product candidates or raw materials or the associated quality systems for compliance with the regulations applicable to the activities being conducted. In 2023, FDA conducted a pre-license inspection of the manufacturing process of RYONCIL which did not result in the issuance of a Form 483 and there were no observed concerns. Although we oversee each contract manufacturer involved in the production of our product and product candidates, we cannot control the manufacturing process of, and are dependent on, the contract manufacturer for compliance with the regulatory requirements. If the contract manufacturer is unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our business, results of operations and financial condition. If the manufacturer fails to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

We will rely on third parties to perform many necessary services for the commercialization of RYONCIL and our product candidates, including services related to the distribution, storage and transportation of our products.

We will rely upon third parties for certain storage, distribution and other logistical services. In accordance with certain laws, regulations and specifications, RYONCIL and our product candidates must be stored and transported at extremely low temperatures within a certain range. If these environmental conditions deviate, RYONCIL's and our product candidates' remaining shelf-lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. If any of the third parties that we intend to rely upon in our storage, distribution and other logistical services process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand may be significantly impaired. In addition, as our cellular therapies will constitute a new form of product, experience in commercial distribution of such therapies in the United States is extremely limited, and as such is subject to execution risk. While we intend to work closely with our selected distribution logistics providers to define appropriate parameters for their activities to ensure product remains intact throughout the process, there is no assurance that such logistics providers will be able to maintain all requirements and handle and distribute our products in a manner that does not significantly impair them, which may impact our ability to satisfy commercial demand. Likewise, the after-effects from the COVID-19 pandemic, geopolitical and economic instability, and climate events may adversely impact access to raw materials and distribution, storage and transportation of our products, and the cost of those activities.

Product recalls or inventory losses caused by unforeseen events may adversely affect our operating results and financial condition.

RYONCIL and our product candidates are manufactured, stored and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture, storage and distribution of RYONCIL and our product candidates, subjects us to risks. For example, during the manufacturing process we have from time to time experienced several different types of issues that have led to a rejection of various batches. Historically, the most common reasons for batch rejections include major process deviations during the production of a specific batch and failure of manufactured product to meet one or more specifications. While product candidate batches released for the use in clinical trials and product batches released for commercialization undergo sample testing, some latent defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in RYONCIL and our product candidates not complying with stability requirements or specifications. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. In the event our production efforts require a recall or result in an inventory loss, our operating results and financial condition may be adversely affected.

Risks Related to Commercialization of Our Product Candidates

Until approval of our next product candidate, we are substantially dependent on the commercial success of RYONCIL. If we are unable to successfully commercialize or experience significant delays in doing so, our business will be materially harmed.

We have only recently received approval for remestemcel-L and plan to commercialize remestemcel-L and sell it under the name RYONCIL beginning in this first quarter of 2025. Our ability to offset our losses and sustain our business will be largely dependent on sales of RYONCIL. Until approval of our next product candidate, our success as a company is substantially dependent on our ability to generate revenue from the sales of RYONCIL, which depend on many factors, including but not limited to, our ability to:

- maintain approval and expand the label of RYONCIL in the United States;
- obtain approval of RYONCIL in other jurisdictions;
- achieve and maintain market acceptance of, and demand for RYONCIL;
- demonstrate in the medical community the safety and efficacy of RYONCIL and its potential advantages over and side effects compared to alternative treatments;
- execute our sales, marketing and distribution strategies for RYONCIL;
- maintain and manage the necessary sales, marketing, distribution and other capabilities and infrastructure that are required to successfully commercialize RYONCIL;
- adapt to any changes to the label for RYONCIL that could place restrictions on how we market and sell RYONCIL, including as a result of adverse events that may be observed in other studies;
- obtain payor coverage of and profitable payment rate for RYONCIL;
- offer RYONCIL at competitive prices as compared to alternative treatments, and our ability to achieve profitability from revenues on the sales of RYONCIL;
- obtain adequate and timely supply of RYONCIL, which may in the future be adversely affected by factors relating to our manufacturing capabilities, after-effects of the COVID-19 pandemic or geopolitical and/or economic instability adversely or the impact of climate events affecting the supply chain;
- comply with applicable legal and regulatory requirements;
- maintain the necessary licenses and permits required for the sale of RYONCIL and a pharmacovigilance system complying with applicable legal and regulatory requirements;
- enforce intellectual property rights in and to RYONCIL; and
- avoid third-party patent interference or intellectual property infringement claims.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we may not be able to generate material and continuing revenue from sales of RYONCIL, which may materially impact the success of our business. As RYONCIL is our first approved product and the remainder of our product candidates are in preclinical or clinical development, we have limited experience as a commercial company and there is limited information about our ability to achieve these factors or overcome many of the challenges encountered by companies commercializing products in the biopharmaceutical industry.

Our future commercial success depends upon attaining significant market acceptance of RYONCIL and our product candidates, if approved, among physicians, patients and healthcare payors.

Even when product development is successful and regulatory approval has been obtained, such as in the case of RYONCIL, our ability to generate significant revenue depends on the acceptance of our products by physicians, payors and patients. Many potential market participants have limited knowledge of, or experience with, cell therapy-based products, so gaining market acceptance and overcoming any safety or efficacy concerns may be more challenging than for more traditional therapies. Our efforts to educate the medical community and third-party payors on the benefits of RYONCIL or our product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more or different resources than are required by the conventional therapies marketed by our competitors. We cannot assure you that our products will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. Alternatively, even if we obtain regulatory approval of our product

candidates, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The market acceptance of RYONCIL and each of our product candidates will depend on a number of factors, including:

- the efficacy and safety of RYONCIL or the product candidate, as demonstrated in clinical trials;
- the clinical indications for which the product is approved, and the label approved by regulatory authorities for use with the product, including any warnings or contraindications that may be required on the label;
- acceptance by physicians, patients, and with pediatric indications by parents/caregivers of the product as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the continued projected growth of markets for our various indications;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our, and our collaborators' sales and marketing efforts; and
- sufficient third-party insurance and other payor (e.g., governmental) coverage and reimbursement.

Market acceptance is critical to our ability to generate significant revenue. RYONCIL, and any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

If, in the future, we are unable to establish our own commercial capabilities across sales, marketing and distribution, or enter into licensing or collaboration agreements for these purposes, we may not be successful in independently commercializing RYONCIL or any future products.

We have limited sales, marketing or distribution infrastructure and experience. Commercializing RYONCIL and our product candidates, if such product candidates obtain regulatory approval, will require significant sales, distribution and marketing capabilities. Where and when appropriate, we may elect to utilize contract sales forces or distribution collaborators to assist in the commercialization of RYONCIL and our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution/price reporting services for RYONCIL and/or our product candidates, the resulting revenue or the profitability from this revenue to us may be lower than if we had sold, marketed and distributed that product ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute RYONCIL or any future products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our current or any future products effectively.

To the extent we are unable to engage third parties to assist us with these functions, we will have to invest significant amounts of financial and management resources, some of which in relation to any future product approvals, will need to be committed prior to any confirmation that product candidate will be approved. For RYONCIL and future products for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel or to develop alternative sales channels;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of account teams to obtain formulary acceptance for our products, allowing for reimbursement and hence patient access;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with multiple products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

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

The biopharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of our potential competitors have significantly greater development, financial, manufacturing, marketing, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in conducting clinical trials, obtaining regulatory approvals, manufacturing pharmaceutical and biologic products and commercializing such therapies. Recent and potential future merger and acquisition activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds that could make RYONCIL or our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing our product candidates or competitors to our product candidates before we do. Specialized, smaller or early-stage companies may also prove to be significant competitors, particularly those with a focus and expertise in cell therapies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and results of operations will suffer.

Our marketed products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), and other laws and regulations, we are prohibited from promoting our products for off-label uses. This means, for example, that we would not be able to make claims about the use of our marketed products outside of their approved indications, and we would not be able to proactively discuss or provide information on off-label uses of such products, with very specific and limited exceptions. The FDA does not, however, prohibit physicians from prescribing products for off-label uses in the practice of medicine. Should the FDA determine that our activities constituted the promotion of off-label use, the FDA could issue a warning or untitled letter or, through the Department of Justice, bring an action for seizure or injunction, and could seek to impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions, and also may figure into civil litigation against us.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. In addition, on August 16, 2022, the U.S. government enacted the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government. There have been a number of judicial challenges to certain aspects of each law. We can provide no assurance that laws such as the Affordable Care Act or the Inflation Reduction Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Currently, the outcome of potential reforms and changes to government negotiation/regulation to healthcare costs are unknown. If changes in policy limit reimbursements that we are able to receive through federal programs, it could negatively impact reimbursement levels from those payors and private payors, and our business, revenues or profitability could be adversely affected.

If we or our collaborators fail to obtain and sustain an adequate level of reimbursement for our products by third-party payors, sales and profitability would be adversely affected.

Our and our collaborators' ability to commercialize any products successfully will depend, in part, on the extent to which coverage and reimbursement for our products and related treatments will be available from government healthcare

programs, private health insurers, managed care plans, and other organizations. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, our revenue and profitability could be materially and adversely affected.

Third-party payors, such as government programs, including Medicare or Medicaid in the United States, or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for medical products and services, and many third-party payors limit or delay coverage of or reimbursement for newly approved healthcare products. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors, including the third-party payor's determination that use of a product, including our RYONCIL product, is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A current trend in the U.S. healthcare industry as well as in other countries around the world is toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for any product, which could result in product revenue and profitability being lower than anticipated.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, such as RYONCIL, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's 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 and treatment codes for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop, including RYONCIL, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Furthermore, reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our existing or future collaborators, if any, may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals which could adversely affect our revenues and profits. In many countries, including for example in Japan, products cannot be commercially launched until reimbursement is approved. Further, the post-approval price negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices which are not sufficient to allow us or our collaborators to generate a profit, our collaborators may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect sales and profitability.

Due to the novel nature of our cell therapy and the potential for RYONCIL or our product candidates to offer therapeutic benefit in a single administration, we face uncertainty related to pricing and reimbursement for RYONCIL and these product candidates.

Our target patient populations for RYONCIL and some of our product candidates may be relatively small, and as a result, the pricing and reimbursement of RYONCIL and our product candidates, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell RYONCIL and our product candidates will be adversely affected. Due to the novel nature of our cell therapy technology, the manner and level at which reimbursement is provided for services related to RYONCIL and our product

candidates (e.g., for administration of our product to patients) is uncertain. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. Further, if the results of our clinical trials and related cost benefit analyses do not clearly demonstrate the efficacy or overall value of RYONCIL or our product candidates in a manner that is meaningful to prescribers and payors, our pricing and reimbursement may be adversely affected.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of RYONCIL or our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be adversely affected.

If the market opportunities for RYONCIL or our product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of RYONCIL and certain of our other product candidates are small, we must be able to successfully identify physicians with access to appropriate patients and achieve a significant market share to maintain profitability and growth.

Our projections of the number of people with diseases targeted by RYONCIL or our product candidates are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. In addition, physicians who we believe have access to patients in need of our products may in fact not often treat the diseases targeted by RYONCIL or our product candidates, and may not be amenable to use of our product. Further, the number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We are exposed to risks related to our licensees and our international operations, and failure to manage these risks may adversely affect our operating results and financial condition.

We and our subsidiaries operate out of Australia, the United States, Singapore, the United Kingdom and Switzerland. We have licensees, with rights to commercialize products based on our MSC technology, including JCR in Japan. Our primary manufacturing collaborator, Lonza, serves us primarily out of their facilities in Singapore, and through contractual relationships with third parties, has access to storage facilities in the U.S., Europe, Australia and Singapore. As a result, a significant portion of our operations are conducted by and/or rely on entities outside the markets in which certain of our trials take place, our suppliers are sourced, our product candidates are developed, and our products may be sold. Accordingly, we import a substantial number of products and/or materials into such markets. We may be denied access to our customers, suppliers or other collaborators or denied the ability to ship products from any of these sites as a result of a closing of the borders of the countries in which we operate, or in which these operations are located, due to economic, legislative, political, health or military conditions in such countries. We may enter into agreements with third parties to market RYONCIL, or any of our product candidates that are approved for commercialization, on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- logistics and regulations associated with shipping cell samples and other perishable items, including infrastructure conditions and transportation delays;

- potential import and export issues and other trade barriers and restrictions with the U.S. Customs and Border Protection and similar bodies in other jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- reduced protection for intellectual property rights in some countries and practical difficulties of enforcing intellectual property and contract rights abroad;
- changes in diplomatic and trade relationships, including new tariffs, trade protection measures, import or export licensing requirements, trade embargoes and other trade barriers;
- tariffs imposed by the U.S. on goods from other countries, including the recently implemented tariffs and additional tariff that have been proposed by the U.S. government on imports from various countries and by the governments of these jurisdictions on certain U.S. goods, and any other possible tariffs that may be imposed on products such as ours, the scope and duration of which, if implemented, remains uncertain;
- deterioration of political relations, for example between Russia and other nations, and between the U.K. and members of the EU, which could have a material adverse effect on our supply chains, and sales and operations in these countries;
- changes in social, political and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in the other countries and jurisdictions into which we sell our products;
- fluctuations in currency exchange rates and the related effect on our results of operations;
- increased financial accounting and reporting burdens and complexities;
- potential increases on tariffs or restrictions on trade generally;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war (such as Russia's invasion of Ukraine) and terrorism, or climate related events and natural disasters including earthquakes, typhoons, floods and fires.

Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the manufacturing materials and/or components that we use in, and which are critical to, implementation of our technology involve the use of animal-derived products, including FBS. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. While FBS is commonly used in the production of various marketed biopharmaceuticals, the suppliers of FBS that meet our strict quality standards are limited in number and region. As such, to the extent that any such suppliers or regions face an interruption in supply (for example, if there is a new occurrence of so-called "mad cow disease"), it may lead to a restricted supply of the serum currently required for our product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture our cell products. The FDA has issued regulations for controls over bovine material in animal feed. These regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may propose new regulations that could affect our operations. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of RYONCIL and our product candidates.

We face an inherent risk of product liability as a result of the human clinical use of our product candidates and face an even greater risk related to the commercialization of our products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product design, 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, and a breach of warranties. Claims could also be asserted under state consumer protection and other acts. If we cannot successfully defend ourselves against product

liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, even if such products are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- initiation of investigations by regulators;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- increased cost of liability insurance;
- loss of revenue;
- the inability to commercialize our products; and
- a decline in our ordinary share price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Additionally, our insurance policies have various exclusions, and we may be subject to a product liability claim for which we have no coverage or reduced coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property for RYONCIL and our product candidates. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our current product or any future products, or fail to otherwise provide us with any competitive advantage. As such, we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to RYONCIL and our product candidates and proprietary technology could have a material adverse impact on our business.

Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent technology in jurisdictions with significant or otherwise relevant commercial opportunities or activities. However, patent protection may not be available for some of the products or technology we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed.

The patent positions of biopharmaceutical products are complex and uncertain.

The scope and extent of patent protection for RYONCIL and our product candidates are particularly uncertain. To date, our principal product candidates have been based on specific subpopulations of known and naturally occurring adult stem cells. We anticipate that the product candidates we develop in the future will continue to include or be based on the same or other naturally occurring stem cells or derivatives or products thereof. Although we have sought and expect to continue to seek patent protection for our product candidates, their methods of use and methods of manufacture, any or all of them may not be subject to effective patent protection. Publication of information related to our products and product

candidates by us or others may prevent us from obtaining or enforcing patents relating to these products and product candidates. Furthermore, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, any of our issued patents may be declared invalid. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic product to compete with our product candidates. We may also face competition from companies who develop a substantially similar product to our other product candidates that may not be covered by any of our patents.

Filing, prosecuting and defending patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, 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. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We maintain certain of our proprietary know-how and technological advances as trade secrets, especially where we do not believe patent protection is appropriate or obtainable, including, but not exclusively, with respect to certain aspects of the manufacturing of our products. However, trade secrets are difficult to protect. We take a number of measures to protect our trade secrets including, limiting disclosure, physical security and confidentiality and non-disclosure agreements. We enter into confidentiality agreements with our employees, consultants, outside scientific collaborators, contract manufacturing partners, sponsored researchers and other advisors and third parties to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial condition.

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope and may no longer be used to prevent the manufacture and sale of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (“USPTO”), may place pending applications at risk of non-issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post-grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patent applications. Furthermore, because of the substantial amount of discovery required in

connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation.

Intellectual property disputes 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/or 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 substantial adverse effect on the market price of our ADSs and ordinary shares. 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. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of litigation proceedings more effectively than we can because of their greater financial resources and personnel. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology or enter into strategic collaborations that would help us bring our product candidates to market. As a result, uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

U.S. patent reform legislation and court decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued U.S. patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Under the current patent laws, a third party that files a patent application in the USPTO before us for a particular invention could therefore be awarded a patent covering such invention even if we had made that invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application.

The current US legislation allows third party submissions of prior art to the USPTO during patent prosecution and additional procedures for attacking the validity of a patent through USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because a lower evidentiary standard applies in USPTO proceedings compared to the evidentiary standards applied in United States federal courts in actions seeking to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if challenged in a district court action. Accordingly, a third party may attempt to use available USPTO procedures to invalidate our patent claims that would not otherwise have been invalidated if first challenged by the third party in a district court action. These post-grant review (PGR) proceedings, which are similar to European “opposition” proceedings and provide third-party petitioners with the ability to challenge the validity of a patent on more expansive grounds than those permitted in other USTPO proceedings, allow for validity to be examined by the USPTO based not only on prior art patents and publications, but also on prior invalidating public use and sales, the presence of non-statutory subject matter in the patent claims and inadequate written description or lack of enablement. Discovery for PGR proceedings is accordingly likely to be expansive given that the issues addressed in PGR are more comprehensive than those addressed in other USPTO proceedings.

As compared to intellectual property-reliant companies generally, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

If third parties claim that intellectual property used by us infringes upon their intellectual property, commercialization of RYONCIL and our product candidates and our operating profits could be adversely affected.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot

provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. Any such claims could also be expensive and time consuming to defend and divert management's attention and resources, and could delay or prevent us from commercializing RYONCIL and our product candidates. Our competitive position could suffer as a result. Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to RYONCIL and our product candidates, we have not conducted a freedom-to-operate search or analysis for our product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that RYONCIL and our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of RYONCIL and our product candidates, our business may be materially harmed.

Depending on the timing, duration and specifics of FDA marketing approval of RYONCIL and our product candidates, if any, one of the U.S. patents covering each of such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, including by the EMA in the EU or the PMDA in Japan. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, if a patent we wish to extend is owned by another party and licensed to us, we may need to obtain approval and cooperation from our licensor to request the extension.

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 before we might face generic or follow-on competition could be shortened and we may not be able to stop our competitors from launching competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Our Business and Industry

If we fail to attract and keep senior management and key scientific, commercial, regulatory affairs and other personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize RYONCIL and our product candidates.

We are highly dependent on members of our executive management, particularly Dr. Silviu Itescu, our Chief Executive Officer. Dr. Itescu was an early pioneer in the study and clinical development of cell therapeutics and is globally recognized in the field of regenerative medicine. The loss of the services of Dr. Itescu or any other member of the executive management team could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, regulatory affairs, sales and marketing personnel will also be 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.

Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements (including arrangements with healthcare providers, opinion leaders, research institutions, distributors and payors) in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of activity relating to pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business

arrangements. 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, or, given we are a listed company in Australia and the United States, breach of insider trading or other securities laws and regulations. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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, including the imposition of significant fines or other sanctions.

We may acquire other companies or assets which could divert our management's attention, result in additional dilution to our shareholders and otherwise disrupt our operations and harm our operating results.

We have in the past and may in the future seek to acquire businesses, products or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. For example, we acquired MSC assets in 2013. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- incurrence of acquisition-related costs;
- diversion of management's attention from other business concerns;
- unanticipated costs or liabilities associated with the acquisition;
- harm to our existing business relationships with collaborators as a result of the acquisition;
- harm to our brand and reputation;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results arising from the impairment assessment process. Acquisitions may also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, results of operations and financial condition may be adversely affected.

We and our collaborators must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We and our collaborators are subject to various federal, state and local environmental laws, rules and regulations, including those relating to the discharge of materials into the air, water and ground, the manufacture, storage, handling, use, transportation and disposal of hazardous and biological materials, and the health and safety of employees with respect to laboratory activities required for the development of products and technologies. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, it could cause an interruption of our commercialization efforts, research and development efforts, or business operations, and we could be held liable for any resulting damages and any such liability could exceed our assets and resources.

We work with outside scientists and their institutions in developing product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our discovery platform.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development. These scientific advisors serve as our link to the specific pools of trial participants we are targeting in that these advisors may:

- identify individuals as potential candidates for study;

- obtain their consent to participate in our research;
- perform medical examinations and gather medical histories;
- conduct the initial analysis of suitability of the individuals to participate in our research based on the foregoing; and
- collect data and biological samples from trial participants periodically in accordance with our study protocols.

These scientists and collaborators are not our employees, rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business.

If our ability to use cumulative carry forward net operating losses is or becomes subject to certain limitations or if certain tax incentive credits from which we may benefit expire or no longer apply to us, our business, results of operations and financial condition may be adversely affected.

We are an Australian company subject to taxation in Australia and other jurisdictions. As of December 31, 2024, our cumulative operating losses have a total potential tax benefit of $211.3 million at local tax rates (excluding other temporary differences). These losses may be available for use once we are in a tax profitable position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdictions. Tax losses are able to be carried forward at their nominal amount indefinitely in Australia and in Singapore, and for up to 20 years in the U.S. as long as certain conditions are met; however, new tax reform legislation in the United States allows for indefinite carryforward of any net operating loss arising in a tax year ending after December 31, 2018, subject to certain conditions. In order to use these tax losses, it is necessary to satisfy certain tests and, as a result, we cannot assure you that the tax losses will be available to offset profits if and when we earn them. Utilization of our net operating loss and research and development credit carryforwards in the U.S. may be subject to substantial annual limitation due to ownership change limitations that could occur in the future generally provided by Section 382 of the Internal Revenue Code of 1986, as amended. In addition, U.S. tax reform introduced a limitation on the amount of net operating losses arising in taxable years beginning after December 31, 2017, that a corporation may deduct in a single tax year equal to the lesser of the available net operating loss carryover or 80 percent of a taxpayer’s pre-net operating loss deduction taxable income. With respect to carryforward net operating losses in the U.S. that are subject to the 20-year carry-forward limit, our carry forward net operating losses first start to expire in 2032.

In addition, we may be eligible for certain research and development tax incentive refundable credits in Australia that may increase our available cash flow. The Australian federal government's Research and Development Tax Incentive grant is available for eligible research and development purposes based on the filing of an annual application. The Australian government may in the future decide to modify the requirements of, reduce the amounts of the research and development tax incentive credits available under, or discontinue its research and development tax incentive program. For instance, the Australian government undertook a review of its Research and Development Tax Incentive program in the May 2020 Federal budget and in October 2020 introduced new legislation for the tax offset applicable to eligible companies for income tax years commencing from July 1, 2021. One of the legislation changes made was to allow a tax offset for companies with an aggregated turnover of A$20.0 million or more. For companies with an aggregated turnover of A$20.0 million or more, the rate of tax offset is the company’s corporate tax rate plus a rate between 8.5% and 16.5% depending on the proportion of research and development expenditures in relation to total expenditures. For companies with an aggregated turnover below A$20.0 million, the rate of the refundable research and development tax offset was set as at 18.5% above the company’s tax rate. If the Research and Development Tax program incentives are revoked or modified, or if we are no longer eligible for such incentives due to other circumstances, our business, results of operations and financial condition may be adversely affected.

We assess, on an annual basis, the quantum of previous research and development tax claims and on-going eligibility to claim this tax incentive in Australia. As of December 31, 2024, tax incentives recoverable of $0.8 million have been recognized within trade and other receivables on our consolidated balance sheet pertaining to an estimate of the research and development tax incentive income from the Research and Development Tax Incentive program relating to a claim for eligible expenditure under the incentive scheme for the year ended June 30, 2024. No income was recognized in the six months ended December 31, 2024. There can be no assurances that we will benefit from these incentives in the

future if our activities are not eligible under the incentive scheme or that the tax incentive credit programs will not be revoked or modified in any way in the future.

Taxing authorities could reallocate our taxable income within our subsidiaries, which could increase our consolidated tax liability.

We conduct operations in multiple tax jurisdictions and the tax laws of those jurisdictions generally require that the transfer pricing between affiliated companies in different jurisdictions be the same as those between unrelated companies dealing at arms' length, and that such prices are supported by contemporaneous documentation. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer pricing as not reflecting arms' length transactions, they could require us to adjust our transfer pricing and thereby reallocate our income to reflect these revised transfer pricing, which could result in a higher tax liability to us, and possibly interest and penalties, and could adversely affect our business, results of operations and financial condition.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex and can be subject to varying interpretations as to whether or not a statute has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute which prohibits, among other things, the knowing and willful payment of remuneration to induce or reward patient referrals, prescribing or recommendation of products, or the generation of business involving any item or service which may be payable by the federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients);
- the federal False Claims Act which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment for government funds (e.g., payment from Medicare or Medicaid) or knowingly making, using, or causing to be made or used a false record or statement, material to a false or fraudulent claim for government funds;
- the federal *Health Insurance Portability and Accountability Act of 1996* ("HIPAA"), as amended by the *Health Information Technology for Economic and Clinical Health Act*, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HIPAA imposes civil and criminal liability for the wrongful access or disclosure of protected health information;
- the federal *Physician Payments Sunshine Act*, created under Section 6002 of the *Patient Protection and Affordable Care Act* ("ACA"), as amended, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, those physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members;
- the FDCA, which, among other things, regulates the testing, development, approval, manufacture, promotion and distribution of drugs, devices and biologics. The FDCA prohibits manufacturers from selling or distributing "adulterated" or "misbranded" products. A drug product may be deemed misbranded if, among other things, (i) the product labeling is false or misleading, fails to contain requisite information or does not bear adequate directions for use; (ii) the product is manufactured at an unregistered facility; or (iii) the product lacks the requisite FDA clearance or approval;
- the U.S. *Foreign Corrupt Practices Act* ("FCPA"), which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and
- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Any failure to comply with these laws, or the regulations adopted thereunder, could result in administrative, civil, and/or criminal penalties, and could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The federal fraud and abuse laws have been interpreted to apply to arrangements between pharmaceutical manufacturers and a variety of health care professionals and healthcare organizations. Although the federal Anti-Kickback Statute has several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, all elements of the potentially applicable exemption or safe harbor must be met in order for the arrangement to be protected, and prosecutors have interpreted the federal healthcare fraud statutes to attack a wide range of conduct by pharmaceutical companies. In addition, most states have statutes or regulations similar to the federal anti-kickback and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Further, the ACA, among other things, amended the intent standard under the Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA makes clear that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the federal False Claims Act. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the *American Recovery and Reinvestment Act 2009* ("ARRA"), Congress amended the privacy and security provisions of HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The EU's General Data Protection Regulation, Canada's *Personal Information Protection and Electronic Documents Act* and other data protection, privacy and similar national, state/provincial and local laws and regulations may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches, and the failure to so comply may lead to fines or penalties.

Our operations are subject to anti-corruption laws, including Australian bribery laws, the United Kingdom Bribery Act, and the FCPA and other anti-corruption laws that apply in countries where we do business.

Anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Although we believe that we have adequate policies and enforcement mechanisms to ensure legal and regulatory compliance with the FCPA, the U.K. Bribery Act 2010 and other similar regulations, we participate in collaborations and relationships with third parties, and it is possible that any of our employees, subcontractors, agents or partners may violate any such legal and regulatory requirements, which may expose us to criminal or civil enforcement actions, including penalties and suspension or disqualification from U.S. federal procurement contracting. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other laws including trade related laws. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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.

In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2) (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 U.S. and (c) our business must be administered principally outside the U.S. 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, in the preparation and issuance of our financial statements for historical and current periods. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer 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.

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

Section 404(a) of the *Sarbanes-Oxley Act of 2002* (the "Sarbanes-Oxley Act") requires that our management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

If either we are unable to conclude that we have effective internal controls over financial reporting or our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, 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 Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on Nasdaq Global Select Market ("Nasdaq").

We have incurred and will continue to 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 continue to be required to devote substantial time to compliance initiatives.

As a company whose ADSs are publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses. The Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and Nasdaq, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to continue 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 have increased and will continue to 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 senior management. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially regulatory investigations and enforcement and/or civil litigation.

We have never declared or paid dividends on our ordinary shares, and we do not anticipate paying dividends in the foreseeable future. Therefore, you must rely on price-appreciation of our ordinary shares or ADSs for a return on your investment.

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under the loan facilities with Oaktree and NovaQuest or other current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment in our ordinary shares or ADSs will likely only occur if our ordinary share or ADS price appreciates. There is no guarantee that our ordinary shares or ADSs will appreciate in value in the future.

Australian takeover 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 laws of Australia. Among other things, we are subject to the Australian *Corporations Act 2001* (the "Corporations Act"). Subject to a range of exceptions, the Corporations Act prohibits 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 to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' opportunity to sell their ordinary shares or ADSs and may further restrict the ability of our shareholders to obtain a premium from such transactions.

Significant disruptions of information technology systems, data security breaches or unauthorized disclosure of sensitive data could adversely affect our business by exposing us to liability and affect our business and reputation.

The Company is increasingly dependent on critical, complex, and interdependent information technology systems (IT systems), including cloud-based software and external servers, some of which are managed or hosted by third parties, to support business processes as well as internal and external communications. The information and data processed and stored in our IT systems, and those of our research collaborators, CROs, contract manufacturers, suppliers, distributors, or other third parties for which we depend to operate our business, may be vulnerable to cybersecurity breaches from unauthorized activity by our employees, contractors or malware, hacking, business email compromise, phishing or other cyberattacks directed by other parties. Such breaches can result in loss, damage, denial-of-service, unauthorized access or misappropriation and may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. In addition, our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. The increase in working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, manufacturing sites, clinical trial sites, and other third parties.

The rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, may mean our measures to prevent, respond to and minimize such risks may be ineffective. If a material incident or interruption were to occur, it could result in a disruption of our development programs and future commercial operations, including due to a loss, corruption or unauthorized disclosure of our proprietary or sensitive information. Additionally, the costs to the company to investigate and mitigate cybersecurity incidents could be significant. Any disruption, security breach, or action by the company, its employees, or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within Australia and the United States and elsewhere where we conduct business, could result in; enforcement actions by both countries state and federal governments or foreign governments, liability or sanctions under data privacy laws including healthcare laws such as the Privacy Act or HIPAA that protect certain types of sensitive information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation which could harm our business and operations.

Risks Related to Our Trading Markets

The market price and trading volume of our ordinary shares and ADSs may be volatile and may be affected by economic conditions beyond our control. Such volatility may lead to securities litigation.

The market price of our ordinary shares and ADSs may be highly volatile and subject to wide fluctuations. In addition, the trading volume of our ordinary shares and ADSs may fluctuate and cause significant price variations to occur. We cannot assure you that the market price of our ordinary shares and ADSs will not fluctuate or significantly decline in the future.

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

- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial and operating results, including potential revenue from the commercialization of RYONCIL, or those of our competitors;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- additions to or departures of our key management personnel;
- issuances by us of debt or equity securities;
- litigation or investigations involving our company, including: shareholder litigation; investigations or audits by regulators into the operations of our company; or proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- changes in trading volume of ADSs on the Nasdaq and of our ordinary shares on the ASX;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, senior management or our shareholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest (such as Russia's invasion of Ukraine);
- natural disasters, the impact of climate change and other calamities;
- changes in market conditions for biopharmaceutical companies; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

In the past, following periods of volatility in the market price of a company's securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management, require significant expenditure for defense costs, and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

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

Our ADSs are listed on the Nasdaq and our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and 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, and vice versa.

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 and/or ADSs could decline.

The trading market for our ordinary shares and ADSs could 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 our company, to the extent such coverage currently exists, or in other cases, may never publish research on our company. If too few securities or industry analysts commence coverage of our company, the trading price for our ordinary shares and ADSs would likely be negatively impacted. If one or more of the analysts who cover us downgrade our ordinary shares or ADSs or publish inaccurate or unfavorable research about our business, the market price of our ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares and/or ADSs could decrease, which might cause our price and trading volume to decline.

Risks Related to Ownership of Our ADSs

An active trading market for the ADSs may not develop in the United States.

Our ADSs are listed in the United States on the Nasdaq under the symbol "MESO." However, we cannot assure you that an active public market in the United States for the ADSs will develop on that exchange, or if developed, that this market will be sustained.

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

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. 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 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 with those companies that prepare financial statements under U.S. GAAP.

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 and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.

As a "foreign private issuer", as defined in Rule 405 under the *Securities Exchange Act of 1933*, as amended (the "Securities Act"), whose ADSs will be listed on the Nasdaq, we will be permitted to, and plan to, follow certain home country corporate governance practices in lieu of certain Nasdaq requirements. For example, we may follow home country practice with regard to certain corporate governance requirements, such as the composition of the board of directors and quorum requirements applicable to shareholders' meetings. This difference may result in a board that is more difficult to remove and less shareholder approvals required generally. In addition, we may follow home country practice instead of the Nasdaq Global Select Market requirement to hold executive sessions and to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions or private placements of securities. The above differences may result in less shareholder oversight and requisite approvals for certain acquisition or financing related decisions. Further, we may follow home country practice instead of the Nasdaq Global Select Market requirement to obtain shareholder approval prior to the establishment or amendment of certain share option, purchase or other compensation plans. This difference may result in less shareholder oversight and requisite approvals for certain company compensation related decisions. A foreign private issuer must disclose in its annual reports filed with the Securities and Exchange Commission, or SEC, and the Nasdaq Global Select Market, the requirements with which it does not comply followed by a description of its applicable home country practice. The Australian home country practices described above may afford less protection to holders of the ADSs than that provided under the Nasdaq Global Select Market rules.

Further, 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, nor are we generally required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, the information may not be disseminated in as timely a manner, or there may be less information publicly available concerning us generally than there is for a company that files as a domestic issuer.

ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares.

ADS holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks.

- As an ADS holder (and not the holder of ordinary shares underlying your ADSs), we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the American depositary receipt, or ADR, depositary as permitted by the deposit agreement.
- Distributions on the ordinary shares represented by your ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.
- We and the ADR depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders.

ADS holders must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis.

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail or email and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon. As soon as practicable after receiving notice from us of any such meeting, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions may be given by ADS holders. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted. Under Australian law and our Constitution, any resolution to be considered at a meeting of the shareholders shall be decided on a show of hands unless a poll is demanded by the shareholders at or before the declaration of the result of the show of hands. Under voting by a show of hands, multiple "yes" votes by ADS holders will only count as one "yes" vote and will be negated by a single "no" vote, unless a poll is demanded.

If we are or become classified as a passive foreign investment company, our U.S. securityholders may suffer adverse tax consequences.

Based upon an analysis of our income and assets for the taxable six months ended December 31, 2024, we do not believe we were a passive foreign investment company (a "PFIC") for our most recent tax year. In general, if at least 75% of our gross income for any taxable year consists of passive income or at least 50% of the average quarterly value of assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, then we will be classified as a PFIC for U.S. federal income tax purposes. Passive income for this purpose generally includes dividends, interest, certain royalties and rents, and gains from commodities and securities transactions. Passive assets for this purpose generally includes assets held for the production of passive income. Accordingly, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing, debt instruments or bank deposits that are readily convertible into cash. Since PFIC status depends upon the composition of our income and assets and the market value of our assets from time to time, and since the determination of PFIC status must be made annually at the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any future taxable year. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of active revenue, and there

can be no assurances that such active revenue will continue, or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. If we were a PFIC for any taxable year during a U.S. investor's holding period for the ordinary shares or ADSs, we would ordinarily continue to be treated as a PFIC for each subsequent year during which the U.S. investor owned the ordinary shares or ADSs. If we were treated as a PFIC, U.S. investors would be subject to special punitive tax rules with respect to any "excess distribution" received from us and any gain realized from a sale or other disposition (including a pledge) of the ordinary shares or ADSs unless a U.S. investor made a timely "qualified electing fund" or "mark-to-market" election. For a more detailed discussion of the U.S. tax consequences to U.S. investors if we were classified as a PFIC, see Item 10.E - "Taxation — Certain Material U.S. Federal Income Tax Considerations to U.S. Holders — Passive Foreign Investment Company".

Changes in foreign currency exchange rates could impact amounts you receive as a result of any dividend or distribution we declare on our ordinary shares.

Any significant change in the value of the Australian dollar may impact amounts you receive in U.S. dollars as a result of any dividend or distribution we declare on our ordinary shares as a holder of our ADSs. More specifically, any dividends that we pay on our ordinary shares will be in Australian dollars. The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses, including any such fees or expenses incurred to convert any such Australian dollars into U.S. dollars. You will receive these distributions in U.S. dollars in proportion to the number of our ordinary shares your ADSs represent. Depreciation of the U.S. dollar against the Australian dollar would have a negative effect on any such distribution payable to you.

You may not receive distributions on our ordinary shares represented by the ADSs or any value for such distribution if it is illegal or impractical to make them available to holders of ADSs.

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

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

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.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of our senior management.

Several of our officers and directors are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the U.S. As a result, it may be impossible to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the U.S. 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 U.S. or elsewhere may be unenforceable in Australia or elsewhere outside the U.S. An award for monetary damages under the 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. The U.S. and Australia do not currently have a treaty or statute providing for recognition and enforcement of the judgments of the other country (other than arbitration awards) in civil and commercial matters. As a result, our public shareholders and holders of the ADSs may have more difficulty in protecting their interests through actions against us, our management, our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mesoblast Limited

Date: February 27, 2025

By: /s/ Silviu Itescu
Name: Silviu Itescu
Title: Chief Executive Officer

Exhibits

99.1 Appendix 4D of Mesoblast Limited ("the Company") for the half-year report for the six months ended December 31, 2024.

Exhibit 99.1

Mesoblast Limited
ABN 68 109 431 870
and Controlled Entities (Mesoblast Group)

HALF-YEAR INFORMATION
FOR THE SIX MONTHS ENDED DECEMBER 31, 2024

PROVIDED TO THE ASX UNDER LISTING RULE 4.2A

This half-year financial report is to be read in conjunction with the financial report for the period ended June 30, 2024.

Rule 4.2A.3

Appendix 4D

Half-Year Report for the six months to December 31, 2024

Name of entity

MESOBLAST LIMITED **ABN 68 109 431 870**

1. Reporting period

Report for the half-year ended	December 31, 2024
Previous corresponding period is the financial year ended and half-year ended	June 30, 2024 December 31, 2023

2. Results for announcement to the market

	Up/down	% change		Amount reported for the half-year ended December 31, 2024 (USD'000)
Revenues from ordinary activities *(item 2.1)*	Down	7%	to	3,156
Loss from ordinary activities after tax attributable to members (*item 2.2*)	Up *	47%	to	47,934
Net loss for the period attributable to members *(item 2.3)* **increase in loss*	Up*	47%	to	47,934

There are no dividends being proposed or declared for the period *(item 2.4 and 2.5)*

Commentary related to the above results
Please refer to the Directors' Report (please see the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations) within the Form 6-K for the six months ended December 31, 2024.

3. Net tangible assets per security *(item 3)*

	December 31, 2024	December 31, 2023
Net tangible (liability) backing per ordinary security (in USD cents)	(7.59) cents	(5.38) cents

A large proportion of the Company's assets are intangible in nature, consisting of goodwill, acquired licenses to patents, in-process research and development acquired, currently marketed products and right-of-use assets. Our intangible assets primarily relate to the acquisition of both Mesoblast, Inc and the culture-expanded Mesenchymal Stem Cell technology. These assets and the associated provision for contingent consideration are excluded from the calculation of net tangible assets per security. As at December 31, 2024 and 2023, the value of deferred tax liabilities was $Nil.

4. Half-Year Financial Statements and Directors' Report

The financial information provided in the Appendix 4D should be read in conjunction with the Report on Form 6-K (incorporating the Half-Year Report) for the six months ended December 31, 2024 which has been prepared in accordance with Australian Accounting Standards.

Directors' Report - please refer to the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations within the Form 6-K.

Half-Year Financial Statement – please refer to the Financial Statements within the Form 6-K.

5. Independent review of the financial report *(item 9)*

The interim financial statements of the Group have been reviewed by the Group's auditors, PricewaterhouseCoopers (PwC). The independent audit review report is attached to the Financial Statements within the Form 6-K.