mesoblast

ANNUAL REPORT 2020

GLOBAL LEADER

IN ALLOGENEIC CELLULAR MEDICINES FOR INFLAMMATORY DISEASES

CONTENTS

MESSAGE FROM THE CHAIRMAN 1
FORM 20-F 2
SHAREHOLDER INFORMATION 228
CORPORATE DIRECTORY 230

CORPORATE GOVERNANCE

Mesoblast Limited and its Board of Directors are committed to implementing and achieving an effective corporate governance framework to ensure that the Company is managed effectively and in an honest and ethical way.

The Company's Corporate Governance statement for the financial year ending 30 June 2020 has been approved by the Board and is available on our website at **http://www.mesoblast.com/company/corporate-governance**

MESSAGE FROM THE CHAIRMAN

Joseph R. Swedish
Chairman

Dear shareholders,

This has been an unprecedented year due to the coronavirus pandemic, its impact on human health, and the economic consequences it has wrought. The Mesoblast leadership responded with great agility and resilience to this urgent challenge, creatively applying our technology platform to develop a potential treatment for moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19.

Through a deep understanding of the science, and utilizing the clinical and regulatory teachings gained from years of meticulous development, our team has harnessed the anti-inflammatory and reparative properties of our mesenchymal lineage cell technology.

The original indication for which our lead allogeneic cell therapy remestemcel-L was developed, pediatric steroid-refractory acute graft versus host disease (SR-aGVHD), has a shared mechanism of action with COVID-19 ARDS. Accordingly, we have now pivoted remestemcel-L to also target ARDS, the principal cause of death in COVID-19 infection.

Remestemcel-L is being rigorously evaluated in a randomized controlled trial to confirm earlier pilot data showing the therapy's effectiveness to enable gravely ill COVID-19 patients to be taken off ventilators in the shortest timeframe possible.

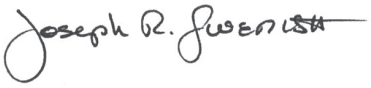
The results, if positive, of this ongoing 300-patient Phase 3 trial in COVID-19 ARDS patients will build upon the totality of the evidence for the effectiveness of remestemcel-L in adults and children with severe and life-threatening inflammatory conditions. If a survival benefit is confirmed, Mesoblast plans to seek potential approval of this therapy in the highest risk patients. In parallel, we will continue to pursue an accelerated approval pathway for remestemcel-L in the treatment of children with SR-aGVHD, a life-threatening condition with no approved therapies for those under 12 years of age.

Beyond remestemcel-L, we believe we have developed the most mature and diverse portfolio of cellular medicines for serious acute and chronic inflammatory conditions, and readouts of Phase 3 trials in these additional programs will underpin both our near-term value proposition and our medium to long-term strategic initiatives.

The Board would especially like to highlight the outstanding external and internal leadership displayed by our Chief Executive Dr Silviu Itescu, and the unwavering diligence and work ethic displayed by the entire Mesoblast team during these very difficult times.

We are deeply grateful for the ongoing support of our investors whose continued confidence has provided us with the capital to successfully prosecute our business strategy.

Sincerely,



Joseph R. Swedish
Chairman

FORM 20-F

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

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

OR

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

For the fiscal year ended June 30, 2020

OR

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

OR

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

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number 001-37626

MESOBLAST LIMITED

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

AUSTRALIA
(Jurisdiction of incorporation or organization)

Level 38, 55 Collins Street
Melbourne, VIC, 3000, Australia
Telephone: +61 (3) 9639 6036
(Address of principal executive offices)

Silviu Itescu
Chief Executive Officer
Telephone: +61 (3) 9639 6036; Fax: +61 (3) 9639 6030
Level 38, 55 Collins Street
Melbourne, VIC, 3000, Australia
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing five Ordinary Shares*	MESO	The NASDAQ Global Select Market

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

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

583,949,612 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

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

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

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

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

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

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

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

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

Table of Contents

INTRODUCTION AND USE OF CERTAIN TERMS 2
FORWARD-LOOKING STATEMENTS 2
PART I 4
Item 1. Identity of Directors, Senior Management 4
Item 2. Offer Statistics and Expected Timetable 4
Item 3. Key Information 4
3.A Selected Financial Data 4
3.B Capitalization and Indebtedness 6
3.C Reasons for the offer and use of proceeds 6
3.D Risk Factors 6
Item 4. Information on the Company 42
4.A History and Development of Mesoblast 42
4.B Business Overview 47
4.C Organizational Structure 70
4.D Property, Plants and Equipment 71
Item 4A. Unresolved Staff Comments 71
Item 5. Operating and Financial Review and Prospects 71
5.A Operating Results 71
5.B Liquidity and Capital Resources 89
5.C Research and Development, Patents and Licenses 92
5.D Trend Information 92
5.E Off-Balance Sheet Arrangements 92
5.F Contractual Obligations and Commitments 93
Item 6. Directors, Senior Management and Employees 94
6.A Directors and Senior Management 98
6.B Compensation 104
6.C Board Practices 124
6.D Employees 126
6.E Share Ownership 127
Item 7. Major Shareholders and Related Party Transactions 128
7.A Major Shareholders 128
7.B Related Party Transactions 128
7.C Interests of Experts and Counsel 128
Item 8. Financial Information 129
8.A Consolidated Statements and Other Financial Information 129
8.B Significant Changes 129
Item 9. The Offer and Listing 129
9.A Offer and Listing Details 129
9.B Plan of Distribution 129
9.C Markets 130
9.D Selling Shareholders 130
9.E Dilution 130
9.F Expenses of the Issue 130

Item 10.	Additional Information	130
10.A	Share Capital	130
10.B	Memorandum and Articles of Association	130
10.C	Material Contracts	135
10.D	Exchange Controls	138
10.E	Taxation	140
10.F	Dividends and Paying Agents	147
10.G	Statement by Experts	147
10.H	Documents on Display	147
10.I	Subsidiary Information	147
Item 11.	Quantitative and Qualitative Disclosures about Market Risk	147
Item 12.	Description of Securities Other than Equity Securities	147
12.A	Debt Securities	148
12.B	Warrants and Rights	148
12.C	Other Securities	148
12.D	American Depositary Shares	148
PART II		149
Item 13.	Defaults, Dividend Arrearages and Delinquencies	149
Item 14.	Material Modifications to the Rights of Security Holders and Use of Proceeds	149
Item 15.	Controls and Procedures	149
Item 16A.	Audit Committee Financial Expert	149
Item 16B.	Code of Ethics	150
Item 16C.	Principal Accountant Fees and Services	150
Item 16D.	Exemptions from the Listing Standards for Audit Committees	150
Item 16E.	Purchases of Equity Securities by the Issuer and Affiliated Purchasers	150
Item 16F.	Change in Registrant’s Certifying Accountant	150
Item 16G.	Corporate Governance	150
Item 16H.	Mine Safety Disclosure	151
PART III		151
Item 17.	Financial Statements	151
Item 18.	Financial Statements	151
Item 19.	Exhibits	225
SIGNATURES		227

INTRODUCTION AND USE OF CERTAIN TERMS

Mesoblast Limited and its consolidated subsidiaries publish consolidated financial statements expressed in U.S. dollars, unless otherwise indicated. This Annual Report on Form 20-F is presented in U.S. dollars, unless otherwise indicated. Our consolidated financial statements found in Item 18 of this annual report on Form 20-F are prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board.

Except where the context requires otherwise and for purposes of this Form 20-F only:

- "ADSs" refers to our American depositary shares, each of which represents ordinary shares, and "ADRs" refers to the American depositary receipts that evidence our ADSs.
- "Mesoblast," "we," "us" or "our" refer to Mesoblast Limited and its subsidiaries.
- "A$" or "Australian dollar" refers to the legal currency of Australia.
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- "AIFRS" refers to the Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board, or AASB.
- "U.S. GAAP" refers to the Generally Accepted Accounting Principles in the United States.
- "FDA" refers to the United States Food and Drug Administration.
- "US$" or "U.S. dollars" refers to the legal currency of the United States.
- "U.S." or "United States" refers to the United States of America.
- "€" or "Euro" refers to the legal currency of the European Union.

Australian Disclosure Requirements

Our ordinary shares are primarily quoted on the Australian Securities Exchange ("ASX") in addition to our listing of our ADSs on the Nasdaq Global Select Market. As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the Australian *Corporations Act 2001* and the *ASX Listing Rules*. Information furnished under the sub-heading "Australian Disclosure Requirements" is intended to comply with ASX listing and *Corporations Act 2001* disclosure requirements and is not intended to fulfill information required by this Annual Report on Form 20-F.

FORWARD-LOOKING STATEMENTS

This Form 20-F includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our current expectations, assumptions, estimates and projections about the Company, our industry, economic conditions in the markets in which we operate, and certain other matters. These statements include, among other things, the discussions of our business strategy and expectations concerning our market position, future operations, margins, profitability, liquidity and capital resources. These statements are subject to 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 the COVID-19 pandemic 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 any 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; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

You should read thoroughly this Form 20-F 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 Form 20-F 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.

This Form 20-F also contains third-party data relating to the biopharmaceutical market that includes projections based on a number of assumptions. The biopharmaceutical market may not grow at the rates projected by market data, or at all. The failure of this market to grow at the projected rates may have a material adverse effect on our business and the market price of our ordinary shares and ADSs. Furthermore, if any one or more of the assumptions underlying the market data turns out to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this Form 20-F relate only to events or information as of the date on which the statements are made in this Form 20-F. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Identity of Directors, Senior Management

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3.A Selected Financial Data

The following selected consolidated financial data presented below has been extracted from our consolidated financial statements prepared in accordance with IFRS as issued by the IASB. Our consolidated financial statements for the years ended June 30, 2020, 2019 and 2018 are included in "Item 18. Financial Statements" in this Form 20-F. The selected financial data as of June 30, 2017 and 2016 and for the years ended June 30, 2017, and 2016 have been derived from the consolidated financial statements of the Company not included in this Annual Report. This data should be read in conjunction with, and are qualified in their entirety by, reference to those statements and the notes thereto.

The summary consolidated financial data should be read in conjunction with "Item 5. Operating and Financial Review and Prospects" and our consolidated financial statements and related notes thereto. Historical results are not necessarily indicative of results to be expected in the future.

	Year ended June 30,				
(in U.S. dollars, in thousands except per share information)	**2020**	**2019**	**2018**	**2017**	**2016**
Consolidated Income Statement Data:					
Revenue:					
Commercialization revenue	$ 6,614	$ 5,003	$ 3,641	$ 1,444	$ 37,969
Milestone revenue	25,000	11,000	13,334	500	3,500
Interest revenue	542	719	366	468	1,079
Total revenue	**32,156**	**16,722**	**17,341**	**2,412**	**42,548**
Research & development	(56,188)	(59,815)	(65,927)	(58,914)	(50,013)
Manufacturing commercialization	(25,309)	(15,358)	(5,508)	(12,065)	(29,763)
Management and administration	(25,609)	(21,625)	(21,907)	(23,007)	(22,500)
Fair value remeasurement of contingent consideration[(1)]	1,380	(6,264)	10,541	(130)	28,112
Other operating income and expenses	(455)	(1,086)	1,312	1,489	2,714
Finance costs	(13,330)	(11,328)	(1,829)	—	—
Impairment of intangible assets	—	—	—	—	(61,919)
Loss before income tax	**(87,355)**	**(98,754)**	**(65,977)**	**(90,215)**	**(90,821)**
Income tax benefit/(expense)	9,415	8,955	30,687	13,400	86,694
Loss attributable to the owners of Mesoblast Limited	**$ (77,940)**	**$ (89,799)**	**$ (35,290)**	**$ (76,815)**	**$ (4,127)**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share[(2)]	(14.74)	(18.16)	(7.58)	(19.25)	(1.13)
Diluted - losses per share[(2)]	(14.74)	(18.16)	(7.58)	(19.25)	(1.13)

(1) For the year ended June 30, 2017, the Group identified an opportunity to enhance the presentation of the fair value remeasurement of contingent consideration and associated unwinding of the discount rate recorded within finance costs in the Consolidated Income Statement. The Group considered that the change in contingent consideration is primarily due to changes in assumptions about the settlement of the contingent consideration and these line items in the Consolidated Income Statement should therefore be reported in aggregate, to provide more relevant information to the users of the financial statements. This change in presentation has been retrospectively applied to the year ended June 30, 2016.

(2) For the year ended June 30, 2018, the Group adjusted its losses per share calculations to reflect the bonus element in the fully underwritten institutional and retail entitlement offer to existing eligible shareholders which occurred in September 2017. This change has been retrospectively applied to the years ended June 30, 2017 and 2016.

	As of June 30,				
(in U.S. dollars, in thousands except per share information)	**2020**	**2019**	**2018**	**2017**	**2016**
Consolidated Balance Sheet Data:					
Cash and cash equivalents	129,328	50,426	37,763	45,761	80,937
Total current assets	136,548	62,522	101,071	63,609	88,823
Total assets	733,602	652,115	692,443	655,686	684,018
Total current liabilities	90,143	44,331	24,003	36,670	29,415
Total liabilities	184,276	171,063	146,435	138,920	155,857
Total net assets	549,326	481,052	546,008	516,766	528,161
Equity:					
Issued capital (538,949,612; 498,626,208; 482,639,654; 428,221,398 and 381,363,137 ordinary shares (no par value) issued as of June 30, 2020, 2019, 2018, 2017 and 2016, respectively)	1,051,450	910,405	889,481	830,425	770,272
Reserves	46,634	40,638	36,719	31,243	25,976
(Accumulated loss)/retained earnings	(548,758)	(469,991)	(380,192)	(344,902)	(268,087)
Total equity	549,326	481,052	546,008	516,766	528,161

	Year ended June 30,				
(in U.S. dollars, in thousands)	**2020**	**2019**	**2018**	**2017**	**2016**
Cash Flow Data:					
Net cash (outflows) in operating activities	(56,365)	(57,790)	(75,012)	(95,471)	(87,996)
Net cash (outflows)/inflows in investing activities	(3,273)	(1,000)	(1,153)	142	(1,727)
Net cash inflows in financing activities	137,044	71,608	68,613	60,005	62,066
Net increase/(decrease) in cash and cash equivalents	**77,406**	**12,818**	**(7,552)**	**(35,324)**	**(27,657)**

Exchange Rate

The Company publishes its consolidated financial statements expressed in U.S. dollars. Mesoblast Limited, the parent entity of the Group, has a functional currency of Australian dollars. For the convenience of the reader, this Annual Report contains translations of certain Australian dollar amounts into U.S. dollars at specified rates. These translations should not be construed as representations that the Australian dollar amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated. On June 30, 2020, for translations of Australian dollars into U.S. dollars, a rate of US$0.6870 = A$1.00 has been used as this was the foreign exchange rate obtained through our bank to settle material inter Group foreign exchange transactions on this day. The Australian dollar into U.S. dollar daily exchange rate as issued by the Reserve Bank of Australia for June 30, 2020 was 0.6863. Other than on June 30, 2020, the translation of Australian dollar into U.S. dollar have been made at the daily exchange rate as issued daily by the Reserve Bank of Australia (http://www.rba.gov.au/statistics/tables/).

Exchange rates for the six months to July 2020 A$1.00 per US$:

	High	**Low**
Most recent six months:		
Month ended February 29, 2020	0.6760	0.6524
Month ended March 31, 2020	0.6620	0.5571
Month ended April 30, 2020	0.6566	0.6035
Month ended May 31, 2020	0.6659	0.6382
Month ended June 30, 2020	0.7000	0.6742
Month ended July 31, 2020	0.7213	0.6895

Exchange rates for the last five fiscal years A$1.00 per US$:

	Average Rate[1]
Annual:	
Fiscal year ended	
June 30, 2016	0.7272
June 30, 2017	0.7542
June 30, 2018	0.7736
June 30, 2019	0.7153
June 30, 2020	0.6715

(1) Determined by calculating the average rate of the exchange rates on the last trading day of each month during the period.

3.B Capitalization and Indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk Factors

You should carefully consider the risks described below and all other information contained in this Annual Report on Form 20-F 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 ordinary shares and ADSs could decline, and you may lose part or all of your investment. This Annual Report on Form 20-F 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 Annual Report on Form 20-F.

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 and 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 year ended June 30, 2020 was $77.9 million. As of June 30, 2020, we have an accumulated deficit of $548.8 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 move toward commercialization, including the scaling up of our manufacturing activities and our establishment of infrastructure and logistics necessary to support potential 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. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may 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 any 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

stem cell product developed by TiGenix, now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") and approved for marketing in the EU), 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 and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for 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 product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales force, marketing and distribution capabilities and necessary supporting infrastructure to effectively seek and maintain market access and ensure compliance with legal and regulatory requirements relating to interactions with healthcare providers and healthcare organizations and to price reporting;
- obtaining market acceptance of our product candidates and stem cell therapy as a viable treatment option;
- addressing any competing technological and market developments;
- obtaining and sustaining an adequate level of reimbursement from payors;
- identifying and validating new stem 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.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing and distributing any 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 require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed 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 June 30, 2020, our cash and cash equivalents were $129.3 million. We expect to continue to incur significant expenses and increase our cumulative operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts. 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 and MPC-300-IV (inflammatory conditions) product candidates;
- 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 collaborations 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 any 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 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 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 our product candidates.

As described in Note 1(i) of our accompanying financial statements, we have an overarching strategy to fund operations predominately through sales of RYONCIL™ ("RYONCIL") and non-dilutive strategic and commercial transactions. In addition to increasing cash inflows through sales of RYONCIL, we intend to enter into new strategic partnerships for our Phase 3 product candidates, drawing on additional funds from existing strategic and financing partnerships, subject to certain conditions, or through equity-based financing. Over the next 12 months some or all of these cash inflows will be required for us to meet our forecast expenditure and continue as a going concern, although there is uncertainty related to our ability to access these cash inflows.

Management and the directors believe that we will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on our ability to continue as a going concern and that we may be unable to realize our assets and discharge our liabilities in the normal course of business. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to obtain adequate funding or partnerships in the future, 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 us.

The terms of our loan facilities with Hercules Capital, Inc. ("Hercules") 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 March 6, 2018, we entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. We drew the first tranche of $35.0 million at closing, and we have subsequently drawn a further $15.0 million. On June 29, 2018, we entered into a loan and security agreement with NovaQuest for a $40.0 million non-dilutive, eight-year term credit facility, repayable from net sales of our allogeneic product candidate RYONCIL in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD"), in the United States and other geographies excluding Asia. We drew the first tranche of $30.0 million on closing. Our loan facilities with Hercules and NovaQuest contain a number of restrictive covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. 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, Hercules 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 Hercules or NovaQuest accelerates the repayment, if any, we may not have sufficient funds to repay our existing debt. If we were unable to repay those amounts, Hercules 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 Hercules, and a portion of our assets relating to the SR-aGVHD product candidate 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 86% of our cash and cash equivalents as of June 30, 2020 were denominated in U.S. dollars and 14% were denominated in Australian dollars. 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, a portion of our research and clinical trials are undertaken in Australia. As such, 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 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 adult stem cell technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. At the moment, no industrially manufactured, non-hematopoietic, allogeneic stem cell products have been approved in the United States.

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 lead product candidates. We have concentrated our product research and development efforts on our mesenchymal lineage adult stem cell platform, a novel type of stem 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 adult stem cells 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 the COVID-19 pandemic.

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 in monitoring and data collection as a result of the COVID-19 pandemic, 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 stem cell therapy trials because of negative publicity from adverse events in the biotechnology or stem cell 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
- the COVID-19 pandemic 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 stem cell 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 Class II-IV CHF, and RYONCIL, which will focus on SR-aGVHD. We have also started developing remestemcel-L in COVID-19 infected patients with moderate to severe acute respiratory distress syndrome ("ARDS") on ventilator support. 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 stem 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 has issued guidance documents in 2018, 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.

On December 21, 2017, the FDA granted RMAT designation for our novel MPC therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices. 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 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.

Any of our 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, 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 adult stem cells, may be misunderstood by the public. Negative public attitudes toward stem cell therapy and publicity and harm from stem cell usage clinically by others could also result in greater governmental regulation of stem 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 stem cells 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 stem cells may lead researchers to leave the field of stem cell 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 U.S. 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 prevention of post-implantation mucosal bleeding in end-stage CHF patients who require a left ventricular assist device ("LVAD"). 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. Under President Trump's administration, 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.

Our completed BLA submission for pediatric SR-aGVHD may not be approved and even if it is approved, we will continue to be closely regulated by FDA.

As a biological product, our allogeneic cellular medicine, RYONCIL, for the treatment of pediatrics with SR-aGVHD, requires regulatory approval from the FDA before it may legally be distributed in U.S. commerce. In particular, RYONCIL will require FDA approval of a BLA under Section 351 of the Public Health Service Act to be commercialized. We initiated the filing of this BLA application in May 2019 and completed the submission on January 31, 2020. The outcome of this BLA application is uncertain, and there is a risk that it may not be approved by the FDA.

We have received Fast Track designation from the FDA for RYONCIL in pediatrics with SR-aGVHD. A biologic product that receives Fast Track designation can be eligible for regulatory benefits, including rolling BLA review. Rolling review of a BLA enables individual modules of the application to be submitted to and reviewed by the FDA on an ongoing basis, rather than waiting for all sections of a BLA to be completed before submission. We have now filed all components of this rolling submission. Priority Review was confirmed on March 31, 2020, and an action date of September 30, 2020 was advised. Fast Track designation may provide for a more streamlined development or approval process but it does not change the standards for approval and may be rescinded by the FDA if the product no longer meets the qualifying criteria.

The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. During the course of review of our BLA, the FDA may request or require additional preclinical, clinical, chemistry and manufacturing, controls (or CMC), or other data and information. The development and provision of these data and information may be time consuming and expensive. Our failure to comply, or the failure of our contract manufacturers to satisfy, applicable FDA CMC requirements could result in a delay or failure to obtain approval of our BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in our submission and may request additional testing or information. The testing and approval process requires substantial time, effort and financial resources, and may take several years to complete. In addition, the FDA or other regulatory agencies may find the data from our clinical studies insufficient to support marketing approval. For example, our Phase 3 study for RYONCIL, which met the primary clinical endpoint with statistical significance, was conducted as a single-arm study due to the seriousness of the condition, the rapid clinical deterioration of affected patients, the mounting literature suggesting a meaningful treatment effect, and the position in the medical community that a randomized controlled trial was neither feasible nor ethical in this patient population. While we have provided the FDA with comparator outcomes from control subjects, it is possible that the FDA may not find the data sufficient for approval. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

We have recently participated in an Oncologic Drugs Advisory Committee ("ODAC") proceeding in connection with the FDA's review of the BLA for our SR-aGVHD product candidate. It is possible that we will have to participate in other Advisory Committee proceedings for other of our product candidates. FDA Advisory Committees are convened to conduct public hearings on matters of importance that come before the FDA, to review the issues involved, and to provide advice and recommendations to the FDA. New product candidates may be referred for review by Advisory Committees whether the FDA has identified issues or concerns in respect of such candidates or not. Advisory Committee input and recommendations may be used at the discretion of the FDA. Advisory Committee proceedings are in part conducted publicly. While the recommendations made by Advisory Committees in respect of marketing applications for any product are not dispositive, such determinations and recommendations are often influential, and may be made available publicly and to the advantage of our competitors. In addition, it is possible that safety findings and recommendations as well as other concerns and considerations raised by Advisory Committee members, who constitute a multi-disciplinary group of experts (including representatives and/or advocates from the consumer sector), may impact the FDA's review of our product candidate submissions or labeling unfavorably. Furthermore, commentary from Advisory Committee proceedings can figure into future product and other litigation.

Even if we receive regulatory approval for our RYONCIL product, such approval may entail limitations on the indicated uses for which such product may be marketed and/or require post-marketing testing and surveillance to monitor safety or efficacy of our product. The FDA may limit further marketing of our product based on the results of post-marketing studies, if compliance with pre- and post-marketing regulatory standards is not maintained, or if problems occur after our product reaches the marketplace such as later discovery of previously unknown problems or concerns with our product, including adverse events of unanticipated severity or frequency, or with our manufacturing processes.

The COVID-19 pandemic could adversely impact the BLA review process for RYONCIL

The FDA has accepted for Priority Review our BLA for RYONCIL. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency.

Our contract manufacturing partner, Lonza, manufactures RYONCIL at its facility in Singapore. Singapore is experiencing a number of COVID-19 cases in its population and has increased the DORSCON level to orange. If new cases continue to be identified, it could negatively impact business continuity at this facility as staff numbers may be affected by quarantine requirements.

If the business continuity at Lonza's Singaporean facility is negatively affected, the FDA could be unable to assess the compliance of such facility with the standards required to assure RYONCIL's continued safety, purity and potency. In this case, the BLA review process for RYONCIL could be negatively affected.

The ability of FDA inspectors to visit the site to conduct GMP inspections may be impacted by regional travel restrictions, and other COVID-19 measures. The FDA may in general have slower response times in assessing our BLA filing. Such an impact may delay the approval of the BLA.

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 each product candidate, 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 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 our product candidates at a commercial scale. We may not be able to manufacture our product candidates in quantities sufficient for development and commercialization if our product candidates are approved, or for any future commercial demand for our product candidates.

We have manufactured clinical and commercial quantities of our mesenchymal lineage adult stem cell product candidates in manufacturing facilities owned by Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd. (collectively referred to as "Lonza"). We have commenced manufacture of commercial batches in preparation for a successful BLA review, and subsequent launch. We anticipate a prior approval inspection of the facilities and our testing laboratories by the FDA. In the event that the inspections result in observations that need to be corrected, it may delay the approval and launch of this product.

In addition, the production of any biopharmaceutical, particularly stem cell-based therapies, involves complex processes and protocols. We cannot provide assurance that such production efforts will enable us to manufacture our product candidates in the quantities and with the quality needed for clinical trials 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. If any of our product candidates are approved for commercialization and marketing, we may be required to manufacture the product in large quantities to meet demand. 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 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 adult stem 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.

The COVID-19 pandemic 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 potential approval and launch of RYONCIL for the treatment of pediatric acute graft versus host disease in the US market. We currently also manufacture our other product candidates with Lonza Singapore.

Due to the COVID-19 pandemic, Singapore is currently experiencing a number of COVID-19 cases in its population and has increased the DORSCON level to orange. If new cases continue to be identified, it could negatively impact business continuity at the facility as staff numbers may be affected by quarantine requirements. The COVID-19 pandemic could also adversely affect our or our contract manufacturer's ability to acquire raw materials or components required in our manufacturing process, including bone marrow. As a result, the manufacturing and the commercialization of RYONCIL and other product candidates could be adversely affected.

We rely on contract manufacturers to supply and manufacture our product candidates. Our business could be harmed if Lonza fails to provide us with sufficient quantities of 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 adult stem cell product candidates for use in the conduct of our clinical trials, and we currently lack the internal resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. As a result, we currently depend on Lonza to manufacture our mesenchymal lineage adult stem cell product candidates. Relying on Lonza to manufacture our mesenchymal lineage adult stem 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 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 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 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 our product candidates in a profitable manner.

We intend to implement a business model under which we control the manufacture and supply of our product candidates, including but not exclusively, through our product suppliers, including Lonza. We and the suppliers of our product candidates, including Lonza, have no experience manufacturing our product candidates at commercial scale. Accordingly, 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 our product candidates in a cost effective manner. Our or our collaborators' inability to sell 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.

Our or our 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 adult stem cell-containing bone marrow from donors, for which we currently rely on our suppliers. Mesenchymal lineage adult stem 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 our product candidates' materials, equipment or supplies and components required to manufacture 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 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 disc repair). 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 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 our product candidates as a result of the COVID-19 outbreak;
- 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 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 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. 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 products 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 Lonza's

manufacturing facilities. The novel nature of our 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 candidates or raw materials or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee each contract manufacturer involved in the production of our 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 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, our product candidates must be stored and transported at extremely low temperatures within a certain range. If these environmental conditions deviate, 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.

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

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 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 or 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 these 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

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

Even when product development is successful and regulatory approval has been obtained, 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, stem cell-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 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, 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 each of our product candidates will depend on a number of factors, including:

- the efficacy and safety of 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. 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 sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in independently commercializing any future products.

We have limited sales, marketing or distribution infrastructure and experience. Commercializing our product candidates, if such product candidates obtain regulatory approval, would 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 our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution/price reporting services for 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 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 will need to be committed prior to any confirmation that any of our proprietary product candidates will be approved. For any 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 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 stem 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, if any of our product candidates are approved by the FDA, we would be 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. There have been a number of judicial and congressional challenges to certain aspects of the Affordable Care Act, and we expect that with the current administration efforts will continue to repeal or significantly amend the Affordable Care Act. We can provide no assurance that the Affordable Care 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 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, 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 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 stem cell therapy and the potential for our product candidates to offer therapeutic benefit in a single administration, we face uncertainty related to pricing and reimbursement for these product candidates.

Our target patient populations for some of our product candidates may be relatively small, and as a result, the pricing and reimbursement of 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 our product candidates will be adversely affected. Due to the novel nature of our stem cell technology, the manner and level at which reimbursement is provided for services related to 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 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 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 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 certain of our 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 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 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, if any such product candidates obtain regulatory approval, 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 and military conditions in such countries. For example, on June 23, 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the European Union (EU) (commonly referred to as “Brexit”). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. On January 31, 2020 the UK formally left the EU and a transition period commenced. There continues to be an uncertain political and economic environment in the United Kingdom and potentially across other European Union member states, which may last for a number of months or years. If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them 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 various imports from China and the EU 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 between the U.K. and the EU, which could have a material adverse effect on our 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 and terrorism, or 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 our product candidates.

We face an inherent risk of product liability as a result of the human clinical use of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product 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 acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. 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;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- increased cost of liability insurance;
- loss of revenue;
- the inability to commercialize our product candidates; 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 of 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 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 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 products 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 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 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. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. 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 America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation and proceedings. These include allowing 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. The new post-grant review (PGR) proceedings added as of September 2012 by the America Invents Act, 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. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 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 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 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 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 our product candidates, our business may be materially harmed.

Depending on the timing, duration and specifics of FDA marketing approval of 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 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 stem 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 from Osiris Therapeutics, Inc. 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 June 30, 2020, our cumulative operating losses have a total potential tax benefit of $128.5 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 2016 and in the May 2018 Federal budget announced its intention to pass certain recommendations of the review panel into law to reduce the research and development tax incentive credits available in certain circumstances. One of the changes announced in May 2018 was to reduce the amount of the research and development tax incentive credits available by capping the annual refundable tax offset amount at A$4.0 million for companies with an annual aggregate turnover of less than A$20.0 million, however, refundable tax offsets related to spend incurred on clinical trials conducted in Australia would not be capped. If the Research and Development Tax program incentives are revoked or modified, or if we no longer qualify as a small-medium business under the A$20.0 million turnover test or we are no longer eligible for such incentives due to other circumstances, our business, results of operations and financial condition may be adversely affected.

Our combined worldwide turnover of the Mesoblast Group has been in excess of A$20.0 million for the years ended June 30, 2020 and 2019 making us ineligible for the refundable cash tax offset for the research and development tax incentive. As a result, no income was recognized from the Research and Development Tax Incentive program for the years ended June 30, 2020 and 2019.

There can be no assurances that we will benefit from these incentives in the future if our annual aggregate turnover is in excess of A$20.0 million or that such 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 prices 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 prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, 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 current administration has indicated an interest in excluding transactions with certain payors or other healthcare providers from safe harbor protection. This may impact the manner in which manufacturers contract with payors, and negatively impact our market opportunities for our products.

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 Hercules 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.

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 quarterly operating results 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;
- natural disasters 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, 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 year ended June 30, 2020, 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 as 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.

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

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Corporations Act, sets forth various rights and obligations that apply to us as an Australian company and which may not apply to a U.S. corporation. These requirements may operate differently than those of many U.S. companies.

Item 4. Information on the Company

4.A History and Development of Mesoblast

Mesoblast Limited

Mesoblast Limited was incorporated on June 8, 2004 as a public company in Australia under the *Corporations Act 2001* with an indefinite duration. On December 16, 2004 we became listed on the Australian Securities Exchange (the "ASX"). On November 13, 2015, we became listed on the Nasdaq Global Select Market ("Nasdaq") and from this date we have been dual-listed in Australia and the U.S.. Our registered office is located at the following address:

Mesoblast Ltd
Level 38
55 Collins Street
Melbourne VIC 3000
Australia
Telephone: +61 3 9639 6036
Web: www.mesoblast.com

Our agent for service of process in the United States is Mesoblast Inc., 505 Fifth Avenue, Level 3, New York, NY 10017. All information we file with the SEC is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at www.sec.gov.

For a list of our significant subsidiaries, see Exhibit 8.1 to this Annual Report.

Important Corporate Developments

Fiscal year 2020 to date of annual report

August — The Oncologic Drugs Advisory Committee ("ODAC") of the United States Food and Drug Administration ("FDA") voted overwhelmingly in favor that available data support the efficacy of RYONCIL™ ("RYONCIL") in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD"). The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act ("PDUFA"). If approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the United States in 2020. There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant for blood cancer.

July — The independent Data Safety Monitoring Board ("DSMB") set a date for early September to complete the first interim analysis of the Phase 3 trial of Mesoblast's allogeneic product candidate remestemcel-L in ventilator-dependent COVID-19 patients with moderate to severe acute respiratory distress syndrome ("ARDS"). The trial's first 90 patients will have completed 30 days of follow up during August, after which the DSMB will perform an interim analysis review of the safety and efficacy data. The DSMB will then inform Mesoblast on whether the trial should proceed as planned, or should stop early. There are currently no approved treatments for COVID-19 ARDS, the primary cause of death in patients infected with COVID-19.

Mesoblast's executive leadership was expanded with the appointment of Dagmar Rosa-Bjorkeson to the role of Chief Operating Officer. Her responsibilities include managing commercial operations, leading the business units, building out key strategic alliances, and overseeing product launches.

An Expanded Access Protocol ("EAP") has been initiated in the United States for compassionate use of remestemcel-L in the treatment of COVID-19 infected children with cardiovascular and other complications of multisystem inflammatory syndrome ("MIS-C"). Patients aged between two months and 17 years may receive one or two doses of remestemcel-L within five days of referral under the EAP. MIS-C is a life-threatening complication of COVID-19 in otherwise healthy children and adolescents that includes massive simultaneous inflammation of multiple critical organs and their vasculature.

June Mesoblast (ASX:MSB) was promoted to inclusion in the S&P/ASX index.

Phase 2 results presented to the 2020 International Society for Cell & Gene Therapy ("ISCT") annual meeting showed that treatment with remestemcel-L in patients with Chronic Obstructive Pulmonary Disease ("COPD") and an elevated state of inflammation resulted in improved respiratory and functional outcomes. The post-hoc analysis from a randomized, placebo-controlled 60-patient Phase 2 trial in patients with COPD showed that remestemcel-L, given in four monthly intravenous doses of 100 million cells, significantly improved respiratory and functional clinical outcomes in patients with elevated levels of the inflammatory biomarker C-reactive protein ("CRP"). Significantly elevated CRP levels are predictive of increased hospitalization and death in patients with COPD, and are seen in various acute lung diseases, including ARDS, a life-threatening complication of COVID-19.

May Clinical outcomes of RYONCIL in children and adults with SR-aGVHD were published in three peer-reviewed articles and an accompanying editorial in the May issue of Biology of Blood and Marrow Transplantation, the official publication of the American Society for Transplantation and Cellular Therapy. The articles highlighted consistent benefits seen across the three distinct trials in patients with the greatest levels of inflammation and the most severe grades of the disease.

Successful completion of a US$90.0 million (A$138.0 million) capital raising via a placement of 43.0 million shares to existing and new institutional investors at a price of A$3.20 per share. A significant portion of the net proceeds will be used to scale-up manufacturing of the Company's lead product candidate remestemcel-L for the treatment of critically ill patients suffering with diseases caused by cytokine release syndromes associated with high mortality, particularly COVID-19 ARDS. Proceeds will also be used for working capital and general corporate purposes.

The first patients were dosed in the Phase 3 randomized placebo-controlled trial in the United States of remestemcel-L in COVID-19 infected patients with moderate to severe ARDS on ventilator support. The trial will randomize up to 300 ventilator-dependent patients in intensive care units to either remestemcel-L or placebo (1:1) on top of maximal care, in line with specific guidance provided by the FDA for robust statistical analysis. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days alive and off mechanical support. Enrollment will occur in up to 30 sites across the United States and is expected to complete within three to four months, with interim analyses planned which could result in stopping the trial early for efficacy or futility.

April A Phase 3 randomized, placebo-controlled trial to rigorously confirm whether remestemcel-L provides a survival benefit in patients with moderate/severe ARDS due to COVID-19 commenced enrollment of up to 300 patients.

There was 83% survival in ventilator-dependent COVID-19 patients (10/12) with moderate/severe ARDS treated with two infusions of remestemcel-L within the first five days under emergency compassionate use at New York City's Mt Sinai hospital during the period March-April 2020. Of these patients, 75% (nine of 12) successfully came off ventilator support within a median of 10 days. These results contrast with only 9% of ventilator-dependent COVID-19 patients being able to come off ventilators with standard of care treatment and only 12% survival in ventilator-dependent COVID-19 patients at two major referral hospital networks in New York during the same time period. This compassionate use treatment experience has informed the design of the clinical protocol for the randomized, placebo-controlled trial of remestemcel-L in ventilator-dependent COVID-19 moderate/severe ARDS patients in the United States.

Mesoblast announced that remestemcel-L will be formally evaluated in a randomized, placebo-controlled trial in patients with ARDS caused by COVID-19. This multi-center Phase 2/3 trial will be conducted in collaboration with the Cardiothoracic Surgical Trials Network ("CTSN"), which was established by the United States National Institutes of Health's National Heart, Lung and Blood Institute ("NHLBI") as a flexible platform for conducting collaborative trials.

The FDA cleared an Investigational New Drug application to treat patients with ARDS caused by COVID-19 with intravenous infusions of remestemcel-L.

The FDA accepted for priority review our BLA filing for RYONCIL for the treatment of children with SR-aGVHD. The FDA set a PDUFA action date of September 30, 2020, and if approved, Mesoblast will make RYONCIL immediately available in the United States.

March Results from a sub-study of 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device ("LVAD"), of 159 randomized patients who received either REVASCOR or saline, were presented at the American College of Cardiology ("ACC") Virtual Scientific Sessions. The conclusions were that REVASCOR had a beneficial effect on LVAD weaning, major mucosal bleeding, serious adverse events, and readmissions in ischemic heart failure patients; that these findings may reflect the effect of REVASCOR on angiogenesis, inflammation and endothelial dysfunction; and warranted further clinical research. End-stage ischemic heart failure patients with LVADs are older and have co-morbidities such as diabetes, thereby closely resembling the majority of patients in our 566-patient Phase 3 trial for advanced chronic heart failure. The full results from these 70 patients will be published in a peer-reviewed journal.

Plans to evaluate remestemcel-L in patients with ARDS, the principal cause of death in COVID-19 infection, were announced, supported by recently published results from an investigator-initiated clinical study conducted in China which reported that allogeneic mesenchymal stem cells ("MSC") cured or significantly improved functional outcomes in all seven treated patients with severe COVID-19 pneumonia. Additionally, in post-hoc analyses of a 60-patient randomized controlled study in COPD, remestemcel-L infusions were well tolerated, significantly reduced inflammatory biomarkers, and significantly improved pulmonary function in those patients with elevated inflammatory biomarkers. Since the same inflammatory biomarkers are also elevated in COVID-19, these data suggest that remestemcel-L could be useful in the treatment of patients with ARDS due to COVID-19.

February The aggregated results from 309 children treated with RYONCIL were presented at the American Society for Transplantation Cellular Therapy and the Center for International Blood & Bone Marrow Transplant Research meeting in Orlando, Florida on February 22. The data showed that treatment with RYONCIL across three separate trials resulted in consistent treatment responses and survival outcomes in children with SR-aGVHD.

The investigator-initiated expanded access protocol using our cryopreserved allogeneic cell therapy product candidate remestemcel-L for steroid-refractory chronic graft versus host disease ("chronic GVHD") resulted in clinically meaningful outcomes in the first three treated patients, two children and one adult, within 28 days after two infusions. On the basis of the results, under the expanded access protocol Mesoblast plans to collaborate with key bone marrow transplant centers to evaluate remestemcel-L in a pivotal trial for chronic GVHD.

Mesoblast filed a completed BLA to the FDA for RYONCIL in the treatment of children with SR-aGVHD on January 31, and requested Priority Review of the BLA by the FDA under the product candidate's existing Fast Track designation.

January The FDA agreed to the selection of RYONCIL as the commercial name for the Company's lead allogeneic cell therapy remestemcel-L in the treatment of SR-aGVHD.

The clinical efficacy and safety data were filed for RYONCIL in the Company's rolling BLA. This included analyses of 309 children with SR-aGVHD who have received RYONCIL across three separate studies and new data in control pediatric subjects from the contemporaneous database of the Mount Sinai Acute GVHD International Consortium (MAGIC). The results demonstrate the effectiveness of RYONCIL in this patient population, with particular efficacy and survival benefit in patients with the most severe forms of SR-aGVHD.

December The independent Data Monitoring Committee ("DMC") overseeing the Phase 3 trial of REVASCOR for advanced chronic heart failure held its 10th and final scheduled meeting, and recommended that the trial continue as planned. The DMC reviewed available data from the 566 randomized patients, including components of the trial's primary and secondary endpoints, and all safety data.

The Phase 3 trial of REVASCOR for advanced chronic heart failure surpassed the number of primary endpoint events required for trial completion. This cardiovascular-outcomes trial initiated final study visits for all surviving patients with a target of last patient/last visit at the end of January 2020.

October Mesoblast entered into an agreement for commercial manufacture of RYONCIL for pediatric SR-aGVHD with Lonza. This agreement will facilitate inventory build ahead of the planned US market launch of RYONCIL and commercial supply to meet Mesoblast's long-term market projections. The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

Successful completion of an A$75.0 million capital raising via a private placement of ordinary shares to existing and new Australian and global institutional investors outside the United States. The net proceeds will principally be used to build product inventory and a targeted US commercial field team in preparation for the potential US commercial launch of RYONCIL in the treatment of pediatric SR-aGVHD. Proceeds will also be used to complete Phase 3 trials for chronic low back pain and advanced heart failure, and for working capital and general corporate purposes.

September Mesoblast entered into a strategic partnership with Grünenthal GmbH ("Grünenthal") to develop and commercialize MPC-06-ID, the Company's Phase 3 allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. Mesoblast may receive up to $150.0 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. These payments include commitments up to $45.0 million within the first year comprising $15.0 million on signing, $20.0 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and $10.0 million on certain clinical and manufacturing outcomes. Cumulative milestone payments could

exceed $1.0 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales. There cannot be any assurance as to the total amount of future milestone and royalty payments that Mesoblast will receive nor when they will be received. Grünenthal and Mesoblast have agreed on an overall development plan for MPC-06-ID to meet European regulatory requirements. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase 3 trial in Europe. The results of the two Phase 3 trials are expected to support both FDA and European Medicines Agency ("EMA") regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

August The FDA provided guidance on the clinical development pathway for marketing authorization of REVASCOR in end-stage heart failure patients implanted with a LVAD. Key outcomes were that the FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, was an important clinical outcome in patients implanted with an LVAD; it confirmed that data from the recently completed 159-patient placebo-controlled trial showing that REVASCOR reduced major mucosal bleeding events could support product marketing authorization through a BLA, with confirmatory clinical data, and agreed on a confirmatory Phase 3 trial of REVASCOR in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

Remestemcel-L will be evaluated under an investigator-initiated IND submission as a potential treatment in children with steroid-refractory chronic GVHD. In both acute and chronic forms of GVHD, the donated bone marrow stem cells view the recipient's body as foreign, and attack the body causing significant morbidity and mortality. Acute GVHD usually manifests within 100 days following a transplant while chronic GVHD generally manifests later (>100 days), and the two may occur separately or within the same patient.

Dr. Fred Grossman was appointed as Chief Medical Officer. His appointment aligns closely with the Company's commercial objectives for its lead products.

July Mesoblast reported increased revenues of 54% for the quarter and 37% for the year on sales of TEMCELL® Hs. Inj. ("TEMCELL") in Japan for the treatment of SR-aGVHD by licensee JCR Pharmaceuticals Co. Ltd.

The Kentgrove Capital equity facility for up to A$120.0 million (approximately US$82.0 million), was extended for two years.

The American Heart Association journal Circulation Research published a Special Article highlighting the important potential clinical benefits of REVASCOR as an immunotherapy in patients with advanced chronic heart failure, stating that there is a biologic rationale for the use of REVASCOR in targeting cardiac inflammation in order to improve heart failure outcomes.

Fiscal year 2019

June The FDA granted Orphan Drug Designation for the use of REVASCOR for the prevention of post implantation mucosal bleeding in heart failure patients implanted with an LVAD.

Health economics and outcomes research data presented at the 24th European Hematology Association Congress indicated that a steroid-refractory state in aGVHD may result in significant deterioration in quality of life and additional direct healthcare costs of an average of up to US$500,000 per patient.

Mesoblast's partnership with JCR in Japan was expanded to the use of TEMCELL for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed hypoxic ischemic encephalopathy ("HIE"). Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan to support its commercialization plans for remestemcel-L in the United States and other major healthcare markets. Mesoblast will receive royalties on TEMCELL product sales for HIE.

May The first component of a rolling submission for a BLA to the FDA for remestemcel-L in the treatment of children with aGVHD was filed. The FDA has agreed to a rolling review of the BLA which enables individual components to be submitted and reviewed on an ongoing basis rather than waiting for all sections to be completed. The rolling process will provide opportunity for ongoing and frequent communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA. The FDA previously granted Fast Track designation for remestemcel-L in aGVHD that allows for a rolling BLA review process and eligibility for priority review once the BLA filing is completed and accepted by the FDA.

March Mesoblast and the International Center for Health Outcomes and Innovation Research ("InCHOIR") entered into a Memorandum of Understanding to conduct a confirmatory clinical trial using REVASCOR for reduction of gastrointestinal ("GI") bleeding in end-stage heart failure patients implanted with an LVAD. GI bleeding episodes are a major life-threatening complication of LVAD implants that occur in 20-40% of recipients in the first six months, resulting in recurrent hospitalizations and compromising quality of life. Confirmation of previous observations that our cell therapy reduced major bleeding episodes and related hospitalizations could identify a therapeutic approach that could greatly benefit these patients.

JCR filed to extend marketing approval of TEMCELL for use in patients with Epidermolysis Bullosa ("EB"). TEMCELL is already approved for the treatment of aGVHD. The parties have amended their License Agreement in order for JCR to access our MSC wound healing patents to enable it to develop and commercialize TEMCELL for EB. Mesoblast will receive royalties on TEMCELL product sales for EB. JCR has received Orphan Designation for TEMCELL in the treatment of EB based on promising results from an investigator-initiated trial at Osaka University Hospital where TEMCELL was subcutaneously administered. JCR also intends to seek a label extension for TEMCELL in Japan for intravenous delivery of TEMCELL.

Joseph R. Swedish was appointed as non-executive Chairman of Mesoblast. Mr Swedish is a highly experienced healthcare executive and leader, most recently serving as Chairman, President and CEO of Anthem Inc., a Fortune 29 company and the leading health benefits provider in the U.S. For 12 consecutive years, Modern Healthcare named Mr Swedish as one of the 100 Most Influential People in Healthcare, ranking in the top 20 of the health sector's most senior-level executives, high-level government administrators, elected officials, academics, and thought-leaders for five consecutive years. He has been a Mesoblast board member since June 2018, and also serves on the boards of IBM Corporation, CDW Corporation, Proteus Digital Health, and Centrexion Therapeutics.

February The last patient was dosed in the Phase 3 events-driven trial of REVASCOR for advanced CHF. The 566-patient trial will complete when sufficient primary endpoint events have accrued. Results from a prior Phase 2 trial identified the patients most likely to benefit from REVASCOR as being those at high risk of recurrent hospitalization events and death. These results guided the trial design and selection criteria for enrollment of high-risk patients in the current Phase 3 trial in order to maximize the probability that the Phase 3 results would confirm the Phase 2 results.

January Mesoblast drew a further US$15.0 million from our US$75.0 million, non-dilutive, four-year credit facility with Hercules Capital, Inc. ("Hercules"). The funds will be used primarily to ramp up our product commercialization programs including building out a targeted sales force for our product candidate for aGVHD. The additional non-dilutive capital was made available after the success of our product candidate REVASCOR in having significantly reduced hospitalization rates from major GI bleeding in patients with end-stage heart failure and LVAD compared with controls in the 159-patient trial.

December Eric Strati, PhD, was appointed to the new position of Senior Vice President, Commercial to drive commercial launch activities of remestemcel-L in the U.S. and Europe for the treatment of aGVHD.

Recent meetings were held with the FDA to support our planned regulatory filing for commercialization of remestemcel-L in aGVHD. We gained agreement from the FDA on the proposed chemistry and manufacturing controls for commercialization. The FDA also provided guidance on the presentation of data from the completed 55-patient Phase 3 trial and the 241-patient EAP to be included in the filing for the proposed indication.

November Announced results of a 159-patient randomized placebo-controlled trial evaluating REVASCOR in the treatment of end-stage heart failure patients implanted with a LVAD which were presented at the 2018 American Heart Association Scientific Sessions.

- The trial succeeded in achieving the clinically meaningful outcome of reduction in GI bleeding and related hospitalizations;
- Results confirm the previous pilot trial, which also demonstrated significant reduction in GI bleeding and related hospitalizations in REVASCOR treated LVAD patients;
- Pilot trial results formed the basis for the FDA Regenerative Medicine Advanced Therapy ("RMAT") designation granted in December 2017; and
- While the trial did not meet the overall primary endpoint of temporary weaning, REVASCOR treatment did significantly improve weaning in the 44% of patients with chronic ischemic heart failure.

October Completion of the transaction with Tasly Pharmaceutical Group ("Tasly") to establish a strategic partnership in China for our allogeneic mesenchymal precursor cell ("MPC") product candidates REVASCOR for heart failure and MPC-25-IC for heart attacks. Tasly received exclusive rights to, and will fund all development, manufacturing and commercialization activities in China for REVASCOR and MPC-25-IC.

- We received $40.0 million on closing and will receive $25.0 million on product regulatory approvals in China, double-digit escalating royalties on net product sales as well as six escalating milestone payments upon the product candidates reaching certain sales thresholds in China;
- Tasly and Mesoblast have established a joint steering committee to oversee, review and co-ordinate the development, manufacturing and commercialization activities for these cardiovascular product candidates in China; and
- The companies plan to leverage each other's clinical trial results in China and the United States and other major jurisdictions respectively to support their respective regulatory submissions for REVASCOR and MPC-25-IC.

September Our heart failure product candidate REVASCOR for use in children with hypoplastic left heart syndrome ("HLHS") was featured at the First Cardiac Regenerative Symposium for Congenital Heart Disease in Baltimore, Maryland. The symposium focused on the potential for using cellular therapies in the treatment of complex congenital heart conditions. This trial has the potential to extend the safety profile of REVASCOR beyond adults, where it is being studied in two complementary late-stage clinical trials in patients with advanced and end-stage CHF, to children with congenital heart disease.

Continued strong survival outcomes through Day 180 in children with SR-aGVHD treated with our Phase 3 product candidate remestemcel-L were announced. Our open-label Phase 3 trial enrolled 55 children with steroid-refractory aGVHD (aged between six months and 17 years) at 32 sites across the United States, with the vast majority (89%) suffering from the most severe form of aGVHD (Grade C/D).

These Phase 3 outcomes are consistent with previous results in 241 children with steroid-refractory aGVHD who failed to respond to multiple biologic agents and were treated under an EAP that followed outcomes through 100 days. The multi-infusion regimen in both the EAP and the Phase 3 trial was well tolerated. Existing Fast Track designation from the FDA allows eligibility for priority review and a rolling BLA review process.

July Shawn Cline Tomasello was appointed as a non-executive director on our board of directors, bringing with her substantial commercial and transactional experience. She was Chief Commercial Officer at Kite Pharma Inc., where she played a pivotal role in the company's acquisition in 2017 by Gilead Sciences, Inc. for $11.9 billion, and was previously Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. for $21.0 billion.

Entered into a $50.0 million financing facility with NovaQuest Capital Management, L.L.C. ("NovaQuest") for the continued development and commercialization of remestemcel-L for children with SR-aGVHD. NovaQuest was formed in 2000 as a strategic investment unit within Quintiles (now IQVIA), the world's largest clinical research organization. On closing, Mesoblast drew $30.0 million and issued $10.0 million in ordinary shares with an additional US$10.0 million to be drawn on marketing approval of remestemcel-L by the FDA. Prior to maturity in July 2026, the loan is only repayable from net sales of remestemcel-L in the treatment of pediatric patients who have failed to respond to steroid treatment for aGVHD, in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. The financing is subordinated to the senior creditor, Hercules.

4.B Business Overview

Mesoblast (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic cellular medicines. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates.

Mesoblast's portfolio of Phase 3 off-the-shelf mesenchymal lineage product candidates are:

- RYONCIL (remestemcel-L) for pediatric SR-aGVHD;
- Remestemcel-L for moderate to severe ARDS due to COVID-19;
- REVASCOR® for advanced chronic heart failure; and
- MPC-06-ID for chronic low back pain ("CLBP") due to degenerative disc disease.

The Company also has a promising emerging pipeline and next generation technologies.

Mesoblast's goal is for RYONCIL to be the first commercially available allogeneic MSC product in the United States. The FDA has accepted for priority review the Company's Biologics License Application ("BLA") to seek approval of RYONCIL to treat pediatric SR-GVHD. On August 13, 2020, the Oncologic Drugs Advisory Committee ("ODAC") of the FDA voted overwhelmingly in favor that the available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The FDA has set an action date under the Prescription Drug User Fee Act ("PDUFA") of September 30, 2020, and if approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the United States in 2020.

The Company's 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 upon receiving marketing authorizations.

Mesoblast's immuno-selected, culture expanded cellular medicines are based on mesenchymal precursor cells ("MPCs") and their progeny, MSCs. These are rare cells (approximately 1:100,000 in bone marrow) found around blood vessels that are central to blood vessel maintenance, repair and regeneration. These cells have a unique immunological profile with immunomodulatory effects that reduce inflammation allowing healing and repair. This mechanism of action enables the targeting of multiple disease pathways across a wide spectrum of complex diseases with significant unmet medical needs.

Mesenchymal lineage cells are collected from the bone marrow of healthy adult donors and proprietary processes are utilized to expand them to a uniform, well characterized, and highly reproducible cell population. This enables manufacturing at industrial scale for commercial purposes. Another key feature of Mesoblast's cells is they can be administered to patients without the need for donor–recipient matching or recipient immune suppression.

Mesoblast's approach to product development is to ensure rigorous scientific investigations are performed with well-characterized cell populations in order to understand mechanisms of action for each potential indication. Extensive preclinical translational studies guide clinical trials that are structured to meet stringent safety and efficacy criteria set by international regulatory agencies. All trials are conducted under the continuing review of independent Data Safety Monitoring Boards comprised of independent medical experts and statisticians. These safeguards are intended to ensure the integrity and reproducibility of results, and to ensure that outcomes observed are scientifically reliable.

Allogeneic, Off-the-Shelf, Commercially Scalable Products

Our technology platform enables development of a diverse range of products derived from the mesenchymal cell lineage in adult tissues. MPCs constitute the earliest known cell type in the mesenchymal lineage in vivo.

MPCs can be isolated using monoclonal antibodies and culture-expanded using methods that enable efficient expansion without differentiation. MSCs are defined biologically in culture following density gradient separation from other tissue cell types and following culture by plastic adherence. MSCs presumably represent culture-expanded in vitro progeny of the undifferentiated MPCs present in vivo. The functional characteristics of each cell type enable product development for specific indications.

Our proprietary mesenchymal lineage cell-based products have distinct biological characteristics enabling their use for allogeneic purposes.

Immune Privilege: Mesenchymal lineage cells are immune privileged, in that they do not express specific cell surface co-stimulatory molecules that initiate immune allogeneic responses.

Expansion: We have developed proprietary methods that enable the large scale expansion of our cells while maintaining their ability to produce the key biomolecules associated with tissue health and repair. This allows us to produce a cellular product intended to demonstrate consistent and well-defined characterization and activity.

In contrast, autologous stem cell products, which are produced from the patient's own stem cells, require individual product regulatory testing and do not benefit from manufacturing economies of scale. Moreover, autologous therapies may be vulnerable to significant patient-to-patient variability.

Products Commercialized by Licensees

Two allogeneic mesenchymal stem cell (MSC) products developed and commercialized by Mesoblast licensees have been approved in Japan and Europe, with both licensees the first to receive full regulatory approval for an allogeneic cellular medicine in these major markets.

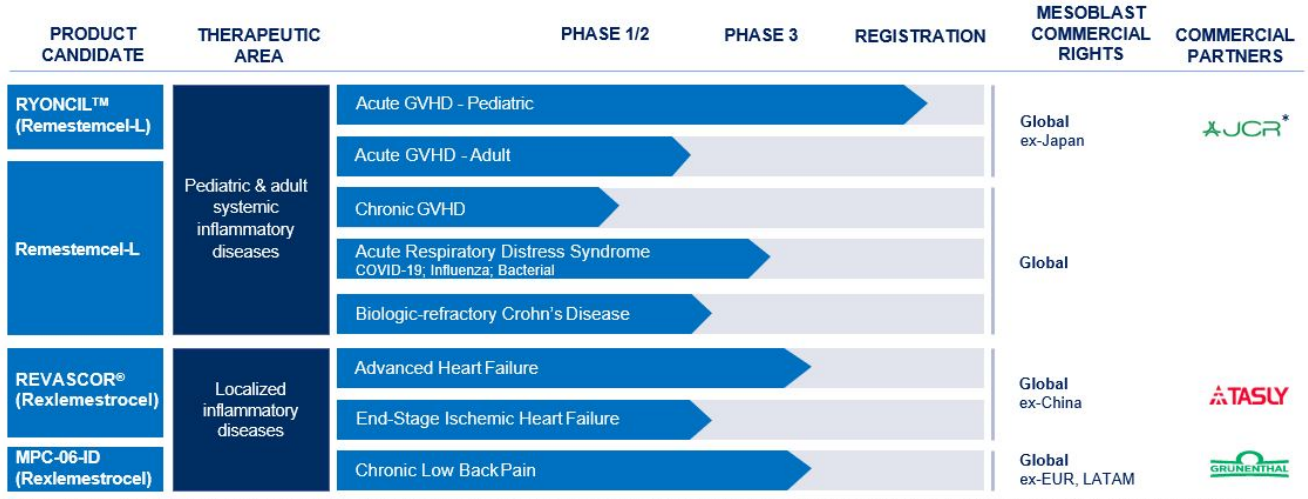
1 Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® Hs. Inj. product in Japan.
2 Mesoblast receives royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae.

This chart is figurative and does not purport to show individual trial progress within a clinical program.

Mesoblast's licensee in Japan, JCR, is marketing its MSC-based product in Japan for the treatment of aGVHD in children and adults. TEMCELL was the first allogeneic cellular medicine to receive full regulatory approval in Japan. Mesoblast receives royalty income on sales of TEMCELL in Japan.

In 2017, Mesoblast granted TiGenix, now a wholly owned subsidiary of Takeda, exclusive access to certain of its patents to support global commercialization of Alofisel®, previously known as Cx601, the first allogeneic MSC therapy to receive central marketing authorization approval from the European Commission. Mesoblast receives royalty income on Takeda's worldwide sales of Alofisel® in the local treatment of perianal fistulae.

Mesoblast Product Candidates



* Mesoblast has the right to use data generated by JCR Pharmaceuticals Co Ltd in Japan to support its development and commercialization plans for remestemcel-L in the US and other major healthcare markets, including for GVHD, Hypoxic Ischemic Encephalopathy and Epidermolysis Bullosa

This chart is figurative and does not purport to show individual trial progress within a clinical program

RYONCIL™ (remestemcel-L) for the Treatment of Steroid Refractory Acute Graft Versus Host Disease

Overview

RYONCIL is an intravenously delivered product candidate for the treatment of steroid-refractory acute graft versus host disease, or SR-aGVHD, following an allogeneic bone marrow transplant.

In a bone marrow transplant, donor cells can attack the recipient, causing GVHD. The donor T-cell mediated inflammatory response involves secretion of TNF-alpha and IFN-gamma, resulting in activation of pro-inflammatory T-cells and tissue damage in the skin, gut and liver, which can be fatal.

RYONCIL is suggested to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions. The mechanism of action is thought to involve down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

This life-threatening disease occurs in approximately 50% of patients who receive an allogeneic bone marrow transplant (BMT). Over 30,000 patients worldwide undergo an allogeneic BMT annually, primarily during treatment for blood cancers, and these numbers are increasing. In patients with the most severe form of SR-aGVHD (Grade C/D or III/IV) mortality can be as high as 90% despite optimal best available therapy. There are currently no FDA-approved treatments in the United States for children under 12 with SR-aGVHD.

Current Status and Anticipated Milestones

Mesoblast submitted its completed BLA to the FDA for RYONCIL in January 2020. The BLA was subsequently accepted for priority review by the FDA on March 30, 2020, with a PDUFA action date set for September 30, 2020. In August 2020, the ODAC to the FDA voted overwhelmingly in favor (nine to one[(1)]) that the available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD.

There are currently no FDA-approved treatments in the US for children under 12 with SR-aGVHD and only one FDA-approved treatment in the US for other SR-aGVHD patients.

We believe the U.S. pediatric SR-aGVHD market requires a small, targeted commercial footprint. The target call point for SR-aGVHD will primarily be board-certified pediatric physicians in hematology/oncology who perform hematopoietic stem cell transplants. In the U.S., there are approximately 80 centers that perform pediatric transplants, with 50% of all transplants occurring at approximately 15 centers. Similarly, there are approximately 110 centers that perform adult transplants with half of those transplants occurring at approximately 20 centers.

The Company has put in place a lifecycle extension strategy to generate evidence-based clinical outcomes to leverage the experience of bringing RYONCIL to market and to maximize the value of remestemcel-L in other pediatric and adult rare diseases that do not require large distribution channels. Planning is underway to conduct a post-marketing study in adult patients with SR-GVHD. In addition, we plan to expand investigator-initiated clinical trials for chronic GVHD and other indications that are currently underway or planned for the near future.

(1) This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.

Remestemcel-L for Moderate to Severe Acute Respiratory Distress Syndrome due to COVID-19 Infection

Overview

COVID-19 ARDS results from a severe inflammatory reaction, referred to as a cytokine storm, to infection from the SARS CoV-2 virus. This cytokine storm can cause significant damage to the lungs and other organs and is the primary cause of death in this high mortality condition. COVID ARDS is a major area of unmet need that typically requires extended hospitalization in intensive care and intervention by mechanical ventilation.

The extensive safety data of remestemcel-L and its anti-inflammatory effects in acute GVHD is a compelling rationale for evaluating remestemcel-L in COVID-19 ARDS. Following intravenous delivery of remestemcel-L, the cells migrate to the areas of inflammation particularly in the lungs resulting in the potential for remestemcel-L to tame the cytokine storm in ARDS.

The clinical protocol evaluating remestemcel-L in patients in the Phase 3 trial was based on results from patients treated with remestemcel-L under an emergency IND/EAP compassionate use at Mount Sinai Hospital in New York. Twelve patients with moderate to severe COVID ARDS on mechanical ventilation were given 2 infusions within one week. Nine of the 12 patients (75%) were successfully taken off the ventilator and discharged from hospital within a median of 10 days.

Over 20 million COVID-19 global cases have been confirmed and over 775,000 deaths, with greater than 5 million cases and 170,000 deaths occurring in the United States. Currently there is no FDA approved therapy in the United States for the specific treatment of moderate-to-severe COVID-19 ARDS.

Current Status and Anticipated Milestones

A randomized placebo-controlled Phase 3 trial of remestemcel-L in ventilator-dependent patients with ARDS due to COVID-19 is currently enrolling, with the first patients dosed in May 2020. The trial will randomize up to 300 ventilator-dependent patients in intensive care units to either remestemcel-L or placebo (1:1) on top of maximal care, in line with specific guidance provided by the FDA for robust statistical analysis. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days alive and off mechanical support.

Up to 30 leading medical centers across the United States are expected to participate in the trial, which is expected to complete recruitment in Q4 CY2020.

The independent Data Safety Monitoring Board ("DSMB") has set a date for early September to complete the first scheduled interim analysis of the trial's first 90 patients. The DSMB will evaluate efficacy and safety and based on that analysis inform Mesoblast on whether the trial should proceed as planned, or should stop early.

REVASCOR® for Advanced and End-stage Heart Failure

Overview

Mesoblast is developing REVASCOR to fill the treatment gap for both advanced and end-stage chronic heart failure (CHF). The objective is to use REVASCOR to prevent or delay further progression of heart failure or cardiac death in patients who are no longer responsive to maximal standard of care heart failure drugs.

REVASCOR consists of 150 million MPCs administered by direct cardiac injection in patients suffering from moderate/severe or end-stage CHF and progressive loss of heart function following damage to the heart muscle caused by a heart attack, coronary artery disease, hypertension, genetic factors, or other causes.

MPCs release a range of factors when triggered by specific receptor-ligand interactions within damaged tissue. Based on preclinical data, we believe that the factors released from the MPCs induce functional cardiac recovery by simultaneous activation of multiple pathways, including induction of endogenous vascular network formation, reduction in harmful inflammation, reduction in cardiac fibrosis, and reversal of endothelial dysfunction through activation of intrinsic tissue precursors.

The unit dose of 150 million cells was based on multiple preclinical large animal studies in ischemic and non-ischemic heart failure models which identified an optimal cell dose above 110 million. A completed Phase 2 dose-ranging study in patients with moderate to advanced CHF of either ischemic or non-ischemic etiology identified the dose of 150 million cells as the most effective for both improvement in left ventricular volumes and remodeling and in prevention of heart failure related hospitalizations or cardiac death.

CHF is a chronic condition characterized by an enlarged heart and insufficient blood flow to the organs and extremities of the body. The condition progresses over time and can be caused by many factors that put an excess demand on the heart muscle, including high blood pressure, incompetent valves, infections of the heart muscle or valves, or congenital heart problems.

CHF is classified in relation to the severity of the symptoms experienced by the patient. The most commonly used classification system for functional severity of heart failure, established by the NYHA, is:

- Class I (mild): patients experience none or very mild symptoms with ordinary physical activity
- Class II (mild): patients experience fatigue and shortness of breath during moderate physical activity
- Class III (moderate): patients experience shortness of breath during even light physical activity
- Class IV or end-stage (severe): patients are exhausted even at rest

Risk for recurrent heart failure-related hospitalizations and terminal cardiac events increases progressively with increases in left ventricular volumes, reduction in left ventricular ejection fraction, and progression in NYHA functional class. About 40% of all heart failure patients have a low ejection fraction (<35-40%), NYHA Class II, III or IV CHF, and are at considerable risk of repeated hospitalizations and death despite maximal drug therapy.

Patients with advanced or Class III/IV CHF continue to represent the greatest unmet medical need despite recent advances in new therapeutic agents for heart failure. In contemporary studies, Class III/IV heart failure patients, characterized by heart failure hospitalizations in the previous 12 months, severely impaired baseline cardiac function, increased systolic and diastolic volumes, and

elevated B-type natriuretic peptide (BNP) levels, have been reported to have a 50% incidence of terminal cardiac events or cardiovascular hospitalization for decompensated heart failure over a median period of 16.6 months.

The definitive method of treating end-stage disease currently is a heart transplant or implanting a mechanical assist device. Although there are many patients awaiting a heart transplant, due to limited supply there were only 3,191 heart transplants performed in the U.S. in 2016.

In 2016, more than 15 million patients in the seven major global pharmaceutical markets are estimated to have been diagnosed with CHF. The American Heart Association estimated in 2017 that prevalence is expected to grow 46% by 2030 in the U.S., affecting more than 8 million Americans. CHF causes severe economic, social, and personal costs. In the U.S., it is estimated that CHF results in direct costs of $60.2 billion annually when identified as a primary diagnosis and $115.0 billion as part of a disease milieu.

Results from our Phase 2 trials in patients with Class II/III CHF and in patients with end-stage CHF requiring mechanical assist devices have shown that our MPCs appear to have the potential to positively impact patients with the advanced forms of CHF due to diminished left ventricular systolic function. We believe that targeting advanced heart failure patients with the most unmet need can provide us with the most effective Phase 3 program, the most efficient path to market, and the opportunity for the most attractive pricing.

Current Status and Anticipated Milestones

Program for Class II/III CHF patients

A multicenter, double-blinded, 1:1 randomized, sham-procedure-controlled Phase 3 trial of Revascor has completed enrollment of 566 patients across North America with NYHA Class II/III disease at high risk of repeated heart failure hospitalizations or a terminal cardiac event (cardiac death, LVAD placement, heart transplant or insertion of an artificial heart). The events-driven trial is expected to read out top line results in 1H FY2021. The enrollment criteria for this trial included a prior decompensated heart failure event (e.g. hospitalization) within the previous nine months and/or very high level of NT-proBNP, a protein used in diagnosis and screening of CHF. These inclusion criteria are expected to result in enrichment for patients with substantial left ventricular contractile abnormality, advanced CHF due to left ventricular systolic dysfunction and higher risk of recurrent decompensated heart failure hospitalizations and TCEs. This target patient population was shown to respond effectively to treatment with Revascor in our previous Phase 2 trial.

The trial's primary efficacy endpoint is a comparison of recurrent non-fatal HF-MACE between either MPC-treated patients or sham-treated controls.

The results of this Phase 3 trial, expected in Q4 CY2020, will contribute to the pivotal data to support regulatory approval in the United States, as well as in China through a partnership with Tasly Pharmaceuticals to develop and commercialize the product for advanced chronic heart failure.

Program in Patients Requiring Mechanical Support

Revascor is also being evaluated in patients with end-stage CHF implanted with a left ventricular assist device ("LVAD").

A Phase 2 trial was conducted by a multi-center team of researchers within the United States National Institutes of Health ("NIH")-funded Cardiothoracic Surgical Trials Network ("CTSN"), led by Icahn School of Medicine at Mount Sinai, New York. The National Institute of Neurological Disorders and Stroke, and the Canadian Institutes for Health Research also supported this trial. Results of this Phase 2 trial were released in November 2018.

The trial was a prospective, multi-center, double-blind, placebo controlled, 2:1 randomized (MPC to placebo), single-dose cohort trial to evaluate the safety and efficacy of injecting a dose of 150 million MPCs into the native myocardium of LVAD recipients. Patients with advanced CHF, implanted with an FDA-approved LVAD as bridge-to-transplant or destination therapy, were eligible to participate in the trial. All patients were followed until 12 months post randomization.

In this Phase 2 trial, the trial did not show a significant difference in the ability for patients to tolerate a wean for a period of 60 minutes. However, in relation to the clinically meaningful endpoint of reduction in major GI bleeding episodes and related hospitalizations, a single injection of Revascor administered directly into the heart resulted in a 76% reduction in major GI bleeding events and in a 65% reduction in associated hospitalizations. This suggests that Revascor reversed endothelial dysfunction which is responsible for the abnormal vasculature in the GI tract and severe bleeding in LVAD patients.

Reduction in GI bleeding and associated hospitalizations in the previous 30-patient pilot trial of Mesoblast's MPCs were the basis of the RMAT designation granted in December 2017 by the FDA for use of Revascor in LVAD patients. GI bleeding episodes are a major life-threatening complication of LVAD implants that occur in 20-40% of recipients in the first six months, resulting in recurrent hospitalizations and compromising quality of life.

During FY2020, the FDA provided guidance on the clinical development pathway for marketing authorization of Revascor in end-stage heart failure patients implanted with a LVAD.

- FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, is an important clinical outcome in patients implanted with an LVAD;
- Data from the recently completed 159-patient placebo-controlled trial showing that Revascor reduced major mucosal bleeding events can support product marketing authorization through a BLA, with confirmatory clinical data; and
- FDA agreed on a confirmatory Phase 3 trial of Revascor in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

A confirmatory trial is planned to be conducted with the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York, in line with an existing Memorandum of Understanding.

Strategic Partnerships

In September 2018, Mesoblast entered into a strategic cardiovascular partnership with Tasly for China. Tasly plans to meet with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China. Tasly and Mesoblast will leverage each other's clinical trial results in China, the U.S. and other territories to support their respective regulatory submissions. In June 2020, Tasly and Mesoblast met with the Center for Drug Evaluation ("CDE") in China clearing the way for a submission of an IND for approval of a China based study in patients with chronic heart failure.

MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease

Overview

MPC-06-ID consists of a unit dose of 6 million MPCs administered by syringe directly into a damaged disc.

In CLBP, damage to the disc is the result of a combination of factors related to aging, genetics, and micro-injuries, which compromises the disc's capacity to act as a fluid-filled cushion between vertebrae and to provide anatomical stability. Damage to the disc also results in an inflammatory response with ingrowth of nerves which results in chronic pain. This combination of anatomic instability and nerve ingrowth results in CLBP and functional disability.

With respect to mechanisms of action in CLBP, extensive pre-clinical studies have established that MLCs have anti-inflammatory effects and secrete multiple paracrine factors that stimulate new proteoglycan and collagen synthesis by chondrocytes in vitro and by resident cells in the nucleus and annulus in vivo.

In 2016, over 7 million people in the U.S. alone were estimated to suffer from CLBP caused by DDD, of which 3.2 million patients have moderate disease. This market is projected to have annual growth rate similar to that of the US population annual growth rate. After failure of conservative measures (medication, injections, epidural steroid, physical therapy etc.), there is a need for treatments that both reduce pain and improve function over a sustained period of time. When disc degeneration has progressed to a point that pain and loss of function can no longer be managed by conservative means, major invasive surgery such as spinal fusion is the most commonly offered option.

All therapies for progressive, severe and debilitating pain due to degenerating intervertebral discs treat the symptoms of the disease. However, they are not disease modifying and do not address the underlying cause of the disease. Surgical intervention is not always successful in addressing the patient's pain and functional deficit. Surgeons estimate that between 50% to 70% of patients ultimately fail back surgery, with failure defined as either not achieving at least a 50% reduction of symptoms within four months or experiencing new-onset pain and spasm. Total costs of low back pain are estimated to be between $100.0 billion and $200.0 billion annually with two thirds attributed to patients' decreased wages and productivity.

As a result, we believe that the most significant unmet need and commercial opportunity in the treatment of CLBP is a therapy that has the ability to impact the chronic pain and disability associated with the condition.

Current Status and Anticipated Milestones

The Phase 3 clinical trial for CLBP completed enrollment in March 2018 with 404 patients enrolled across 48 centers in the United States and Australia randomized 2:1 to receive either 6 million MPCs or saline control. The trial's primary endpoint of Overall Treatment Success (using a composite of 50% improvement in lower back pain and 15 point improvement in function at both 12 and 24 months with no treatment or surgical interventions at the treated level through 24 months) is an acceptable endpoint, as per guidance from the FDA. Follow-up of patients in the Phase 3 trial of MPC-06-ID to a 24-month assessment of safety and efficacy has been completed, with an ongoing quality review of all data being finalized at the study sites. A data readout is expected Q4 CY2020.

Strategic Partnerships

Grünenthal, a global leader in pain management, and Mesoblast entered into a strategic partnership to develop and commercialize MPC-06-ID for the treatment of chronic low back pain associated with degenerative disc disease in patients who have exhausted conservative treatment options in Europe and Latin America. The companies have agreed on an overall development plan for the product to meet European regulatory requirements. As part of this plan, they are collaborating on the study design for a confirmatory Phase 3 trial in Europe, with the results of the two Phase 3 trials expected to support both FDA and European Medicines Agency regulatory approvals for MPC-06-ID.

Complementary Technologies

In addition to having the most mature and diverse allogeneic cell therapy product pipeline and technology platform in the field of cellular medicines, we have strategically targeted the acquisition of rights to technologies that are complementary to and synergistic with our mesenchymal lineage cell technology platform. The aim of this activity is to maintain our technology leadership position in the regenerative medicine space, while simultaneously expanding our targeted disease applications and managing the life-cycle of our current lead programs.

Our complementary technologies and additional product candidates include other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies.

Manufacturing and Supply Chain

Our manufacturing strategy for our cellular product candidates focuses on the following important factors:

(i) ability for product delineation to protect pricing and partner markets by creating distinct products using discrete manufacturing processes, culture conditions, formulations, routes of administration, and/or dose regimens;
(ii) establishing proprietary commercial scale-up and supply to meet increasing demand;
(iii) implementing efficiencies and yield improvement measures to reduce cost-of-goods;
(iv) maintaining regulatory compliance with best practices; and
(v) establishing and maintaining multiple manufacturing sites for product supply risk mitigation.

The stem cell manufacturing and distribution process generally involves five major steps.

- Procure bone marrow—acquire bone marrow from healthy adults with specific FDA-defined criteria, which is accompanied by significant laboratory testing to establish the usability of the donated tissues.
- Create master cell banks—isolate MLCs from the donated bone marrow and perform a preliminary expansion to create master cell banks. Each individual master cell bank comes from a single donor.
- Expand to therapeutic quantities—expand master cell banks to produce therapeutic quantities, a process that can yield thousands of doses per master cell bank, with the ultimate number depending on the dose for the respective product candidate being produced.
- Formulate, package and cryopreserve.
- Distribute—our cellular products are cryopreserved at the manufacturer and shipped to storage sites in the U.S. and other jurisdictions via cryoshippers. Those distribution centers then re-package and send the products on to treatment centers in cryoshippers. Treatment centers will either move the products into their own freezers or receive the cryoshipper in “real time” and product stays in the cryoshipper until thawed for patient use within a well-defined window. We intend to continue utilizing this approach in the future.

To date our product candidates have been manufactured in two-dimensional, or 2D, planar, 10-layer cell factories, using media containing fetal bovine serum, or FBS.

The relatively small patient numbers and orphan drug designation for RYONCIL lead us to believe that 2D manufacturing will be adequate to meet demand for this product candidate if fully approved. We also believe that 2D manufacturing process and facilities are commercially feasible for Phase 3 trial supply and the initial launch of MPC-06-ID for CLBP.

However, to build up commercial supply for certain of our product candidates long-term, we are developing novel manufacturing processes using three-dimensional, or 3D, bioreactors with greater capacity to improve efficiency and yields, with resulting lower-cost of goods. We intend to evaluate products produced in 3D bioreactors in pre-clinical and potentially clinical studies, which may serve as FDA required comparability studies to 2D if successful.

We are also focusing on the introduction of FBS-free media which has the potential to result in efficiency and yield improvements to the current 2D process. We intend to conduct comparability studies to illustrate that products produced with this media are equivalent to those produced using FBS based media. While we remain confident in our ability to deliver successful outcomes from each of these activities, any unexpected issues or challenges faced in doing so could delay our programs or prevent us from continuing our programs.

Our manufacturing activities to date have met stringent criteria set by international regulatory agencies, including the FDA. By using well-characterized cell populations, our manufacturing processes promote reproducibility and batch-to-batch consistency for our allogeneic cell product candidates. We have developed robust quality assurance procedures and lot release assays to support this reproducibility and consistency.

Intellectual Property

We have a large patent portfolio of issued and pending claims covering compositions of matter, uses for our mesenchymal lineage cell-based technologies and other proprietary regenerative product candidates and technologies, as well as for elements of our manufacturing processes, with approximately 1,100 patents and patent applications across 82 patent families as of August 2020.

One of our major objectives is to continue to protect and expand our extensive estate of patent rights and trade secrets, which we believe enables us to deliver commercial advantages and long-term protection for our product candidates based on our proprietary technologies, and support our corporate strategy to target large, mature and emerging healthcare markets for our exploratory therapeutic product candidates.

More specifically, our patent estate includes issued patent and patent applications in major markets, including, but not limited to, the United States, Europe, Japan and China. The patents that we have obtained, and continue to apply for, cover mesenchymal lineage cell technologies and product candidates derived from these technologies, irrespective of the tissue source, including bone marrow, adipose, placenta, umbilical cord and dental pulp.

These patents cover, among other technology areas, a variety of MLCs (including MPCs and MSCs), and the use of MLC for expansion of hematopoietic stem cells, or HSCs. Among the indication-specific issued or pending patents covering product candidates derived from our mesenchymal lineage cells are those which are directed to our lead product candidates: aGVHD, ARDS, CLBP, CHF and chronic inflammatory conditions such as RA. We also have issued and pending patents covering other pipeline indications, including diabetic kidney disease, inflammatory bowel disease (e.g., Crohn’s disease), neurologic diseases, eye diseases and additional orthopedic diseases. In addition, we have in-licensed patents covering complementary technologies, such as other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies, as part of our strategy to expand our targeted disease applications and manage the life-cycle of our current lead programs.

Our patent portfolio also includes issued and pending coverage of proprietary manufacturing processes that are being used with our current two-dimensional manufacturing platform as well as the 3D bioreactor manufacturing processes currently under development. These cell manufacturing patents cover isolation, expansion, purification, scale up, culture conditions, aggregates minimization, cryopreservation, release testing and potency assays. In addition, we maintain as a trade secret, among other things, our proprietary FBS-free media used in our 3D bioreactor manufacturing processes.

We maintain trade secrets covering a significant body of know-how and proprietary information relating to our core product candidates and technologies. We protect our confidential know-how and trade secrets in a number of ways, including requiring all employees and third parties that have access to our confidential information to sign non-disclosure agreements, limiting access to confidential information on a need-to-know basis, maintaining our confidential information on secure computers, and providing our contract manufacturers with certain key ingredients for our manufacturing process.

In addition, in many major jurisdictions there are other means that may be available to us by which we would be able to extend the period during which we have commercial exclusivity for our product candidates, which include, but are not limited to the exclusive right to reference our data, orphan drug exclusivity and patent term extensions.

As part of our strategy, we seek patent protection for our product candidates and technologies in major jurisdictions including the United States, Europe, Japan, China, and Australia and file independent and/or counterpart patents and patent applications in other jurisdictions globally that we deem appropriate under the circumstances, including India, Canada, Hong Kong, Israel, Korea and Singapore. As of August 2020, our patent portfolio includes the following patents and patent applications in the following major jurisdictions: 82 granted U.S. patents and 49 pending U.S. patent applications; 61 granted Japanese patents and 29 pending Japanese patent applications; 27 granted Chinese patents and 24 pending Chinese patent applications; 55 granted European patents and 29 pending European patent applications; and 58 granted Australian patents and 30 pending Australian patent applications.

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business, only in those cases in which we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology and associated product candidates, and typically only in those jurisdictions that we believe present significant commercial opportunities to us. In those cases where we choose neither to seek patent protection nor protect the inventions as trade secrets, we may publish the inventions so that it defensively becomes prior art in order for us to secure a freedom to operate position and to prevent third parties from patenting the invention.

We also seek to protect as trade secrets our proprietary and confidential know-how and technologies that are either not patentable or where we deem it inadvisable to seek patent protection. To this end, we generally require all third parties with whom we share confidential information and our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information. These agreements with our employees and consultants engaged in the development of our technologies require disclosure and assignment to us of the ideas, developments, discoveries and inventions, and associated intellectual property rights, important to our business. Additionally, these confidentiality agreements, among others, require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

License and Collaboration Agreements

All of our revenue relates to up-front, royalty and milestone payments recognized under the license and collaboration agreements below. For further information on the categorical revenue breakdown during the last three fiscal years, see "Item 18. Financial Statements – Note 3".

Grünenthal arrangement

In September 2019, Mesoblast entered into a strategic partnership with Grünenthal GmbH (Grünenthal) to develop and commercialize MPC-06-ID, the Company's Phase 3 allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. Mesoblast may receive up to $150.0 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. These payments include commitments up to $45.0 million within the first year comprising $15.0 million on signing, $20.0 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and $10.0 million on certain clinical and manufacturing outcomes. Cumulative milestone payments could exceed $1.0 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales. There cannot be any assurance as to the total amount of future milestone and royalty payments that Mesoblast will receive nor when they will be received. Grünenthal and Mesoblast have agreed on an overall development plan for MPC-06-ID to meet European regulatory requirements. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase 3 trial in Europe. The results of the two Phase 3 trials are expected to support both FDA and EMA regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

JCR Pharmaceuticals Co., Ltd.—Hematological Malignancies and Hepatocytes Collaboration in Japan

In October 2013, we acquired all of Osiris Therapeutics, Inc.'s business and assets related to culture expanded MSCs. These assets included assumption of a collaboration agreement with JCR ("JCR Agreement"), which will continue in existence until the later of 15 years from the first commercial sale of any product covered by the agreement and expiration of the last Osiris patent covering any such product. JCR is a research and development oriented pharmaceutical company in Japan. Under the JCR Agreement we assumed from Osiris, 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 HSCs 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. Under the JCR Agreement, JCR obtained rights in Japan to our MSCs, for the treatment of aGVHD. JCR also has a right of

first negotiation to obtain rights to commercialize MSC-based products for additional orphan designations in Japan. We retain all rights to those products outside of Japan.

JCR received full approval in September 2015 for its MSC-based product for the treatment of children and adults with aGVHD, TEMCELL. TEMCELL is the first culture-expanded allogeneic stem cell product to be approved in Japan. It was launched in Japan in February 2016.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. With respect to the First JCR Field, we are entitled to future payments of up to $1.0 million in the aggregate 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, we are entitled to a double digit profit share in the fifties.

Intellectual property is licensed both ways under the JCR Agreement, with JCR receiving exclusive and non-exclusive rights as described above from us and granting us non-exclusive, royalty-free rights (excluding in the First JCR Field and Second JCR Field in Japan) under the intellectual property arising out of JCR's development or commercialization of MSC-based products licensed in Japan.

JCR has the right to terminate the JCR Agreement for any reason, and we have a limited right to terminate the JCR Agreement, including a right to terminate in the event of an uncured material breach by JCR. In the event of a termination of the JCR Agreement other than for our breach, JCR must provide us with its owned product registrations and technical data related to MSC-based products licensed in Japan and all licenses of our intellectual property rights will revert to us.

We have expanded our partnership with JCR in Japan for two new indications: for wound healing in patients with EB in October 2018, and for neonatal HIE, a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. We will receive royalties on TEMCELL product sales for EB and HIE, if and when such indications receive marketing approval in Japan.

We have the right to use all safety and efficacy data generated by JCR in Japan to support our development and commercialization plans for our MSC product candidate remestemcel-L in the United States and other major healthcare markets, including for GVHD, EB and HIE.

Lonza—Manufacturing Collaboration

In September 2011, we entered into a manufacturing services agreement, or MSA, with Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., collectively referred to as Lonza, a global leader in biopharmaceutical manufacturing. Under the MSA, we pay Lonza on a fee for service basis to provide us with manufacturing process development capabilities for our product candidates, including formulation development, establishment and maintenance of master cell banks, records preparation, process validation, manufacturing and other services.

We have agreed to order a certain percentage of our clinical requirements and commercial requirements for MPC products from Lonza. Lonza has agreed not to manufacture or supply commercially biosimilar versions of any of our product candidates to any third party, during the term of the MSA, subject to our meeting certain thresholds for sales of our products.

We can trigger a process requiring Lonza to construct a purpose-built manufacturing facility exclusively for our product candidates. In return if we exercise this option, we will purchase agreed quantities of our product candidates from this facility. We also have a right to buy out this manufacturing facility at a pre-agreed price two years after the facility receives regulatory approval.

The MSA will expire on the three-year anniversary of the date of the first commercial sale of product supplied under the MSA, unless it is sooner terminated. We have the option of extending the MSA for an additional 10 years, followed by the option to extend for successive three-year periods subject to Lonza's reasonable consent. We may terminate the MSA with two years prior written notice, and Lonza may terminate with five years prior written notice. The MSA may also terminate for other reasons, including if the manufacture or development of a product is suspended or abandoned due to the results of clinical trials or guidance from a regulatory authority. In the event we request that Lonza construct the manufacturing facility described above, neither we nor Lonza may terminate before the third anniversary of the date the facility receives regulatory approval to manufacture our product candidates, except in certain limited circumstances. Upon expiration or termination of the MSA, we have the right to require Lonza to transfer certain technologies and lease the Singapore facility or the portion of such facility where our product candidates are manufactured, subject to good faith negotiations.

We currently rely, and expect to continue to rely, on Lonza for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of our product candidates if marketing approval is obtained.

In October 2019, we entered into an agreement with Lonza for commercial manufacture of RYONCIL for pediatric SR-aGVHD. This agreement will facilitate inventory build ahead of the planned US market launch of RYONCIL and commercial supply to meet Mesoblast's long-term market projections. The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

Singapore Economic Development Board (EDB)—Singapore Operations

In May 2014, the Economic Development Board of Singapore, or EDB, granted us certain financial incentives tied to revenues generated by our Singapore operations, among other things. These incentives include two separate 15-year periods (each broken into five-year increments) of potential incentives, one related primarily to non-manufacturing activities and the other related to manufacturing activities. We will be eligible for these incentives if we meet certain investment or activity thresholds in Singapore, including employment levels, amounts of business or manufacturing related expenses, and the performance of various services including business development, planning, manufacturing, intellectual property management, marketing and distribution.

For example, in order to obtain full financial benefits from the EDB for our manufacturing-related incentives, we must manufacture at least 50% of the global volume of our first three commercial products in Singapore (subject to certain exceptions), and we would be required to construct and operate a manufacturing facility in Singapore, and hire and maintain a specified number of professionals (including supply chain personnel) in connection with the operation of that facility. The activities under our MSA with Lonza could be used to fulfill all or part of the requirements to obtain the EDB financial incentives.

Central Adelaide Local Health Network Incorporated—Mesenchymal Precursor Cell Intellectual Property

In October 2004, we, through our wholly-owned subsidiary, Angioblast Systems Inc., now Mesoblast, Inc., 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, we are 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) and single-digit royalties on net sales of the specified products for applications outside the specified fields. Additionally, we are obligated to pay CALHNI a double-digit percentage in the teens of any revenue that we receive in exchange for a grant of a sublicense to the Medvet IP in the specified fields. Under the IP Deed, we also granted to Medvet a non-exclusive, royalty-free license to the Medvet IP for non-commercial, internal research and academic research.

Pursuant to the IP Deed, we were assigned the rights in three U.S. patents or patent applications (including all substitutions, continuations, continuations-in-part, divisional, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition and foreign equivalents thereof) and all future intellectual property rights, including improvements, that might arise from research conducted at CALHNI related to MPCs and methods of isolating, culturing and expanding MPCs and their use in any therapeutic area. We also acquired all related materials, information and know-how.

Osiris Acquisition—Continuing Obligations

In October 2013, we and Osiris entered into a purchase agreement, as amended, or the Osiris Purchase Agreement, under which we acquired all of Osiris' business and assets related to culture expanded MSCs. Pursuant to the Osiris Purchase Agreement, we also agreed to make certain milestone and royalty payments to Osiris pertaining to remestemcel-L for the treatment of aGVHD and Crohn's disease. Each milestone payment is for a fixed dollar amount and may be paid in cash or our ordinary shares or ADSs, at our option. The maximum amount of future milestone payments we may be required to make to Osiris is $40.0 million. Any ordinary shares or ADSs we issue as consideration for a milestone payment will be subject to a contractual one year holding period, which may be waived in our discretion. In the event that the price of our ordinary shares or ADSs decreases between the issue date and the expiration of any applicable holding period, we will be required to make an additional payment to Osiris equal to the reduction in the share price multiplied by the amount of issued shares under that milestone payment. This additional payment can be made either wholly in cash or 50% in cash and 50% in our ordinary shares, in our discretion. We have also agreed to pay varying earnout amounts as a percentage of annual net sales of acquired products, ranging from low single-digit to 10% of annual sales in excess of $750.0

million. These royalty payments will cease after the earlier of a ten year commercial sales period and the first sale of a competing product.

Tasly Pharmaceutical Group — Cardiovascular Alliance for China

In July 2018, we entered into a Development and Commercialization Agreement with Tasly.

The Development and Commercialization Agreement provides Tasly with exclusive rights to develop, manufacture and commercialize in China REVASCOR for the treatment or prevention of CHF and MPC-25-IC for the treatment or prevention of AMI. Tasly will fund all development, manufacturing and commercialization activities in China for REVASCOR and MPC-25-IC. On closing, we received a $20.0 million upfront technology access fee. Further, we will receive $25.0 million upon product regulatory approvals in China. Mesoblast will receive double-digit escalating royalties on net product sales. Mesoblast is eligible to receive six escalating milestone payments upon the product candidates reaching certain sales thresholds in China.

Tasly can terminate the Development and Commercialization Agreement with a specified amount of notice, on the later of (a) third anniversary of the agreement coming into effect and (b) receipt of marketing approval in China for each of REVASCOR or MPC-25-IC. Mesoblast has termination rights with respect to certain patent challenges by Tasly and if certain competing activities are undertaken by Tasly. Either party may terminate the agreement on material breach of the agreement if such breach is not cured within the specified cure period or if certain events related to bankruptcy of the other party occur.

TiGenix NV – patent license for treatment of fistulae

In December 2017, we entered into a Patent License Agreement with TiGenix, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived MSC product Alofisel®, previously known as Cx601, a product candidate of Takeda, 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, we received $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment and a further payment of $5.9 million (€5.0 million) before withholding tax 12 months after the patent license agreement date. We are entitled to further payments of up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

The agreement will continue in full force in each country (other than the United States) until the date upon which the last issued claim of any licensed patent covering Alofisel® expires in such country (currently expected to be 2029) or, with respect to the United States, until the later of (i) the date upon which the last issued claim of any licensed patent covering Alofisel® in the United States expires (currently expected to be around 2031) or (ii) the expiration of the regulatory exclusivity period in the United States with an agreed maximum term.

Either we or Takeda may terminate the agreement for any material breach that is not cured within 90 days after notice thereof. We also have the right to terminate the agreement, with a written notice in the event that Takeda file a petition in bankruptcy or insolvency or Takeda makes an assignment of substantially all of its assets for the benefit of its creditors.

Takeda have the right to terminate their obligation to pay royalties for net sales in a specific country if it is of the opinion that there is no issued claim of any licensed patent covering Alofisel® in such country, subject to referral of the matter to the joint oversight/cooperation committee established under the agreement if we disagree.

Competition

The biotechnology and pharmaceutical industries are highly competitive and are characterized by rapidly advancing technologies and a strong emphasis on proprietary products. Any product candidates that we and our collaborators successfully develop and commercialize will compete with existing products and new products that may become available in the future.

A number of our potential competitors, particularly large biopharmaceutical companies, have significantly greater financial resources and general expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our market has been characterized by significant consolidation by pharmaceutical and biotechnology companies, which is likely to result in even more resources being concentrated among a smaller number of our potential competitors.

Government Regulation

We are developing cellular therapy product candidates. These products are subject to extensive legislation. Governmental authorities around the world, including the FDA, are charged with the administration and enforcement of numerous laws and regulations that impact all aspects of the development, production, importing, testing, approval, labeling, promotion, advertising, and sale of products such as ours. Such governmental authorities are also charged with administering what is often a lengthy and technical review and approval process before candidate therapies such as ours may be marketed for any use. Authorization or approval for marketing must generally be obtained from the local health authorities in each country in which the product is to be sold. Approval and authorization procedures may differ from country to country, as may the requirements for maintaining approvals. It is typical however for these procedures to require evidence of rigorous testing and documentation regarding the candidate therapy, which may include significant non-clinical and clinical evaluations. Extensive controls and requirements apply to the non-clinical and clinical development of our therapeutic candidates. Those requirements and their enforcement and implementation by local regulatory authorities around the world significantly impact whether a product candidate can be developed into a marketable product, and notably impact the cost, resources and timing for any such development. Changes in regulatory requirements and differences in requirements from country to country may also increase the costs of bringing new technologies such as ours to market and maintaining approvals, if obtained.

To obtain marketing approval of a new product, an extensive dossier of evidence establishing the safety, efficacy and quality of the product must be submitted for review by regulatory authorities. Dossier form and substance, while often similar may have notable differences in different countries. Submission of an application to regulators does not guarantee approval to market that product, despite the fact that criteria for approval in many countries may be quite similar. Some regulatory authorities may require additional data and analyses, and may have standards that apply that are more stringent than others for review of the submitted dossier and content. Additionally, the review process, risk tolerance, and openness to new technologies may vary from country to country.

Obtaining marketing approval can take several months to several years, depending on the country, the quality of the data, the efficiencies and procedures of the reviewing regulatory authority and their familiarity with the product technology. Some countries, like the US, may have accelerated approval processes for certain categories of products, for example products which represent a breakthrough in the field, or which meet certain thresholds and have obtained certain designations of particular interest. Nevertheless, ultimate availability to patients may be affected, even post approval, by requirements in some countries to negotiate selling prices and reimbursement terms with government regulators or other payors.

Maintaining marketing approval may require the conduct of additional post-approval studies in some situations, and the continued capture, monitoring and assessment of safety and other information about the product, as well as adherence to requirements to ensure the purity and integrity of manufactured product. The process for obtaining and maintaining regulatory authorizations and approvals to market our products and the subsequent compliance with appropriate federal, state, local and foreign laws and regulations require the expenditure of substantial time and the commitment of significant financial and other resources, and we may not be able to obtain the required regulatory approvals.

Product Development Process

All of our product candidates are regulated as biological products by the Center for Biologics Evaluation and Research in the FDA. In the United States, biological products are subject to federal regulation under the federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service ("PHS") Act, and other federal, state, local and foreign statutes and regulations. Both the FDCA and the PHS Act, as applicable, and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, advertising and other promotional practices involving drugs and biological products. Before clinical testing of a new drug or biological product may commence, the sponsor of the clinical study must submit an application for investigational new drug ("IND") application to FDA, which must include, among other information, the proposed clinical study protocol(s). To obtain marketing authorization once clinical testing has concluded, a BLA must be submitted for FDA approval.

The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory studies, meaning in vivo and in vitro experiments in which an investigational product is studied prospectively in a test system under laboratory conditions to determine its safety, must be conducted according to cGLP (good laboratory practice) regulations, as well as, in the case of nonclinical laboratory studies involving animal test systems, in accordance with applicable requirements for the humane use of laboratory animals and other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical studies may begin;

- performance of adequate and well-controlled human clinical studies according to the FDA's cGCPs (good clinical practices) and all other applicable regulatory requirements for the protection of human research subjects and their health information, to establish the safety, purity and potency of the proposed product for its intended use and to ensure the product has an appropriate risk-benefit profile;
- development and demonstration of a manufacturing process that can produce product of consistent and adequate quality;
- submission to the FDA of a BLA for marketing approval demonstrating the quality, safety, and efficacy of the product which must be supported by substantial evidence from adequate and well-controlled clinical investigations as well as demonstration of mode of action through non-clinical studies, evidence to support appropriate manufacturing capabilities and controls, and evidence of the stability of the product in the form it is intended to be provided;
- negotiation with FDA of proposed product labeling (and determination of appropriate risk mitigation strategies and programs, if any required), as well as participation in any required advisory committee proceedings;
- satisfactory completion of an FDA inspection of all manufacturing, testing and distribution facilities where the product is produced, tested or stored and distributed, to assess compliance with cGMP (good manufacturing practices) to assure that the facilities, methods and controls for production are adequate to preserve the product's identity, strength, purity and potency;
- potential FDA inspection of nonclinical facilities and likely inspection of select clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA.

Human testing of a biological product candidate is preceded by preclinical testing, including nonclinical laboratory studies in which the product candidate is studied prospectively in a test system under laboratory conditions to determine its safety. A test system may include any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study covered by the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a product candidate at any time during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence unless FDA removes the clinical hold and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical studies involve the administration of the product candidate to subjects under the supervision of qualified independent investigators, generally physicians or other qualified scientists and medical personnel who are not employed by or under the study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events, or AEs, should occur. Each new protocol and certain amendments to the protocol must be submitted to the FDA. Clinical studies must be conducted in accordance with the FDA's cGCP regulations and guidance, and monitored to ensure compliance with applicable regulatory requirements. These include the requirement that written informed consent is obtained from all subjects who participate in the study. Further, each clinical study must be reviewed and approved by an independent Institutional Review Board, or IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent document that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Throughout the study, certain information about certain serious adverse events must be reported to the IRB, in some cases on an expedited basis, and to FDA (as well as to regulators in other countries in which studies of the product are also being conducted).

Human clinical studies are typically conducted in three sequential phases that may in some cases overlap or be combined:

- ***Phase 1***. The product candidate is initially introduced into a small number of human subjects. In the case of cellular therapy products, the initial human testing is conducted in patients with the disease or condition targeted by the biological product candidate. Phase 1 studies are intended to determine the metabolism and pharmacologic actions (including adverse reactions), the side effects associated with increasing doses, immunogenicity, and, if possible, to gain early

evidence of effectiveness. The information obtained in Phase 1 should be sufficient to permit the design of well-controlled, scientifically valid Phase 2 studies.

- ***Phase 2***. Controlled clinical studies are conducted in a larger number of human subjects to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study. Phase 2 studies are intended to assess side effects and risks, and to examine exposure–response relationships, and to further explore pharmacologic actions and immunogenicity associated with the drug. These studies also provide helpful information for the design of phase 3 studies.
- ***Phase 3***. Assuming preliminary evidence suggesting effectiveness has been obtained in phase 2 (generally considered to be "proof of concept"), controlled studies are conducted in a larger group of subjects to gather additional information about effectiveness and safety in order to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. In some cases FDA may require a Phase 4 study to be performed as a condition of product approval. Sponsors also can voluntarily conduct Phase 4 studies to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up or in select populations. FDA regulations extend to all phases of clinical development, and apply to sponsors and investigators of clinical studies. FDA oversight includes inspection of the sites and investigators involved in conducting the studies.

Concurrent with clinical studies, companies usually complete additional animal studies, and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things; the sponsor must develop methods for testing the identity, purity and potency of the final biological product. All such testing and controls requires the application of significant human and financial resources.

Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical studies of a product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each BLA must be accompanied by a substantial user fee. PDUFA also imposes an annual product fee for biologics and an annual establishment fee on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Additionally, an application fee is not assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews the BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any marketing application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective, for its intended use, and has an acceptable purity

profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the application without a REMS, if required.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with IND study and cGCP requirements. To assure cGMP and cGCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the marketing application, it will issue a complete response letter describing specific deficiencies in the application identified by the FDA. Additionally, the complete response letter may recommend actions that the applicant might take to place the application in a condition for approval. Such recommended actions could include the conduct of additional studies. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-approval clinical studies, to further assess a product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to complete its review of 90% of standard BLAs within 10 months from filing and 90% of priority BLAs within six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the application sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and the commitment of substantial human and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Other post-approval requirements applicable to drug and biological products include reporting post marketing surveillance to continuously monitor the safety of the approved product. This is done through the collection of spontaneous reports of adverse events and side effects, the assessment of safety signals, if any, and prescription event monitoring, among other methods. FDA maintains a system of postmarketing surveillance because all possible side effects of a new drug may not be evident in preapproval studies, which involve only several hundred to several thousand patients. Through postmarketing surveillance and risk assessment programs, FDA and sponsors seek to identify adverse events that did not appear during the drug approval process. In addition, FDA monitors adverse events such as adverse reactions and poisonings. FDA may use this information for a variety of purposes to identify safety signals not previously identified with the product, to update drug labeling, and, on rare occasions, to reevaluate the approval or marketing decision with respect to a product.

In addition, post-approval regulatory requirements include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process,

the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of drug and biological products. The FDA will also conduct routine scheduled and unannounced inspections of drug production and control facilities and processes, using field investigators and analysts, to assure ongoing safety and effectiveness of approved marketed products. Inspections may be made in conjunction with regulators from other jurisdictions and in certain cases, inspection findings and observations may be made public or may impair our ability to use the inspected facility, or to continue to produce and market a product.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct- to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet and notably, social media. In addition, discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. Sanctions authorized under FDA's legal authorities could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Violations of the FDCA may serve as a basis for the refusal of, or exclusion from, government contracts, including federal reimbursement programs, as well as other adverse consequences including lawsuits and actions by state attorneys general. Any agency or judicial enforcement action could have a material adverse effect on us. Drug and biological product manufacturers and other entities involved in the manufacture and distribution of approved drug or biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to a manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a new drug application, or NDA, or BLA plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Under the Hatch-Waxman Amendments, a drug product containing a new chemical entity as its active ingredient is entitled to five years of market exclusivity, and a product for which the sponsor is required to generate new clinical data is entitled to three years of market exclusivity. A drug or biological product can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical

results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A new biologic is granted 12 years of exclusivity from the time of first licensure during which a biosimilar may not be launched.

Government Regulation Outside of the U.S.

European Union Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. In particular, we view the EU and Japan as important jurisdictions for our business.

For purposes of developing our products, we must obtain the requisite approvals from regulatory authorities in each country prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the EU, for example, a clinical trial application ("CTA"), must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The EU has two main procedures for obtaining marketing authorizations in the EU Member States: a centralized procedure or national authorization procedure, under the latter of which one can seek go through the mutual recognition procedure or the decentralized procedure. All biotechnology products are assessed through the centralized procedure.

Under the centralized authorization procedure, sponsors submit a single marketing-authorization application to the EMA. This allows the marketing-authorization holder to market the product and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization. EMA's Committee for Medicinal products for Human Use ("CHMP") carries out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not. Once granted by the EMA, the centralized marketing authorization is valid in all EU Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for biotechnology products.

Any product candidates we seek to commercialize in the EU are subject to review and approval by the European Medicines Authority ("EMA"). Submissions for marketing authorization to the EMA must be received and validated by that body which appoints a Rapporteur and Co-Rapporteur to review it. The entire review process must be completed within 210 days, with a "clock-stop" at day 120 to allow the submitting company to respond to questions set forth in the Rapporteur and Co-Rapporteur's assessment report. Once the company responds in full, the clock for review re-starts on day 121. If further clarification is needed, the EMA may request an Oral Explanation on day 180, and the company submitting the application must appear before the CHMP to provide the requested information. On day 210, the CHMP will vote to recommend for or against the approval of the application. The final decision of EMA for marketing authorization following a positive CHMP recommendation is typically made within 60 days, with a draft decision within 15 days of the CHMP recommendation.

After Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMA (if approval was granted under the Centralized Procedure) or to the National Health Authorities (if approval was granted under the DCP or the MRP). In addition, pharmacovigilance measures must be implemented and monitored to ensure appropriate adverse event collection, evaluation and expedited reporting, as well as timely updates to any applicable risk management plans. For some medications, post approval studies may be required to complement available data with additional data to evaluate long term effects or to gather additional efficacy data.

European marketing authorizations have an initial duration of five years. After this time, the marketing authorization may be renewed by the competent authority on the basis of re-evaluation of the risk/benefit balance. Any marketing authorization which is not followed within three years of its granting by the actual placing on the market of the corresponding medicinal product ceases to be valid.

EU Exclusivity Periods

To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the U.S. is similar to that required in the EU, with the exception of, among other things, country-specific document requirements. The EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

In addition to law and regulation specific to drug development, we note that new data protection regulations that have gone into effect in Europe are likely to have a significant impact on our activities, personnel, and may have an impact on our ability to timely complete clinical trials and effectively develop and commercialize our product candidates. The General Data Protection Regulation (the "GDPR") was approved and adopted by the EU Parliament in April 2016 and went into effect on May 25, 2018. Unlike a Directive, the GDPR does not require any enabling legislation to be passed by any government. The GDPR not only applies to organizations located within the EU but may also apply to organizations located outside of the EU if they offer goods or services to, or monitor the behavior of, EU data subjects or if they process the personal data of subjects residing in the European Union. The implications of this regulation are therefore far reaching and may impose significant burdens on the Company and its processes and systems. Additionally, the UK government has implemented a Data Protection Bill, which also went into effect on May 25, 2018, that substantially implements the GDPR. For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, coverage, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with cGCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government programs such as Medicare or Medicaid, managed care plans, private health insurers, and other organizations. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors may attempt to control costs by limiting coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication, and by limiting the amount of reimbursement for particular procedures or drug treatments. In addition, in the United States, participation in government health programs such as Medicare and Medicaid are subject to complex rules and controls relating to price reporting and calculation of prices to ensure that pricing provided to government entities for periodic reporting purposes is aligned and compliant with numerous complex statutory requirements. The infrastructure and/or external resources necessary to ensure continued compliance with these requirements is extensive and manufacturers are subject to audit both by the Centers for Medicare and Medicaid Services and by State Medicaid authorities.

The cost of pharmaceuticals and devices continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that the third-party payors reimbursement policies will not adversely affect our ability to sell our product profitably.

Healthcare Reform

In the U.S. and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The Medicare Modernization Act expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a negative effect on our expenses and profitability in the future. Furthermore, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Sequestration cuts went into effect on April 1, 2013, and the Bipartisan Budget Act of 2013 extended sequestration for Medicare for another two years, through 2023. A bill signed by President Obama on February 15, 2014, further extended these cuts for an additional year, through fiscal year 2024. On January 21, 2014, President Obama signed the fiscal year 2014 omnibus appropriations bill, modifying for fiscal year 2014 and fiscal year 2015 the cuts that went into effect under the sequester on March 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

The current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical industry as a whole is currently unknown. But, any changes to the ACA are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

While the status of the ACA under the current administration remains in question, it is possible that healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, and formulary restrictions among private payors including the largest pharmacy benefit managers have increased over recent months, especially as regards to new and high cost market entrants. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In addition, different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may be marketed only once a reimbursement price has been agreed upon. Some of these countries may require, as condition of obtaining reimbursement or pricing approval, the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross- border imports from low-priced markets exert a commercial pressure on pricing within a country.

Other Healthcare Laws and Compliance Requirements

In the U.S., the research, manufacturing, distribution, sale and promotion of drug products, including biologics, and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, divisions of the U.S. Department of Health and Human Services, including the Office of Inspector General and the Centers for Medicare and Medicaid Services, the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with fraud and abuse laws such as the federal Anti-Kickback Statute, as amended, the federal False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on

the other. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Even the award of grant moneys, or the provision of in kind support, publicity and even authorship, in certain cases, may be deemed to be "remuneration." Although there are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exception and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the recently enacted ACA, so that the government need no longer prove, for purposes of establishing intent under the federal Anti-Kickback Statute, that a person or entity had actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below). Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to the referral of patients for healthcare items or services reimbursed by any third-party payor, including private payors. In at least some cases, these state laws do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government and share in any recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's label), and allegations as to misrepresentations with respect to the services rendered.

Substantial resources have been allocated by both the Department of Justice and the Federal Bureau of Investigation, among other branches of the US government to identify and investigate possible health care fraud activities. Recent investigations include those relating to allegedly egregious price increases by manufacturers and alleged fraud involving co-pay arrangements supported by sponsors. As new theories of liability arise, there is a corresponding cost of doing business in order to maintain compliance.

Our future activities relating to the reporting of discount and rebate information and other information affecting federal, provincial, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created several new federal crimes including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud provision of HIPAA prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements provision prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

There are also an increasing number of state "sunshine" laws that require manufacturers to make reports to states on pricing and marketing information, as well as regarding payments to healthcare professionals. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make

periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit certain other sales and marketing practices. State laws are not harmonized and contain different reporting requirements and restrictions which must be noted and adhered to. We currently do not report under these state laws, but will be required to do if we are successful in obtaining marketing authorization for our products. We will need to develop the infrastructure or rely on third party contractors to assist us in our compliance with these laws, and failure to comply may result in financial and other penalties and consequences. In addition, beginning in 2013, a similar "sunshine" federal requirement began requiring manufacturers to track and report to the federal government certain payments and other transfers of value made to certain covered recipients, including physicians and other healthcare professionals, and teaching hospitals. In addition to payments, reporting may encompass requirements to report on ownership or investment interests held by physicians and their immediate family members. The efforts and resources needed to track and report payments go well beyond our affiliates operating in the United States, as reporting is required also for payments made by affiliated entities in many cases to US covered recipients. In other jurisdictions (eg, Australia, Japan and Europe) similar "sunshine-like" laws have also been adopted, which may require disclosure of certain payment and other information to covered recipients. Extensive administration and systems, including to aggregate and categorize spend, are necessary in order to enable compliant and timely reporting under these requirements. The US federal government began disclosing the reported information on a publicly available website in 2014. These laws may affect our development, sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise fail to comply with these laws, we could be subject to the penalty and sanctions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of premarketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-approval requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Australian Disclosure Requirements

Business Strategies and Prospects for Future Years

We are focused on the following core strategic imperatives:

- continue to innovate and optimize our disruptive technology platform for cell-based therapeutics;
- develop a portfolio of clinically distinct products;
- focus on bringing late-stage products to market and portfolio prioritization;
- enabling manufacturing scale-up to meet demands of the portfolio;
- leverage talent base to continue to establish a culture of shared leadership and accountability;
- focus on strategic partnerships;
- focus on prudent cash management; and
- continue to strengthen our substantial and robust intellectual property estate.

Dividends

No dividends were paid during the course of the fiscal year ended June 30, 2020. There are no dividends or distributions recommended or declared for payment to members, but not yet paid, during the year.

4.C Organizational Structure

See "Item 4. Information on the Company – 4.B Business Overview – Overview", "Item 18. Financial Statements – Note 12" and Exhibit 8.1 to this Annual Report.

4.D Property, Plants and Equipment

We lease approximately 11,150 square feet of office space in Melbourne, Australia, where our headquarters are located. We pay approximately A$834,000 per year for this lease, which expires in April 2026. We also lease approximately 15,600 square feet in New York City, where significant development and commercial activities are conducted. We pay $1,073,000 per year for this lease, which expires in May 2021. We also lease laboratory and office space in Singapore. We pay approximately S$267,000 per year for this lease, which expires in August 2022. We also lease laboratory and office space in Texas and pay approximately $202,000 per year for this lease, which expires in May 2022. All of our manufacturing operations are currently located at Lonza's manufacturing facilities. See "Item 4.B Business Overview – Manufacturing and Supply Chain."

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

5.A Operating Results

This operating and financial review should be read together with our consolidated financial statements in this Annual Report, which have been prepared in accordance with IFRS as published by the IASB.

Financial Overview

We have incurred significant losses since our inception. We have incurred net losses during most of our fiscal periods since our inception. For the year ended June 30, 2020, we had an accumulated deficit of $548.8 million. Our net loss for the year ended June 30, 2020 was $77.9 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;
- seek to identify, assess, acquire, and/or develop other product candidates and technologies;
- 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 expect our management and administration expenses to remain relatively consistent over the next 12 months. We expect our research and development expenditure to increase as we seek to expand the market opportunity for our late stage clinical products, however if we are able to successfully partner one or more of our late stage clinical products, our research and development expenditure may decrease. Subject to us achieving successful regulatory approval, we expect an increase in our total expenses driven by an increase in our product manufacturing and selling, general and administrative expenses as we move towards commercialization. Therefore, 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. We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our 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 up-front, 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 balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified within non-current liabilities.

In the year ended June 30, 2020, we recognized $6.6 million in commercialization revenue relating to royalty income earned on sales of TEMCELL® Hs. Inj., a registered trademark of JCR Pharmaceuticals Co. Ltd. (“TEMCELL”), in Japan by our licensee, JCR Pharmaceuticals Co. Ltd. (“JCR”), compared with $5.0 million for the year ended June 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2020, we recognized $15.0 million in milestone revenue for the up-front fee received in October 2019 in relation to our strategic partnership with Grünenthal for the development and commercialization in Europe and Latin America of our Phase 3 allogeneic MPC product, MPC-06-ID for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Upon signing of this strategic partnership agreement on September 9, 2019, we recognized revenue of $15.0 million in the year ended June 30, 2020 for the up-front fee receivable from Grünenthal as the performance obligation in regard to this milestone had been satisfied as the right of use license of IP had been transferred to Grünenthal upon signing of the contract. There was no milestone revenue recognized in relation to this strategic partnership with Grünenthal in the year ended June 30, 2019.

In the years ended June 30, 2020 and 2019, we recognized $10.0 million in milestone revenue in each respective period from the $20.0 million up-front payment received in October 2018 in relation to our strategic alliance with Tasly Pharmaceutical Group (“Tasly”) for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. Tasly has received exclusive rights to, and will fund all development, manufacturing and commercialization activities in China for MPC-150-IM and MPC-25-IC. In the year ended June 30, 2019, upon completion of this strategic alliance in September 2018, we recognized revenue of $10.0 million for the up-front technology access fee receivable from Tasly as this is the portion of revenue that control had been transferred to Tasly. In the year ended June 30, 2020, we recognized the remaining $10.0 million of the up-front technology access fee received as the control for this portion of revenue was transferred to Tasly during this period.

In the year ended June 30, 2019, we also recognized $1.0 million in milestone revenue upon our licensee JCR achieving a sales milestone on cumulative net sales of TEMCELL in Japan. This amount was recorded in revenue as there were no further performance obligations required in regard to this milestone. There was no milestone revenue recognized in the year ended June 30, 2020 in relation to the JCR partnership.

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

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 of 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 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
- provision for the carrying value of pre-launch inventory costs on the balance sheet.

Management and Administration. Management and administration expenses consist primarily of salaries and related costs including share-based incentives for employees in executive, corporate and administrative functions. 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 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 probability of success, market penetration, developmental timelines, product pricing, and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration. As the net result of changes to the key assumptions and the time period shortening, we recognized net remeasurement gain of $1.3 million and a net remeasurement loss of $6.3 million for the years ended June 30, 2020 and 2019, respectively.

Other Operating Income and Expenses. Other operating income and expenses primarily comprise remeasurement of borrowing arrangements and foreign exchange gains and losses.

Remeasurement of borrowing arrangements pertains to our loan and security agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest"). Remeasurement of borrowing arrangements is recognized when changes in our estimated net sales trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. In the year ended June 30, 2020, we recognized a remeasurement loss of $0.8 million as a net result of changes

to the key assumptions in product pricing, rebates, development timelines and market penetration. In the year ended June 30, 2019, we recognized a remeasurement loss of $0.7 million as a net result of changes to the key assumptions in development timelines and market penetration.

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. We recognized a foreign exchange gain of $0.2 million in the year ended June 30, 2020 and a foreign exchange loss of $0.2 million in the year ended June 30, 2019.

Finance Costs. Finance costs consist 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 pertains to our loan and security agreements with Hercules Capital, Inc. ("Hercules") and NovaQuest. Remeasurement of borrowing arrangements is recognized 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. In the years ended June 30, 2020 and 2019, we recognized remeasurement gains of $1.3 million and $0.4 million in relation to our existing credit facility with Hercules and a remeasurement gain of $0.1 million and $Nil in relation to our existing credit facility with NovaQuest, respectively.

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. We recognized a non-cash income tax benefit of $9.4 million in the year ended June 30, 2020 and $9.0 million in the year ended June 30, 2019.

Results of Operations

Comparison of Our Results for the Year ended June 30, 2020 with the Year ended June 30, 2019

The following table summarizes our results of operations for the years ended June 30, 2020 and 2019, 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 June 30, 2020	2019	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 6,614	$ 5,003	1,611	32%
Milestone revenue	25,000	11,000	14,000	127%
Interest revenue	542	719	(177)	(25%)
Total revenue	**32,156**	**16,722**	**15,434**	**92%**
Research & development	(56,188)	(59,815)	3,627	(6%)
Manufacturing commercialization	(25,309)	(15,358)	(9,951)	65%
Management and administration	(25,609)	(21,625)	(3,984)	18%
Fair value remeasurement of contingent consideration	1,380	(6,264)	7,644	(122%)
Other operating income and expenses	(455)	(1,086)	631	(58%)
Finance costs	(13,330)	(11,328)	(2,002)	18%
Loss before income tax	**(87,355)**	**(98,754)**	**11,399**	**(12%)**
Income tax benefit	9,415	8,955	460	5%
Loss attributable to the owners of Mesoblast Limited	**$ (77,940)**	**$ (89,799)**	**11,859**	**(13%)**

Losses per share from continuing operations attributable to the ordinary equity holders:	Cents	Cents	Cents	% Change
Basic - losses per share	(14.74)	(18.16)	3.43	(19%)
Diluted - losses per share	(14.74)	(18.16)	3.43	(19%)

Revenue

Revenues were $32.1 million for the year ended June 30, 2020, compared with $16.7 million for the year ended June 30, 2019, an increase of $15.4 million. The following table shows the movement within revenue for the years ended June 30, 2020 and 2019, together with the changes in those items.

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Revenue:				
Milestone revenue	25,000	11,000	14,000	127%
Commercialization revenue	6,614	5,003	1,611	32%
Interest revenue	542	719	(177)	(25%)
Revenue	**$ 32,156**	**$ 16,722**	**15,434**	**92%**

Milestone revenue was $25.0 million in the year ended June 30, 2020, an increase of $14.0 million as compared with $11.0 million in the year ended June 30, 2019. This $14.0 million increase in the year ended June 30, 2020 is due to the recognition of $15.0 million in milestone revenue for the up-front fee received in October 2019 upon completion of the strategic partnership with Grünenthal for the development and commercialization in Europe and Latin America of our Phase 3 allogeneic MPC product, MPC-06-ID on September 9, 2019. There was no milestone revenue recognized in relation to the strategic partnership with Grünenthal in the year ended June 30, 2019. Additionally, in the years ended June 30, 2020 and 2019, we recognized $10.0 million in milestone revenue in each respective period from the $20.0 million up-front payment received in October 2018 in relation to our strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. We also recognized $1.0 million in milestone revenue during the year ended June 30, 2019, upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan whereas no milestone revenue was recognized in the year ended June 30, 2020.

Commercialization revenue from royalty income earned on sales of TEMCELL in Japan by our licensee JCR was $6.6 million in the year ended June 30, 2020, an increase of $1.6 million (32%) as compared with $5.0 million in the year ended June 30, 2019.

The $0.2 million decrease in interest revenue for the year ended June 30, 2020 compared with the year ended June 30, 2019 was primarily driven by lower interest rates on US$ cash deposits in the year ended June 30, 2020, when compared with the year ended June 30, 2019.

Research and development

Research and development expenses were $56.2 million for the year ended June 30, 2020, compared with $59.8 million for the year ended June 30, 2019, a decrease of $3.6 million. The $3.6 million decrease in research and development expenses primarily reflects a decrease in third party costs partially offset by an increase in product support costs for research and development and pre-commercial functions as we prepare for the potential launch of RYONCIL in the United States.

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Research and development:				
Third party costs	26,912	38,365	(11,453)	(30%)
Product support costs	24,995	17,002	7,993	47%
Intellectual property support costs	2,826	2,993	(167)	(6%)
Amortization of current marketed products	1,455	1,455	—	0%
Research and development	**$ 56,188**	**$ 59,815**	**(3,627)**	**(6%)**

Third party costs, which consist of all external expenditure on our research and development programs, decreased by $11.4 million in the year ended June 30, 2020 compared with the year ended June 30, 2019.

This $11.4 million decrease in third party costs was due to a reduction in our third party costs for our Phase 3 clinical trials. In the year ended June 30, 2020, our Phase 3 clinical trials for MPC-150-IM (CHF), MPC-06-ID (CLBP) and remestemcel-L (for pediatric SR-aGVHD) enrollment was complete and costs were being incurred as patients were monitored during follow up visits and other testing was completed, whereas in the year ended June 30, 2019, these clinical trials were enrolling patients and resulting in increased activities and costs. In the year ended June 30, 2020, we incurred costs associated with clinical enrollment for our Phase 3 clinical trial for the treatment of moderate to severe acute respiratory distress syndrome (“ARDS”) in COVID-19 patients as we

commenced this trial in April 2020. In the year ended June 30, 2020, we also incurred costs of $2.0m associated with our pre-commercial activities as we prepare for the potential 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 $8.0 million, for the year ended June 30, 2020 compared with the year ended June 30, 2019.

Within this $8.0 million increase in product support costs is an increase of $5.0 million in for personnel in research and development functions the year ended June 30, 2020 is primarily due to an increase of $2.4 million across salaries and associated costs as full time equivalents increased by 5.1 (11%) from 46.1 for the year ended June 30, 2019 to 51.2 for the year ended June 30, 2020. There was also an increase of $0.6 million in recruitment expenses, $1.3 million in consulting expenses and $0.9 million in share-based payment expenses and a reduction in travel expenses of $0.2 million for the year ended June 30, 2020 compared with the year ended June 30, 2019.

Within this $8.0 million increase in product support costs is an increase of $3.0 million in for personnel in pre-commercial functions the year ended June 30, 2020 is primarily due to an increase of $2.3 million across salaries and associated costs as full time equivalents increased by 6.6 (660%) from 1.0 for the year ended June 30, 2019 to 7.6 for the year ended June 30, 2020 as we prepare for the potential launch of RYONCIL in the United States. There was also an increase of $0.3 million in recruitment expenses, $0.3 million in share-based payment expenses and $0.1 million in travel expenses for the year ended June 30, 2020 compared with the year ended June 30, 2019.

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 all costs of renewing our granted patents. These costs have decreased by $0.2 million in the year ended June 30, 2020 compared with the year ended June 30, 2019 due to decreased activities across our entire patent portfolio.

Manufacturing commercialization

Manufacturing commercialization expenses were $25.3 million for the year ended June 30, 2020, compared with $15.4 million for the year ended June 30, 2019, an increase of $9.9 million. This increase primarily reflects an increase in platform technology costs.

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Manufacturing commercialization:				
Platform technology	23,342	13,508	9,834	73%
Manufacturing support costs	1,967	1,850	117	6%
Manufacturing commercialization	**$ 25,309**	**$ 15,358**	**9,951**	**65%**

Platform technology costs, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC and MSC based products, increased by $9.8 million for the year ended June 30, 2020 compared with year ended June 30, 2019. The increase was primarily due to increased spend for stock build in preparation for the potential launch of RYONCIL and for the increased spend on manufacturing of clinical supply for our COVID-19 ARDS Phase 3 clinical trial which commenced in April 2020, offset by process validation activities required ahead of the BLA filing of RYONCIL winding down as they reach completion in the year ended June 30, 2020.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, increased by $0.1 million for the year ended June 30, 2020 compared with the year ended June 30, 2019 due to an increase in share-based payment expenses.

Management and administration

Management and administration expenses were $25.6 million for the year ended June 30, 2020, compared with $21.6 million for the year ended June 30, 2019, an increase of $4.0 million. This increase was primarily due to an increase in labor and associated expenses.

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Management and administration:				
Labor and associated expenses	13,409	9,953	3,456	35%
Corporate overheads	8,891	8,107	784	10%
Legal and professional fees	3,309	3,565	(256)	(7%)
Management and administration	**$ 25,609**	**$ 21,625**	**3,984**	**18%**

Labor and associated expenses increased by $3.5 million from $9.9 million for the year ended June 30, 2019 to $13.4 million for the year ended June 30, 2020. This $3.5 million increase is primarily due to an increase in overall costs of salaries and associated expenses by $0.7 million in the year ended June 30, 2020 compared with the year ended June 30, 2019 due to one-off restructuring costs and full time equivalents increasing by 1.2 (5%) from 25.7 for the year ended June 30, 2019 to 26.9 for the year ended June 30, 2020. There was also an increase of $1.9 million in share-based payment expenses, $1.0 million across consulting and recruitment expenses and $0.2 million in short-term incentives for the year ended June 30, 2020 compared with the year ended June 30, 2019. Labor and associated expenses also experienced favorable exchange rate fluctuations of $0.3 million in the year ended June 30, 2020 compared with the year ended June 30, 2019, as the A$ weakened against the US$ given the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

Corporate overhead expenses increased by $0.8 million from $8.1 million for the year ended June 30, 2019 to $8.9 million for the year ended June 30, 2020 due to an increase in insurance premiums and information technology support services.

Legal and professional fees decreased by $0.3 million from $3.6 million for the year ended June 30, 2019 to $3.3 million for the year ended June 30, 2020 as legal activities decreased in the period.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $1.3 million gain for the year ended June 30, 2020 compared with a $6.3 million loss for the year ended June 30, 2019. The $1.3 million gain for the year ended June 30, 2020 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain was a net result of changes to the key assumptions of the contingent consideration valuation such as development timelines, 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.

The $6.3 million loss for the year ended June 30, 2019 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss was a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, development timelines, product pricing 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.

Other operating income and expenses

In other operating income and expenses, we recognized an expense of $0.5 million for the year ended June 30, 2020, compared with $1.1 million in expenses for the year ended June 30, 2019, a decrease in expense of $0.6 million. The following table shows movements within other operating income and expenses for the years ended June 30, 2020 and 2019, together with the changes in those items:

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Other operating income and expenses:				
Remeasurement of borrowing arrangements	779	752	27	4%
Foreign exchange losses/(gains) (net)	(246)	208	(454)	NM
Government grant revenue	(78)	—	(78)	NM
Foreign withholding tax	—	52	(52)	(100%)
Research and development tax incentive income	—	74	(74)	(100%)
Other operating income and expenses	**$ 455**	**$ 1,086**	**(631)**	**(58%)**

* NM = not meaningful.

In the year ended June 30, 2020, we recognized a $0.8 million loss in relation to the adjustment of the carrying amount of our financial liability to reflect the revised future cash flows as a net result of changes to the key assumption in product pricing, rebates, development timelines and market penetration in relation to our existing credit facility with NovaQuest.

In the year ended June 30, 2019, we recognized a $0.7 million loss in relation to the adjustment of the carrying amount of our financial liability to reflect the revised future cash flows as a net result of changes to the key assumption in development timelines and market penetration in relation to our existing credit facility with NovaQuest.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors. In the year ended June 30, 2019 we recognized a foreign exchange loss of $0.2 million. In the year ended June 30, 2020, we recognized a foreign exchange gain of $0.2 million, primarily due to movements in exchange rates on US$ receivables held in Mesoblast Limited as the A$ depreciated against the US$ during the period the US$ receivables were held.

Foreign withholding tax decreased by $0.1 million from $0.1 million for the year ended June 30, 2019 to $Nil for the year ended June 30, 2020.

We recorded a $0.1 million loss in research and development tax incentive income for the year ended June 30, 2019 in relation to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2018. There was no research and development tax incentive income recognized in the year ended June 30, 2020.

Finance costs

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Finance costs:				
Remeasurement of borrowing arrangements	(1,386)	(376)	(1,010)	NM
Interest expense	14,716	11,704	3,012	26%
Finance costs	**$ 13,330**	**$ 11,328**	**2,002**	**18%**

* NM = not meaningful.

In the year ended June 30, 2020, we recognized a $1.4 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 from our existing credit facilities with Hercules and NovaQuest, an increase of $1.0 million as compared with $0.4 million for the year ended June 30, 2019.

Interest expenses increased by $3.0 million from $11.7 million for the year ended June 30, 2019 to $14.7 million for the year ended June 30, 2020.

In the year ended June 30, 2020, we recognized $7.9 million of interest expenses in relation to our loan and security agreement with Hercules, an increase of $1.5 million as compared with $6.4 million for the year ended June 30, 2019. Within this $7.9 million recognized in the year ended June 30, 2020, $5.0 million was recognized with regard to interest expense payable on the loan balance within the year and a further $2.9 million of interest expense was recognized with regard to the amortization of transaction costs incurred on the outstanding loan principal using the effective interest rate method over the period of initial recognition through maturity.

In the year ended June 30, 2020, we recognized $6.3 million of interest expenses in relation to our loan and security agreement with NovaQuest, an increase of $1.0 million as compared with $5.3 million for the year ended June 30, 2019. Interest expenses relating to the NovaQuest loan are accrued on the loan principal balance until paid and all interest payments will be deferred until after the first commercial sale of our allogeneic product candidate RYONCIL for pediatric SR-aGVHD.

In the year ended June 30, 2020, in line with IFRS 16 *Leases*, we also recognized interest expenses of $0.5 million in relation to lease charges compared with $Nil in the year ended June 30, 2019.

Loss after income tax

(in U.S. dollars, in thousands)	Year ended June 30, 2020	2019	$ Change	% Change
Loss before income tax	(87,355)	(98,754)	11,399	(12%)
Income tax benefit	9,415	8,955	460	5%
Loss after income tax	**$ (77,940)**	**$ (89,799)**	**11,859**	**(13%)**

Loss before income tax was $87.4 million for the year ended June 30, 2020 compared with $98.8 million for the year ended June 30, 2019, a decrease in the loss by $11.4 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

A non-cash income tax benefit of $9.4 million was recognized in the year ended June 30, 2020, 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 $9.0 million was recognized in the year ended June 30, 2019 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

Comparison of Our Results for the Year ended June 30, 2019 with the Year ended June 30, 2018

For results of operations for the years ended June 30, 2019 and 2018, together with the changes in those items in dollars and as a percentage and the related discussions on these results, refer to Results of Operations within "Item 5.A Operating Results" in our annual report on Form 20-F for the year ended June 30, 2019, filed with the SEC on September 9, 2019.

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 U.S. GAAP. Our significant accounting policies are described in "Item 18 Financial Statements – Note 22".

Quantitative and Qualitative Disclosure about Market Risk

The following sections provide quantitative information on our exposure to interest rate risk, share 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 further assessment on our market risks, see "Item 18. Financial Statements – Note 10(a)."

Foreign currency exchange risk

We have foreign currency amounts owing primarily in our Australian based entity, whose functional currency is the A$, relating to clinical, regulatory and overhead activities. We also have foreign currency amounts in our Switzerland and Singapore based entities, whose functional currencies are the US$. 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 our financial performance.

We manage the currency risk by evaluating levels to hold in each currency by assessing our future activities which will likely be incurred in those currencies which enables us to minimize foreign currency deposits held in each entity.

Interest rate risk

Our main interest rate risk arises from the portion of our long-term borrowings with a floating interest rate, which exposes us to cash flow interest rate risk. As interest rates fluctuate, the amount of interest payable on financing where the interest rate is not fixed will also fluctuate. Interest rate risk can be managed by interest rate swaps, which can be entered into to convert the floating interest rate to a fixed interest rate as required. Additionally, we can repay the loan facility at our discretion and we can also refinance if we are able to achieve terms suitable to us in the marketplace or from our existing lenders.

Upon entering the agreement with Hercules, we completed a cost benefit analysis of entering an interest rate swap arrangement. We did not enter into any interest rate swaps during the year ended June 30, 2020.

We are also exposed to interest rate risk that arises through movements in interest income we earn on our deposits. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by periodically reviewing interest rates available for suitable interest bearing accounts to ensure we earn interest at market rates. We ensure that sufficient funds are available, in at call accounts, to meet our working capital requirements.

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. We are exposed to price risk which arises from long-term borrowings under our facility with NovaQuest, where the timing and amount 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 Income Statement as remeasurement of borrowing arrangements within other operating income and expenses in the period the revision is made.

We are 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.

We do not consider any exposure to price risk other than those already described above.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with IFRS. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in our consolidated financial statements included in the annual report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We adopted IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018, using the modified retrospective approach. Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by the standard.

First, contracts with customers within the scope of IFRS 15 are identified. Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration we expect to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

There was no cumulative impact of the adoption of IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018.

Revenues from contracts with customers comprise commercialization and milestone revenue. We also have revenue from research and development tax incentives and interest revenue.

Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent upon the achievement of 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 revenue or deferred consideration in our consolidated balance sheets, depending on the nature of arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified within non-current liabilities.

Milestone revenue

We apply the five-step method under the standard to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration. We estimate the transaction price of the contingent milestone using the most likely amount method. We include in the transaction price some or all of the amount of the contingent milestone only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations.

When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of IP (such as cumulative net sales targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Licenses of intellectual property

When licenses of IP are distinct from other goods or services promised in the contract, we recognize the transaction price allocated to the license as revenue upon transfer of control of the license to the customer. We evaluate all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a "right to access" license. This is when we undertake activities that significantly affect the IP to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of our activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a "right to use" license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

Sales-based or usage-based royalties

Licenses of IP can include royalties that are based on the customer's usage of the IP or sale of products that contain the IP. We apply the specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based or usage-based royalties promised in a license of IP. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Grünenthal arrangement

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

We received a non-refundable upfront payment of $15.0 million in October 2019, on signing of the contract with Grünenthal. We 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. We may receive up to an additional $132.50 million in payments if certain milestones are satisfied in relation to clinical, manufacturing, regulatory and reimbursement approval prior to product launch. We are further entitled to receive milestones payments based on regulatory and cumulative product sales milestones, as well as tiered double-digit royalties on product sales.

The strategic partnership with Grünenthal includes a license of IP and the provision of development services. Under IFRS 15 *Revenue from contracts with customers*, we have identified three distinct performance obligations in the strategic partnership with Grünenthal. The three performance obligations identified are the right of use license of IP, research & development and chemistry, manufacturing and controls ("R&D and CMC") services and other development services. The license of IP was considered distinct from the development services as it is capable of being granted separately and the development services do not significantly modify or customize the license nor are the license and development services significantly interrelated or interdependent. We also evaluated the promises in the development services and determined the R&D and CMC services were distinct from the other development services as they are not significantly interrelated or interdependent.

The standalone selling price for each performance obligation is not directly observable, so we have estimated the standalone selling price through the most appropriate methods to ensure the estimate represents the price we would charge for the goods or services if they were sold separately. We have considered the application and results of a combination of methods and utilized the cost plus a margin approach as the primary method. For R&D and CMC services, we estimated the standalone selling price to be $85.0 million. For the other development services we estimated the standalone selling price to be $10.0 million. Significant judgement was applied in determining the standalone selling price and the variable consideration that was allocated to each performance obligation. Based on this analysis, the $15.0 million upfront payment was allocated to the license of IP performance obligation. Upon signing of this strategic partnership in September 2019, we recognized $15.0 million in revenue for the right of use license of IP as this performance obligation was considered completely satisfied at this date.

We evaluated the constraint over the remaining variable consideration under the contract and determined that all of the milestone payments relating to the R&D and CMC services and other development services were considered constrained as at June 30, 2020. As part of this evaluation, we considered a variety of factors, including whether the receipt of the milestone payments is outside of our control or contingent on the outcome of clinical trials and the impact of certain repayment clauses. We will continue to evaluate the constraint over variable consideration in future periods. Additionally, we apply the sales-based and usage-based royalty exception for licenses of intellectual property and therefore will recognize royalties and sales-based milestone payments as revenue when the subsequent sale or usage occurs.

The $2.5 million milestone payment received in December 2019 from Grünenthal was considered constrained and resulted in deferred consideration as of June 30, 2020. In future periods, additional milestone payments from Grünenthal may result in deferred consideration as revenue recognition of R&D and CMC services and other development services will be dependent upon the assessment of the constraint over variable consideration as well as the percentage of progress towards meeting the development service performance obligations over time.

There was no milestone revenue recognized in relation to this strategic partnership with Grünenthal in the year ended June 30, 2019.

Tasly arrangement

In July 2018, we entered into a strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. Tasly received exclusive rights for MPC-150-IM and MPC-25-IC in China and Tasly will fund all development, manufacturing and commercialization activities in China.

We received a $20.0 million up-front technology access fee from Tasly upon closing of this strategic alliance in October 2018. We are 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.

Under IFRS 15, upon completion of this strategic alliance in September 2018, we recognized $10.0 million in milestone revenue from the $20.0 million up-front technology access fee received in October 2018 as this was the portion of revenue that control was transferred to Tasly and the remaining $10.0 million from the $20.0 million up-front payment was recognized as deferred consideration on our consolidated balance sheet. In the year ended June 30, 2020, the deferred consideration amount was recognized in revenue as the control for this portion of revenue was transferred to Tasly based on our decision regarding the exercise of our rights in the terms and conditions of the agreement.

TiGenix arrangement

In December 2017, we entered into a patent license agreement with TiGenix, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived 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. We are entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we will receive single digit royalties on net sales of Alofisel®.

In the year ended June 30, 2020, we commenced earning royalty income on sales of Alofisel® in Europe by our licensee Takeda. To date, royalty income earned on sales of Alofisel® in Europe by our licensee Takeda has not been significant.

JCR arrangement

In October 2013, we acquired all of Osiris' culture-expanded, MSC-based assets. 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 we are 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 we assumed from Osiris, 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, we are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. 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, we are entitled to a double digit profit share. We 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 hypoxic ischemic encephalopathy ("HIE"), a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. We will receive royalties on TEMCELL product sales for EB and HIE, if and when JCR begins selling TEMCELL for such indications in Japan. We apply the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognize royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the year ended June 30, 2020, we recognized $6.6 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $5.0 million for the year ended June 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2019, we recognized $1.0 million in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan. This amount was recorded in revenue as there are were no further performance obligations required in regard to this items. There was no milestone revenue recognized in year ended June 30, 2020.

Goodwill

We have recognized goodwill as a result of two separate acquisitions. Goodwill of $118.4 million was recognized on acquisition of Angioblast Systems Inc. in 2010, $13.9 million was recognized on the acquisition of the MSC assets from Osiris ("MSC business combination") in 2013 and $2.1 million was recognized on finalization of the MSC business combination of Osiris in 2015. In all cases the goodwill recognized represented excess in the purchase price over the net identifiable assets and in-process research and development acquired in the transaction. We have a single operating unit and all goodwill has been allocated to that unit.

The goodwill resulting from these acquisitions is tested for impairment in accordance with IAS 36 *Impairment of Assets* which requires testing be performed at any time during an annual period, provided the test is performed at the same time every year. We test for impairment annually in the third quarter of each year. A full assessment was performed at March 31, 2020 and no impairment of goodwill was identified. Additionally, assets must be tested for impairment if there is an indication that an asset may be impaired. The recoverable amounts of our assets and cash-generating units have been determined based on fair value less costs to sell calculations, which require the use of certain assumptions. See Note 6 of our consolidated financial statements and the related note thereto included in our 20-F for more information regarding the assumptions used in determining the fair value less costs to sell.

In-process research and development

IFRS requires that acquired in-process research and development be measured at fair value and carried as an indefinite life intangible asset subject to impairment reviews. We have recognized in-process research and development as a result of two separate acquisitions. In-process research and development of $387.0 million was recognized on the acquisition of Angioblast Systems Inc. in 2010 and $126.7 million was recognized on the acquisition of assets from Osiris in 2013 and $24.0 million was reclassified to current marketed products upon the TEMCELL asset becoming available for use in Japan. In 2016, we fully impaired $61.9 million of in-process research and development relating to our product candidates, MPC-MICRO-IO for the treatment of age-related macular degeneration and MPC-CBE for the expansion of hematopoietic stem cells within cord blood, as we suspended further patient enrollment of the Phase IIa MPC-MICRO-IO clinical trial and the Phase III MPC-CBE clinical trial as we prioritized the funding of our Tier 1 product candidates. The remaining carrying amount of in-process research and development as at June 30, 2020 and June 30, 2019 was $427.8 million. We still believe these product candidates remain viable upon further funding, or partnership, and accordingly these products should not be regarded as abandoned, where typically, abandoned programs would be closed down and the related research and development efforts are considered impaired and the asset is fully expensed.

All in-process research and development recognized on our balance sheet is a result of a business acquisition and is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form. Indefinite life intangible assets are not amortized but rather are tested for impairment annually in the third quarter of each year in accordance with IAS 36 *Impairment of Assets* which requires testing annually, or whenever there is an indication that an asset may be impaired. A full assessment was performed at March 31, 2020 and no impairment of the in-process research and development was identified. There was no impairment charge recognized during the years ended June 30, 2020 and 2019.

In-process research and development will continue to be tested for impairment until the related research and development efforts are either completed or abandoned. At the time of completion, when the asset becomes available for use, all costs recognized in in-process research and development that related to the completed asset are transferred to the intangible asset category, current marketed products, at the asset's historical cost.

Current marketed products

Current marketed products contain products that are currently being marketed. The assets are recognized on our balance sheet as a result of business acquisitions or reclassifications from in-process research and development upon completion. Upon completion, when assets become available for use, assets are reclassified from in-process research and development to current marketed products at the historical value that they were recognized at within the in-process research and development category.

Upon reclassification to the current marketed products category, management determines the remaining useful life of the intangible assets and amortizes them from the date they become available for use. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and any other relevant factors.

Management has chosen to amortize all intangible assets with a finite useful life on a straight-line basis over the useful life of the asset. Current marketed products are tested for impairment in accordance with IAS 36 *Impairment of Assets* which requires testing whenever there is an indication that an asset may be impaired.

In February 2016, we reclassified $24.0 million from in-process research and development to current marketed products upon the TEMCELL asset becoming available for use in Japan.

Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

We impair assets in accordance with IAS 36 *Impairment of Assets.* IAS 36 outlines that an impairment loss must be recognized if an asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). The recoverable amounts of our assets and cash-generating units have been determined based on fair value less costs to sell calculations, which require the use of certain assumptions. See Note 6(b)(v) of our consolidated financial statements and the related note thereto included in our annual report for more information regarding the assumptions used in determining the fair value less costs to sell.

Management maintains internal valuations of each asset annually (or more frequently should indicators of impairment be identified) and valuations from independent experts are requested periodically, within every three year period. The internal valuations are continually reviewed by management and consideration is given as to whether there are indicators of impairment which would warrant impairment testing. An external valuation of our assets was carried out by an independent expert as at March 31, 2020 with the recoverable amount of each asset exceeding its carrying amount.

The recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts in the annual impairment testing completed in March 2020 and, therefore, no impairment charges were recorded.

Inventories

Inventories are included in the financial statements at the lower of cost (including raw materials, direct labour, 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 37 *Provisions, Contingent Liabilities and Contingent Assets*; the provision is then reversed at the point when a high probability of regulatory approval is determined.

We consider 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 will be reversed through Manufacturing Commercialization expenses. As of June 30, 2020, there was $8.8 million of pre-launch inventory recognized on the balance sheet that was fully provided for.

Investments and other financial assets

We invest our cash in term deposits and other similar low risk products. We classify investments as either a cash equivalent or a short-term investment in accordance with IAS 7 *Statement of Cash Flows*. For a deposit to be classified as a cash equivalent it should be held for the purpose of meeting short-term cash commitments rather than for investment or other purposes and IAS 7 outlines that:

- it must be readily convertible to a known amount of cash (qualifies when it has a short maturity, of say, 3 months or less from the date of acquisition); and
- it must be subject to insignificant risk of change of value.

We review the terms and conditions of each deposit to determine if it is a cash equivalent in accordance with IAS 7.

Deposits with maturity dates between 3 months and 12 months are classified as short term investments. The carrying amount of short-term investments approximates fair value due to the short maturities of these instruments, and there are no unrealized gains or losses associated with these instruments. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset and liability.

As at June 30, 2020 and June 30, 2019, we did not hold any deposits with maturity dates between 3 months and 12 months and therefore we did not hold any deposits classified as short term investments.

Fair Value Measurements

For financial instruments that are measured on the balance sheet at fair value, IFRS 7 *Financial Instruments: Disclosures* requires disclosure of the fair value measurements by level of the following fair value measurement hierarchy:

- 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 us 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) and equity securities (unlisted).

Our level 3 asset 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 June 30, 2020 and June 30, 2019.

Our level 3 liabilities consist of a contingent consideration provision related to the acquisition of Osiris' MSC business. Level 3 liabilities were 100% of total liabilities measured at fair value as at June 30, 2020 and June 30, 2019. There were no transfers between any of the levels for recurring fair value measurements during the year.

The following table summarizes the assumptions, techniques, and significant unobservable inputs used in level 3 fair value measurements:

(in U.S. dollars, in thousands, except percent data) Description	Fair value as of June 30, 2020	2019	Valuation technique	Unobservable inputs[1]	Range of inputs (weighted average) Year Ended June 30, 2020	2019	Relationship of unobservable inputs to fair value
Contingent consideration provision	45,166	47,534	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.4%. Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2020: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 3%. Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Year ended June 30, 2020: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 3%. Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

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

Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred of liabilities assumed, is recognized as remeasurement of borrowing arrangements within other operating income and expenses.

Borrowings are classified as current liabilities unless we have an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

Net deferred tax assets

Deferred tax assets are recognized for unused tax losses based on the scheduling of reversals of deferred tax liabilities and to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized. We have recorded deferred tax assets that relate to operating tax losses and deductible temporary differences to offset taxable temporary differences (deferred tax liabilities).

Accrued research and development and manufacturing commercialization expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Examples of estimated accrued expenses include fees paid to:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, process development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones.

In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. To date, there have been no material differences from our estimates to the amount actually incurred.

Australian Disclosure Requirements

Significant Changes in the State of Affairs

There have been no significant changes within the state of our affairs during the year ended June 30, 2020 except as noted in the "Important Corporate Developments" section included in Item 4.A.

Likely Developments and Expected Results of Operations

In April 2020, the U.S. Food and Drug Administration ("FDA") accepted for priority review our Biologics License Application ("BLA") filing of RYONCIL for the treatment of children with steroid-refractory acute graft versus host disease ("SR-aGVHD"), a life-threatening complication of an allogeneic bone marrow transplant. In August 2020, the Oncologic Drugs Advisory Committee ("ODAC") of the FDA voted overwhelmingly in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act ("PDUFA"). If approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the United States in 2020.

Other significant milestones are expected in the upcoming financial year in relation to our other Tier 1 product candidates, as detailed elsewhere in this report.

Environmental Regulations

Our operations are not subject to any significant environmental regulations under either Commonwealth of Australia or State/Territory legislation. We consider that adequate systems are in place to manage our obligations and are not aware of any breach of environmental requirements pertaining to us.

5.B Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses from operations since our inception in 2004 and as of June 30, 2020, we had an accumulated deficit of $548.8 million. We had cash and cash equivalents of $129.3 million as of June 30, 2020 and incurred net cash outflows from operations of $56.4 million for the year ended June 30, 2020.

We have an overarching strategy to fund operations predominately through sales of RYONCIL and non-dilutive strategic and commercial transactions. In addition to increasing cash inflows through sales of RYONCIL, we intend to enter into new strategic partnerships for our Phase 3 product candidates, drawing on up to $67.5 million additional funds from existing strategic and financing partnerships, subject to certain conditions, or through equity-based financing. Over the next 12 months some or all of these cash inflows will be required for us to meet our forecast expenditure and continue as a going concern, although there is uncertainty related to our ability to access these cash inflows.

Management and the directors believe that we will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on our ability to continue as a going concern and that we may be unable to realize our assets and discharge our liabilities in the normal course of business.

References to matters that may cast significant doubt about our ability to continue as a going concern also raise substantial doubt as contemplated by the Public Company Accounting Oversight Board standards. For our audited financial statements, see "Item 18 Financial Statements" included in our Form 20-F.

Audit Report

Our auditor has included an "emphasis of matter" paragraph in the audit report relating to our ability to continue as a going concern (refer Note 1(i)).

Cash flows

	Year ended June 30,			
(in U.S. dollars, in thousands)	**2020**	**2019**	**$ Change**	**% Change**
Cash Flow Data:				
Net cash (outflows) in operating activities	(56,365)	(57,790)	1,425	(2%)
Net cash (outflows) in investing activities	(3,273)	(1,000)	(2,273)	NM
Net cash inflows by financing activities	137,044	71,608	65,436	91%
Net increase in cash and cash equivalents	**77,406**	**12,818**	**64,588**	**NM**

Comparison of cash flows for the Year ended June 30, 2020 with the Year ended June 30, 2019

Net cash outflows in operating activities

Net cash outflows for operating activities were $56.4 million for the year ended June 30, 2020, compared with $57.8 million for the year ended June 30, 2019, a decrease of $1.4 million. The decrease of $1.4 million is due to a decrease in cash outflows of $7.2 million in the year ended June 30, 2020 compared with the year ended June 30, 2019, offset by a decrease in cash inflows of $5.8 million.

Outflows for payments to suppliers and employees and interest and other costs of finance paid decreased by $7.2 million from $90.9 million for the year ended June 30, 2019 to $83.7 million for the year ended June 30, 2020 primarily due to a decrease in payments in relation to research and development costs.

The $5.8 million decrease of inflows primarily comprised: inflows from milestone payments received decreased by $20.0 million in relation to the up-front technology access fee received upon closing of the strategic alliance with Tasly in October 2018; inflows from milestone payments received decreased by $5.4 million in relation to payments received on our patent license agreement with Takeda in December 2017; inflows from cumulative net sales milestone payments received on TEMCELL in Japan decreased by $1.0 million during the year ended June 30, 2020, compared with the year ended June 30, 2019; these decreases in inflows were offset by a $17.5 million increase from up-front fee and milestone payment received in relation to our strategic partnership with Grünenthal; and inflows from royalty income earned on sales of TEMCELL in Japan increased by $3.3 million during the year ended June 30, 2020, compared with the year ended June 30, 2019.

Net cash inflows in investing activities

Net cash outflows for investing activities increased by $2.3 million in the year ended June 30, 2020, compared with the year ended June 30, 2019 primarily due to a $2.0 million increase in payments for fixed assets, such as plant and equipment and intellectual property and a $0.3 million increase in payments for contingent consideration in the year ended June 30, 2020 when compared with the year ended June 30, 2019.

Net cash inflows in financing activities

Net cash inflows for financing activities were $137.0 million for the year ended June 30, 2020, compared with $71.6 million for the year ended June 30, 2019, an increase of $65.4 million. This increase in the year ended June 30, 2020, was primarily due to gross proceeds of $50.6 million received from share placements to existing and new Australian and global institutional investors in October 2019, and gross proceeds of $88.8 million from share placements to existing and new institutional investors in May 2020. The net cash inflows in the year ended June 30, 2019 include a $28.9 million receipt of net proceeds drawn pursuant to a non-dilutive, eight-year credit facility with NovaQuest, a $14.6 million receipt of net proceeds from drawing a further tranche of funding from our existing credit facility with Hercules, a $10.0 million receipt of gross proceeds from a share placement with NovaQuest in July 2018 and a $20.0 million receipt of gross proceeds from a share placement with Tasly in October 2018. We also received $5.2 million in receipts from share option exercises during the year ended June 30, 2020, compared to $0.3 million for the year ended June 30, 2019. These receipts were offset by a $1.6 million payment for lease liabilities during the year ended June 30, 2020, compared to $Nil for the year ended June 30, 2019 due to the adoption of IFRS 16 *Leases* on July 1, 2019. Additionally, there were $6.3 million and $0.6 million of payments for associated capital raising costs and $Nil and $1.6 million of payments for other associated borrowings cost in the years ended June 30, 2020 and 2019, respectively, a net increase in outflows for capital raising and borrowing costs of $4.1 million.

Comparison of cash flows for the Year ended June 30, 2019 with the Year ended June 30, 2018

For discussion on comparison of cash flows for the years ended June 30, 2019 and 2018, refer to Cash Flows within “Item 5.B Liquidity and Capital Resources” in our annual report on Form 20-F for the year ended June 30, 2019, filed with the SEC on September 9, 2019.

Operating Capital Requirements

We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize more of our cell-based product candidates. We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our cell-based product candidates, and begin to commercialize any approved products 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 anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our research and development expenses and our management and administration expenses to remain relatively consistent over the next 12 months. Subject to us achieving successful regulatory approval we expect an increase in our total expenses driven by an increase in our product manufacturing and selling, general and administrative expenses as we move towards commercialization. Therefore, 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

Hercules

In March 2018, we entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. We drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019. An additional $25.0 million may be drawn, subject to certain conditions. The loan matures in March 2022.

In August 2020, we amended the terms of the loan agreement to defer principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45% per annum. At June 30, 2019, in line with increases in the U.S. prime rate, the interest rate was 10.45%. On August 1, September 19 and October 31, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20%, 9.95% and 9.70%, respectively, and remains at 9.70% at June 30, 2020 in line with the amended terms of the loan agreement. As at June 30, 2020, we recognized $3.6 million in interest payable within twelve months as a current liability.

In the years ended June 30, 2020 and 2019, we recognized gains of $1.3 million and $0.4 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurement gains relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility.

NovaQuest

On June 29, 2018, we drew the first tranche of $30.0 million of the principal amount from the $40.0 million loan and security agreement with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of RYONCIL for the treatment in pediatric SR-aGVHD. We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of RYONCIL for pediatric SR-aGVHD are significantly higher than current forecasts.

If there are no net sales of RYONCIL for pediatric SR-aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing (“the payment cap”), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD is less than the 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 as we approach the potential approval of RYONCIL for pediatric SR-aGVHD (Prescription Drug User Fee Act (“PDUFA”) date of September 30, 2020) may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment 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 other operating income and expenses and finance costs in the period the revision is made.

As of June 30, 2020, management have assumed that RYONCIL for pediatric SR-aGVHD will obtain BLA approval at the PDUFA action date of September 30, 2020. In August 2020, the ODAC of the FDA voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. An FDA decision could lead to a remeasurement of the carrying value of the NovaQuest borrowings as management update net sales forecasts and other key assumptions.

As at June 30, 2020, we have recognized a current liability of $4.5 million which represents the present value of interest payable of $4.2 million and $0.3 million loan administration fee which is payable annually in June.

In the years ended June 30, 2020 and 2019, we recognized losses of $0.8 million and $0.7 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within other operating income. In the years ended June 30, 2020 and 2019, we recognized gains of $0.1 million and $Nil, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurements relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility with NovaQuest.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group's floating rate loan with the senior creditor, Hercules.

Compliance with loan covenants

Our loan facilities with Hercules 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. In addition, under our loan and security agreement with Hercules, we are obliged to maintain certain levels of cash in the United States and a minimum unrestricted cash balance across the Group.

We have complied with the financial and other restrictive covenants of our borrowing facilities during the year ended June 30, 2020.

5.C Research and Development, Patents and Licenses

For a description of the amount spent during each of the last two fiscal years on company-sponsored research and development activities, as well as the components of research and development expenses, see "Item 5.A Operating Results – Results of Operations."

For a description of our research and development process, see "Item 4.B Business Overview."

5.D Trend Information

As a biotechnology company which primarily is still in the development stage, we are subject to costs of our clinical trials and other work necessary to support applications for regulatory approval of our product candidates. Health regulators have increased their focus on product safety. In addition, regulators have also increased their attention on whether or not a new product offers evidence of substantial treatment effect. These developments have led to requests for more clinical trial data, for the inclusion of a higher number of patients in clinical trials, and for more detailed analyses of the trials. In light of these developments, we expect these aspects of our research and development expenses may need to increase as we continue to fund our programs to the market. Notwithstanding this upward trend, our research and development expenses may still fluctuate from period to period due to varied rates of patient enrollment and the timing of our clinical trials as our existing trials are completed and new trials commence. We cannot predict with any degree of accuracy the outcome of our research or commercialization efforts.

5.E 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 below.

5.F 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 June 30, 2020.

The maturity profile of the anticipated future contractual cash flows in relation to our contractual obligations and commitments on an undiscounted basis 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
Borrowings[1][2][3]	(35,995)	(35,915)	(51,218)	(17,510)	(140,638)
Trade payables	(24,972)	—	—	—	(24,972)
Lease liabilities[4]	(4,026)	(2,377)	(4,204)	(593)	(11,200)
Purchase commitments[4]	(17,272)	(9,087)	(17,892)	—	(44,251)
	(82,265)	**(47,379)**	**(73,314)**	**(18,103)**	**(221,061)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at June 30, 2020 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 pediatric SR-aGVHD**.**

(3) In August 2020, we amended the terms of the Hercules loan agreement to defer the commencement of principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability and are included in the contractual cash flows due within one year, on an undiscounted basis, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments on the Hercules borrowings can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

(4) In the year ended June 30, 2020, we entered into a manufacturing service agreement with Lonza for the supply of commercial product for the potential approval and launch of RYONCIL for the treatment of pediatric acute graft versus host disease in the US market. This agreement contains lease and non-lease components with a non-cancellable term of 4.5 years. The agreement contains a minimum financial commitment of $49.5 million. We have accounted for the lease component within the agreement as a lease liability separately from the non-lease components. As of June 30, 2020, the minimum financial commitment of the lease and non-lease components are $5.3 million and $44.2 million, respectively, disclosed within the contractual obligations as lease liabilities and purchase commitments on an undiscounted basis, respectively. If there is a significant delay in the expected approval date of the BLA for RYONCIL by the FDA then the minimum financial commitment under this manufacturing services agreement will reduce by $28.3 million, with $2.0 million of this reduction relating to the lease component and $26.3 million relating to the non-lease component of the agreement.

We do not have any other purchase commitments as of June 30, 2020.

Lease commitment – as lessee:

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 also lease a manufacturing suite under the non-cancellable manufacturing services agreement with Lonza for the supply of commercial product for the potential approval and launch of RYONCIL for the treatment of pediatric acute graft versus host disease in the US market expiring within 5 years. We adopted IFRS 16 *Leases* on July 1, 2019. Our principal accounting policy from July 1, 2019, are that leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use. For principal accounting policies relating to the comparative year, refer to our annual report on Form 20-F for the year ended June 30, 2019. Comparatives have not been restated as permitted under the specific transition provisions in the standard. A reconciliation between the operating lease commitments disclosed applying IAS 17 at June 30, 2019 and the lease liabilities recognized at July 1, 2019 is described in Note 13 to our consolidated financial statements.

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 June 30, 2020 we have assessed these contingent liabilities to be remote.

Capital commitments

We did not have any commitments for future capital expenditure outstanding as of June 30, 2020.

Item 6. Directors, Senior Management and Employees

(Start of the Remuneration Report for **Australian Disclosure Requirements**)

The Mesoblast board of directors ("the Board") presents the 2019/2020 Remuneration Report, which has been prepared in accordance with the relevant Corporations Act 2001 ("Corporations Act") and accounting standards requirements.

The remuneration report sets out remuneration information for our company's key management personnel ("KMP") as defined in the International Accounting Standards 24 'Related Party Disclosures' and the Australian Corporations Act 2001 for the financial year ended June 30, 2020.

The remuneration report has been audited as required by s308 (3C) of the Corporations Act.

Introductory Comments from Donal O'Dwyer, Nomination and Remuneration Committee Chairman

A pivotal year

The 2020 financial year has been a pivotal year for Mesoblast as we prepare for potential commercialization of remestemcel-L, which requires shifts in hiring in company focus. Multiple other major corporate milestones have also been achieved and are set out later in this report. In particular, the possibility of using our stem cells for the treatment of COVID-19 sufferers has been a testament to the dedication, agility and responsiveness of our management and personnel.

This year has also seen the implementation of changes to our remuneration framework in response to feedback from proxy advisers and investors including:

- Decreasing the amount of annual cash that the CEO could earn through a reduction in STI.
- Decreasing the weighting of the CEO's fixed remuneration to 40% of total remuneration (down from 50%), and increasing the weight of pay contingent on performance to 60%.
- Halving the CEO's short-term incentive opportunity to 20% of total remuneration (down from 50%).
- Requiring the CEO's incentive payments to be partly in long term incentives, consisting of an option grant subject to milestone performance conditions which must be achieved over 3 years. If achieved earlier, vesting is restricted so that it is only by the third year that all options will have vested.
- Requiring KMP and executive options to be subject to both milestone achievement and continued service before vesting.
- Disclosing KMP LTI performance conditions.

These changes result in lower cash costs, preserving our cash reserves for investing in research and commercialization.

We have received positive feedback on the changes, which were well received by investors with an appreciation of the biotechnology industry.

There are still some concerns among investors, mainly to do with remuneration settings that reflect our status as a global biotechnology company with the majority of employees based in the US. I will address these concerns here.

CEO remuneration is higher than ASX-listed companies of similar market capitalization

This was correct, although since then the market value has substantially increased (157%[(1)]), which will have improved relativities and is likely to have neutralized this concern. In determining appropriate remuneration, ASX-listed companies are not the primary benchmark we use, as most employees are based in the USA, and most have skills in-demand globally, rather than locally. Hence, we benchmark to where we source employees from, or where we could lose them to, including the CEO.

Milestone performance conditions not preferred

Traditional financial metrics are not meaningful, nor can they be effectively used to accurately reflect the performance of our company. What creates lasting shareholder value are successful outcomes from research and development, entry into new collaborations and achievement of other planned and well-considered corporate objectives. Success will only result in significant reward under the LTI if the market values our achievements. If it does, our share price increases. The LTI options become valuable. If not, the options have no intrinsic value. This combination of milestones and payment in options work in tandem for a sober, fair payment for performance aligned with shareholder returns. This is a standard biotechnology company practice.

Long term incentive vesting period too short

Within biotechnology, basing long term incentives on achievement of performance milestones is a tried and true measure of aligning pay with performance. The other factor that is critical is time. While we allow three years for milestones, earlier is better, because we will have achieved it using less cash expense than if achieved at the end of 3 years. Therefore, we have configured the plan to allow for early vesting for early achievement, but only to a point. We still insist that even if all milestones are achieved early, some options remain unvested for 3 years, to ensure that, if given a choice with a limited budget, employees focus on those milestones most likely to deliver the most value over the longer term, as well as encouraging employee retention. We believe that this framework is innovative, and a great fit for the nature of our business. We acknowledge it does not look and feel like a typical ASX-listed company LTI, and therefore may not meet the standard guidelines applied by many, but we are not typical. We are open to considering alternatively designed incentives that address the value drivers of milestone achievement, time to achieve them, prioritization of milestones with most value potential given limited resourcing, and impact on longer term share price. But so far we have not found any quite as effective.

(1) The market capitalization has increased 157% from June 30, 2019 to June 30, 2020.

Disclosure of KMP LTI performance targets

Mesoblast agrees that performance requirements on which executive incentive payments are made must be disclosed in the interests of good governance. When milestone targets are commercially sensitive, the general terms of the milestone are disclosed. Once achieved, the specifics of milestones will be disclosed.

Consistency of bonus payment and lack of STI deferral

The board believes that incentive opportunities have been beneficial in motivating disciplined research and development within a constrained annual budget. Within biotechnology companies the key to long-term value creation is a relentless focus on a highly detailed, rigorous R&D program. While share price movements can be volatile depending on the success of this program as it unfolds, the program itself must nevertheless be worked through systematically and with extreme care. This must not be volatile.

In most years we have achieved this systematic progress in our R&D program, which is reflected in STI outcomes. This is what would be expected in a well-managed and governed biotechnology company.

The underlying value of biotechnology companies such as Mesoblast rely on progress in research ultimately resulting in product approval and application. Success on this journey can be measured by investor participation in capital raisings, and revenue trending upwards from securing licensing agreements stemming from R&D progress. Mesoblast is performing on both of these measures.

We have no deferral of STI. On review, the board considered that:

- STI is not a heavily weighted part of the remuneration framework across the Company
- there was sufficient remuneration deferred already, in the form of unvested options, that would be at risk in the event of poor conduct, mismanagement or reputational damage.

Dilution

Some feedback indicated a concern with potential dilution caused by our employee option plan. Given the recent growth in Mesoblast's market value and the potential presented by our planned commercialization, current dilution levels from our share plan are not excessive by biotechnology company standards. However, we recognize that biotechnology company practices relying on the application of options in lieu of cash remuneration are unusual in other industries, and so may not be familiar to many external stakeholders. Therefore, despite the application of options being a standard industry practice, we will continue to consider alternatives that provide the same upside opportunity as options, but with less dilution.

COVID-19

COVID-19 has not led to a material deterioration in Mesoblast's financial circumstances, nor required Mesoblast to utilize government support. Mesoblast has actively implemented a COVID-19 program focused on employee safety and has instituted various changes to working requirements to minimize threats to our employees arising from the pandemic. These include facilities to work from home, safe social distancing methods, supervision and rotational shifts in our research laboratories, and extension to already thorough hygiene practices from our research areas to all places of work. As a result, the impact on our work schedule and efficiency has been minimal, and all employees were fully retained.

Mesoblast is facing some challenges from the pandemic. Our clinical trials that are not treating COVID-19 infected patients are experiencing some delays given reduced capacity at hospitals for completing activities and impacts on patient mobility for treatments or final visits. In addition, health regulators may rate other treatments as higher priorities due to the crisis.

On the other hand, COVID-19 has presented potentially significant opportunities for Mesoblast. At the initial onset of the pandemic Mesoblast was pleased to be able to offer remestemcel-L to sufferers of COVID-19 after the US FDA cleared it for investigational use in patients with acute respiratory distress syndrome (ARDS) caused by COVID-19.

With agility, dedication, and expertise, employees at various levels of Mesoblast quickly commenced clinical research that has the potential to result in a treatment for COVID-19 infected patients and provide significant benefit to patients and shareholders. The results of a major clinical study currently recruiting in the US are expected before the year end.

Concluding remarks

The design of our remuneration framework enables us to respond rapidly to reorient priorities such as the COVID-19 pandemic.

Feedback on Mesoblast's remuneration has been listened to. The board has responded with several changes to its framework. Others are still being considered. Other aspects of our remuneration, upon review, were found to be ideal for our business. These have been retained, although with the commitment to do a better job of explaining why it suits our business and is in the interests of our shareholders.

We trust you will agree and support our remuneration framework with these latest changes and welcome your further feedback.

Donal O'Dwyer

Nomination and Remuneration Committee Chairman

6.A Key Management Personnel

Key management personnel (KMP), defined as individuals who have authority and responsibility for planning, directing and controlling the activities of the company, directly or indirectly, and including all directors, are listed in Table 1.

Table 1 – Mesoblast KMP during FY2020

Name	Position	Country	Portion of year served as KMP
Non-executive directors			
Joseph Swedish	Independent Chairman, Board of Directors Member, Audit and Risk Committee	US	Full Year
William Burns	Independent Vice Chair, Board of Directors Member, Nomination and Remuneration Committee	Switzerland	Full Year
Donal O'Dwyer	Independent Non-executive Director Chair, Nomination and Remuneration Committee Member, Audit and Risk Committee	Australia	Full Year
Michael Spooner	Independent Non-executive Director Chair, Audit and Risk Committee Member, Nomination and Remuneration Committee	Australia	Full Year
Eric Rose	Independent Non-executive Director	US	Full Year
Shawn Cline Tomasello	Independent Non-executive Director	US	Full Year
Executive director			
Silviu Itescu	Chief Executive Officer Executive Director	Australia	Full Year
Other executive KMP			
Josh Muntner	Chief Financial Officer	US	Full Year

Details of Directors and Senior Management

Board of Directors

Joseph Swedish, MHA

Appointed as Chairman of the Board of Directors on April 1, 2019.

Experience and expertise

Joseph. R. Swedish has more than four decades of healthcare leadership experience serving major United States healthcare enterprises. He is the co-founder and a partner at Concord Health Partners that is an investment management firm focused on health care companies that can enhance the value of care delivery through products, services, and technologies.

Mr Swedish was Chairman, President and Chief Executive Officer of Anthem, Inc., (2013 – 2018) and subsequently he served as a Senior Adviser (2018 – 2020). Anthem, Inc. is America's leading health benefits provider. Prior to joining Anthem, Inc., Mr Swedish was CEO for several major integrated healthcare delivery systems, including Trinity Health and Centura Health. Currently, he sits on the Board of Directors of IBM Corporation, CDW Corporation and Centrexion Therapeutics. Mr Swedish is past Chairman of Duke University's Fuqua School of Business Board of Visitors and is a current member. Previously, he was Chairman of the Catholic Health Association and America's Health Insurance Plans (AHIP). Mr Swedish received a bachelor's degree from the University of North Carolina at Charlotte and his master's degree in health administration from Duke University. His extensive experience as a leader in the US healthcare sector with twenty-five years as CEO, particularly in resource allocation and reimbursement metrics, provides industry, leadership and management experience as Mesoblast transitions to a commercial stage company.

Other current directorships of listed public companies
Non-Executive Director, IBM Corporation (since 2017)
Non-Executive Director, CDW Corporation (since 2015)

Former directorships of listed public companies within the last 3 years
Executive Chairman, Anthem, Inc. (2013 - 2018)

William Burns, BA

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. Burns has served on our board of directors since 2014 and was appointed Vice Chairman in 2016. He spent his entire management career at the Beecham Group and F. Hoffmann-La Roche Ltd. He was Chief Executive Officer of Roche Pharmaceuticals from 2001 to 2009, when he joined the board of directors of F. Hoffmann-La Roche Ltd. until he retired in 2014. He is the Chair of Molecular Partners, and has been a Non-Executive Director of Shire PLC, Chugai Pharmaceutical Co., Genentech, Crucell, and Chairman of Biotie Therapies Corp. from 2014 until its sale to Acorda Therapeutics Inc. in 2016. Mr Burns is also a member of the Oncology Advisory Board of the Universities of Cologne/Bonn in Germany. In 2014, he was appointed a trustee of the Institute of Cancer Research, London, and from March 2016 until April 2020 a Governor of The Wellcome Trust in London, UK. His extensive experience in the pharmaceutical industry, specifically as a member of the board of directors of other pharmaceutical companies, provides pharmaceutical, healthcare, industry, leadership and management expertise.

Other current directorships of listed public companies
Chair of Molecular Partners (since 2018)

Former directorships of listed public companies within the last 3 years
Non-executive Director, Shire (UK) (2010 – 2018)

Donal O'Dwyer, BE, MBA

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. O'Dwyer has served on our board of directors since 2004. He has over 25 years of experience as a senior executive in the global cardiovascular and medical devices industries. From 1996 to 2003, Mr. O'Dwyer worked for Cordis Cardiology, the cardiology division of Johnson & Johnson's Cordis Corporation, initially as its president (Europe) and from 2000 as its worldwide president.

Prior to joining Cordis, Mr. O'Dwyer worked with Baxter Healthcare, rising from plant manager in Ireland to president of the Cardiovascular Group, Europe, now Edwards Lifesciences. Mr. O'Dwyer is a qualified civil engineer with an MBA. He is on the board of directors of a number of life sciences companies including Cochlear Limited, Fisher & Paykel Healthcare Ltd and NIB Holdings Ltd. With his experience as a senior executive and a director, as well as his extensive experience in the cardiovascular and medical devices industries, Mr. O'Dwyer provides business, science, engineering and management expertise.

Other current directorships of listed public companies
Non-executive Director, Cochlear Ltd (since 2005)
Non-executive Director, Fisher & Paykel Healthcare (since 2013)
Non-executive Director, NIB Holdings Ltd (since 2016)

Former directorships of listed public companies within the last 3 years
Non-executive Director, CardieX Ltd (formerly called Atcor Medical Holdings Ltd) (since 2004 – 2019)

Michael Spooner, BCom, ACA, MAICD

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. Spooner has served on our board of directors since 2004. During this period he has filled various roles including as Executive Chairman from the date of our Australian IPO in 2004 until 2007. Over the past several years, Mr. Spooner has served on the board of directors in various capacities at several Australian and international biotechnology companies, including BiVacor Pty Ltd (2009-2013), Advanced Surgical Design & Manufacture Limited (2010-2011), Peplin, Inc. (2004-2009), Hawaii Biotech, Inc. (2010-2012), Hunter Immunology Limited (2007-2008), and Ventracor Limited (2001-2003). He is the chairman of Simavita Limited since May 2016 and Chairman of MicrofuidX since February 2018. Prior to returning to Australia in 2001, Mr. Spooner spent much of his career internationally where he served in various roles including as a partner to PA Consulting Group, a UK-based management consultancy and a Principal Partner and Director of Consulting Services with PricewaterhouseCoopers (Coopers & Lybrand) in Hong Kong. In addition Mr. Spooner has owned and operated several international companies providing services and has consulted to a number of U.S. and Asian public companies. Mr. Spooner provides executive management, commercial, business strategy and accounting expertise as well as established relationships with investment firms and business communities worldwide.

Other current directorships of listed public companies
Chairman, Simavita Ltd (since 2016)

Former directorships of listed public companies within the last 3 years
None

Eric Rose, MD

Non-Executive Member of the Board of Directors

Experience and expertise

Dr. Rose has served on our board of directors since 2013. He is currently Executive Chairman of SIGA Technologies. From 2008 through 2012, Dr. Rose served as the Edmond A. Guggenheim Professor and Chairman of the Department of Health Evidence and Policy at the Mount Sinai School of Medicine. From 1994 through 2007, Dr. Rose served as Chairman of the Department of Surgery and Surgeon-in-Chief of the Columbia Presbyterian Center of New York Presbyterian Hospital. From 1982 through 1992, he led the Columbia Presbyterian heart transplantation program in the United States. Dr. Rose currently sits on the board of directors of ABIOMED. His experience as a surgeon, researcher and businessman provides medical, pharmaceutical, scientific and industry expertise.

Other current directorships of listed public companies
Non-executive Chairman, SIGA Technologies, Inc. (since 2018)
Non-executive Director, ABIOMED, Inc. (2007 – 2012, 2014 – present)

Former directorships of listed public companies within the last 3 years
None

Shawn Cline Tomasello, BS, MBA

Appointed to the Board as a Non-Executive Director on July 11, 2018.

Experience and expertise

With more than 30 years' experience in the pharmaceutical and biotech industries, Shawn Cline Tomasello has substantial commercial and transactional experience. Since 2015, Ms Tomasello has been Chief Commercial Officer at leading immuno-oncology cell therapy company Kite Pharma, where she played a pivotal role in the company's acquisition in 2017 by Gilead Sciences for $11.9 billion. Prior to this she served as Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. for $21 billion. Ms Tomasello previously was President of the Americas, Hematology and Oncology at Celgene Corporation where she managed over $4 billion in product revenues, and was instrumental in various global expansion and acquisition strategies. She has also held senior positions at Genentech, Pfizer Laboratories, Miles Pharmaceuticals and Procter & Gamble. Ms Tomasello currently serves on the Board of Directors of Principia Biopharma, Inc., Abeona Therapeutics, Inc., Gamida Cell, Ltd. and UroGen Pharma, Ltd. She previously served on the Board of Clementia Pharmaceuticals, Inc. which was acquired by Ipsen, SA. and Diplomat Specialty which was acquired by United Healthcare. She received a MBA from Murray State University and a B.S. in Marketing from the University of Cincinnati. Her extensive experience in the pharmaceutical and biotech industries, particularly in the commercial and transactional fields, provides industry, leadership and management expertise.

Other current directorships of listed public companies
Director, Gamida Cell, Ltd. (since 2019)
Director, UroGen Pharma, Ltd. (since 2019)
Director, Principia Biopharma, Inc. (since 2019)
Director, Abeona Therapeutics, Inc. (since 2020)

Former directorships of listed public companies within the last 3 years
Director, Clementia Pharmaceuticals, Inc. which was acquired by Ipsen, SA. (2018 – 2019)
Non-Executive Director, Diplomat Pharmacy, Inc. (2015 – 2020)

Charlie Harrison, BA, LLB (Hons)

Joint Company Secretary

Experience and expertise

Mr Harrison joined Mesoblast as a legal counsel in 2013. He was previously a senior associate at the international law firm Allens, working in their Hong Kong and Melbourne offices for nine years as a corporate lawyer. Mr Harrison has an Arts/Law degree from the University of Melbourne. He was appointed Company Secretary in 2014.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
None

Niva Sivakumar – BCom, LLB

Joint Company Secretary

Experience and expertise

Ms Sivakumar joined Mesoblast's legal team in 2014 and is a member of the company's Intellectual Property Committee. Previously, she was a senior associate in the corporate and commercial teams at major law firm, Dentons, and a senior lawyer at K&L Gates. Ms Sivakumar has a Commerce/Law degree from the University of Melbourne. She was included in The Legal 500's Guide to Australia's Rising Stars 2019.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
None

Senior Management

Silviu Itescu, MBBS (Hons), FRACP, FACP, FACRA

Chief Executive Officer

Executive Member of the Board of Directors

Experience and expertise

Dr. Itescu is our Chief Executive Officer ("CEO"). He has served our board of directors since our founding in 2004, was Executive Director from 2007 to 2011, and became CEO and Managing Director in 2011. Prior to founding Mesoblast in 2004, Dr. Itescu established an international reputation as a physician scientist in the fields of stem cell biology, autoimmune diseases, organ transplantation, and heart failure. He has been a faculty member of Columbia University in New York, and of Melbourne and Monash universities in Australia. In 2011, Dr. Itescu was named BioSpectrum Asia Person of the Year. In 2013, he received the inaugural Key Innovator Award from the Vatican's Pontifical Council for Culture for his leadership in translational science and clinical medicine in relation to adult stem cell therapy. Dr. Itescu has consulted for various international pharmaceutical companies, has been an adviser to biotechnology and health care investor groups, and has served on the board of directors of several publicly listed life sciences companies.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
None

Dagmar Rosa-Bjorkeson, MS, MBA

Chief Operating Officer

Dagmar Rosa-Bjorkeson has more than 25 years of global experience in the pharmaceutical industry, including executive leadership in corporate and product strategy, market development and operational execution. She has led multiple successful product launches, including Gilenya® for multiple sclerosis and Elidel® for atopic eczema. During her 17 years at Novartis, Ms Rosa-Bjorkeson was Vice President and Head of its Multiple Sclerosis Business Unit; Vice President, Business Development and Licensing in the United States; and Country Head and President for Novartis Sweden. More recently, she served as Executive Vice President and President, Biosimilars, at Baxalta, now a wholly owned subsidiary of Takeda Pharmaceutical Company. Ms Rosa-Bjorkeson was also Executive Vice President and Chief Strategy and Development Officer at Mallinckrodt Pharmaceuticals. She holds an MBA in Marketing, an MS in Chemistry and a BS, Chemistry from the University of Texas.

Josh Muntner, BFA, MBA

Chief Financial Officer

Mr Muntner has accrued 20 years' experience in healthcare investment banking and corporate finance, and has been involved in a wide range of healthcare-related transactions with approximately $11.0 billion in value. Most recently, he led corporate development and financial transactions at Nasdaq-listed biotechnology company, ContraFect Corporation. Previously, Mr Muntner served as Managing Director and Co-Head of Healthcare Investment Banking at Janney Montgomery Scott, and spent nine years at Oppenheimer & Co. and its U.S. predecessor, CIBC World Markets. He also served as an investment banker at Prudential Securities. Mr Muntner has a BFA from Carnegie Mellon and a MBA from the Anderson School at UCLA.

Peter Howard, BSc, LLB (Hons)

General Counsel

Mr. Howard has served as our General Counsel and Corporate Executive since July 2011. As external counsel and partner at Australian law firm, Middletons (now, K&L Gates), Mr. Howard has been integrally involved with Mesoblast since its inception and public listing on the ASX in 2004. More generally, Mr. Howard has extensive experience with many biopharmaceutical firms and major research institutions, covering public listings, private financings, strategic, licensing, intellectual property and mergers and acquisition activities. He has done so in several roles, including as a partner at a major law firm, entrepreneur, director and senior executive.

Paul Simmons, PhD

Head of Research and New Product Development

Dr. Simmons has served as our Head of Research and New Product Development since 2011. He has nearly 30 years of experience in stem cell research, especially research in basic hematopoiesis and in precursor cells for the stromal system of the bone marrow, and served as President of the International Society of Stem Cell Research, or ISSCR, from 2006 to 2007. Prior to joining Mesoblast, Dr. Simmons held the C. Harold and Lorine G. Wallace Distinguished University Chair at the University of Texas Health from 2008 to 2011 and served as the inaugural Professor and Director of the Centre for Stem Cell Research at the Brown Foundation Institute of Molecular Medicine from 2006 to 2011. Dr. Simmons is, or has served as, an associate editor, a member of the editorial board, or a reviewer on multiple scientific and medical journals including Experimental Hematology, Cytotherapy and Stem Cell Research, Cell Stem Cell, Stem Reports, Science and Nature.

John McMannis, PhD

Head of Manufacturing

Dr. McMannis has served as our Head of Manufacturing since 2011. He has 27 years of experience in clinical cellular therapy trials in both academic and commercial environments. Before joining Mesoblast, Dr. McMannis served at the University of Texas MD Anderson Cancer Center as a Professor of Medicine from 1999 to 2011, and as the Director of the Cell Therapy Laboratory from 1999 to 2011, and as the Technical Director of the Cord Blood Bank from 2008 to 2011. Before his tenure at the University of Texas MD Anderson Cancer Center, Dr. McMannis was a Senior Director Technical Affairs at the Immunotherapy Division of Baxter and Therapy Scientist at COBE BCT (now Terumo BCT). Dr. McMannis has served on the scientific advisory boards at BioSafe SA, Biolife Solutions, Inc., and General Electric and on the board of directors for the American Association of Blood Banks, or AABB, and the National Marrow Donor Program, or NMDP, which operates the “Be the Match” donor program.

Geraldine Storton, BSc, MMS, MBA

Head of Regulatory Affairs and Quality Management

Ms. Storton is a seasoned pharmaceutical executive with more than 24 years’ experience across the full value chain of Pharmaceutical and Medical Device Research and Development, production and commercialization worldwide. She has an extensive background in regulatory affairs and quality, most recently as a consultant to cell therapy companies. Prior to this, Ms. Storton held executive roles at Hospira, and its predecessor companies in both regulatory affairs and quality, with a focus on major program management. As Vice President, Program Management, Quality, at Hospira headquarters in Chicago, she led a company-wide quality remediation program to improve compliance in manufacturing across 15 facilities worldwide. As Regional Director, Commercial Quality ANZ, Asia and Japan, Ms. Storton was responsible for quality oversight and management of all products sold in Asia Pacific countries. Her responsibilities included regulatory compliance, batch release, field actions, complaints management, change control, due diligence and new product launch. As director of global regulatory operations, Ms. Storton managed development and registration of new products and on-market management of the existing product portfolio for all Hospira’s products developed or manufactured within Asia Pacific for global distribution. She joined Mesoblast in December 2015.

Michael Schuster, MBA

Pharma Partnering

Mr. Schuster, who joined Mesoblast in 2004, leads the Group's partnering discussions. Previously he was the head of the Group's investor relations outreach program and was part of the founding executive team at both Mesoblast Limited and Angioblast Systems, Inc. Mr. Schuster was Executive Vice President of Global Therapeutic Programs from 2010 to 2013 and was the Director of Business Development and Vice President of Operations from 2004 to 2010. He holds an undergraduate degree in science from Tufts University, a Master’s degree in Immunology & Microbiology from New York Medical College, and an MBA from Fordham University in New York.

Eric Strati Pharm.D., MBA

Pharma Partnering

Eric Strati has over 17 years of experience across a broad range of industries within the healthcare sector including pharmaceutical, biotechnology, investment banking, and pharmacy benefit management. Prior to joining Mesoblast in 2015, Dr Strati held various commercial leadership roles including new product planning, lifecycle management, sales, marketing, and payer strategy. Previous positions include most recently as Executive Director, Managed Markets at Novartis, medical affairs positions at Genzyme and Bristol-Myers Squibb, and Vice President of Global Pharmaceutical Equity Research at HSBC. He earned his Bachelors of Science in Pharmacy and MBA in Health Systems Management from Union University, and Doctor of Pharmacy from University of Kansas.

Fred Grossman D.O. FAPA

Chief Medical Officer – Appointed August 19, 2019

Dr. Grossman joined Mesoblast in August 2019 and leads the Medical Affairs, Drug Safety Clinical Operations and Biostatistics teams. Dr Grossmann is a Board-Certified psychiatrist and Fellow of the American Psychiatric Association with over 30 years of experience in research, academia, and practice. He has held executive positions leading and building clinical development, medical affairs, and pharmacovigilance in large and small pharmaceutical companies including Eli Lilly, Johnson & Johnson, Bristol Myers Squibb, Sunovion, Glenmark, and NeuroRx. Dr. Grossman has developed and supported the launch of numerous blockbuster medications addressing significant unmet medical needs across multiple therapeutic areas including CNS, immunology, immuno-oncolology, respiratory, cardiovascular/metabolics, and virology. He has close relationships with thought leaders worldwide and has negotiated directly with the FDA and Global Health Authorities for approval of many drugs across therapeutic areas. He has numerous publications and presentations and has held several academic appointments.

Donna Skerrett, MD

Chief Medical Officer – Resigned effective date August 19, 2019, at which point she was appointed as an adviser for our Graft Versus Host Disease program.

Dr Skerrett has more than 20 years of combined experience in transfusion medicine, cellular therapy, and transplantation. She was Director of Transfusion Medicine and Cellular Therapy at Weill Cornell Medical Center in New York from 2004 to 2011, and previously served as Associate Director of Transfusion Medicine and Director of Stem Cell Facilities at Columbia University's New York-Presbyterian Hospital. From 2004, she held various roles at Mesoblast in clinical and regulatory affairs and was Chief Medical Officer from 2011 to 2019.

There are no family relationships among any of our directors and senior management. The business address of each of our directors and senior management is Mesoblast Limited, Level 38, 55 Collins Street, Melbourne, VIC 3000, Australia.

Directors' Interests

The relevant interest of each director, as defined by section 608 of the Corporations Act, in the share capital of Mesoblast, as notified by the directors to the ASX in accordance with section 205G(1) of the Corporations Act, at the date of this report is as follows:

Table 2 – Director Interests

Director	Mesoblast Limited ordinary shares	Options over Mesoblast Limited Ordinary Shares
Silviu Itescu	68,958,928	1,885,334
Josh Muntner	—	800,000
William Burns	63,000	220,000
Donal O'Dwyer	1,234,392	100,000
Eric Rose	—	220,000
Michael Spooner	1,069,000	100,000
Joseph Swedish	—	500,000
Shawn Cline Tomasello	—	200,000

Meeting of Directors

The number of meetings our board of directors (including committee meetings of directors) held during the year ended June 30, 2020 and the number of meetings attended by each director were:

Table 3 – Meeting of Directors

	Board of Directors		Audit and Risk Committee		Nomination and Remuneration Committee	
Director	A	B	A	B	A	B
Joseph Swedish	14	13	4	4	—	—
William Burns	14	12	—	—	5	5
Silviu Itescu	14	14	—	—	—	—
Donal O'Dwyer	14	14	4	4	5	5
Eric Rose	14	14	—	—	—	—
Shawn Tomasello	14	13	—	—	—	—
Michael Spooner	14	14	4	4	5	5

A = Number of meetings held during the time the director held office or was a member of the committee.

B = Number of meetings attended by board/committee members

— = Not a member of the relevant committee

6.B Compensation

KMP Remuneration Governance

The Board is responsible for Mesoblast's remuneration strategy and approach. The Nomination and Remuneration Committee advises the Board on remuneration and incentive policies and practices generally, and makes specific recommendations on remuneration packages and other terms of employment for executive Directors, other senior executives and non-executive Directors.

The Nomination and Remuneration Committee is wholly comprised of independent members: Donal O'Dwyer (Chair), William Burns and Michael Spooner. The board is satisfied that Donal O'Dwyer and Michael Spooner are independent despite their long-standing tenure on the board and Mr. Spooner's brief role as an executive Chairman following the company's incorporation.

The Nomination and Remuneration Committee is primarily responsible for making recommendations to the Board on:

- Board appointments
- Non-executive director fees
- Executive remuneration framework
- Remuneration for executive directors, namely the CEO, and other key executives
- Short-term and long-term incentive awards
- Share ownership plans

The Nomination and Remuneration Committee's objective is to ensure remuneration policies are fair and competitive and have regard for industry benchmarks whilst being aligned with the objectives of our company.

The Committee receives proposals from the executive team, which it critically reviews. When appropriate the Nomination and Remuneration Committee will seek advice or recommendations from independent expert consultants. Advice provided by consultants during the year did not constitute a 'remuneration recommendation' as a defined in section 9B of the Corporations Act and was received free from any undue influence by Key Management Personnel to whom the advice related.

Executive Remuneration Strategy

The Company's remuneration strategy is designed to ensure Mesoblast can:

- Attract and retain experienced leaders and emerging experts in an innovative field and on a global basis
- Reward performance that will lead in the long term to improved patient outcomes and increased shareholder wealth.

Our team is small. Mesoblast has only 102 employees, 69% of whom are in the US, with the remainder in Australia, Singapore and Switzerland. Retaining these employees, who often are at the top of their respective fields (over half of Mesoblast employees have a masters or PhD), is imperative in ensuring Mesoblast can continue in a consistent manner to work towards what are difficult, complex and long-term goals.

Biopharmaceutical product development is a highly specialized and speculative undertaking and it involves a substantial degree of risk. To achieve and maintain long term profitability, companies must successfully develop product candidates, obtain regulatory approval, and manufacture, market and sell those products for which regulatory approval is obtained. If this occurs, revenues depend on the size of markets in which product candidates receive approval, the 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. Not all companies succeed in these activities, and not all companies generate revenue from product sales that is significant enough to achieve profitability.

To have a chance of success, it is imperative that executives

a) possess the specialized skills to understand the complex products being developed and the various regulatory requirements imposed across the globe

b) apply high degrees of discipline to ensure research and trials are undertaken safely and effectively, to a rigorous standard and schedule, within tight budget constraints

c) seek to deliver earlier, with lower costs, key, well-defined milestones critical to progressing Mesoblast technology

d) stay focused on the end goal of commercialization.

While it may be many years from initial research until milestones lead to profitable outcomes, this does not reduce the importance of the milestones themselves. Without the interim milestone steps on the way to therapy commercialization, the extensive safety and efficacy data required would not be sufficient and approval by global regulatory authorities would not be achievable. Time and costs are an important component part in this process of research, testing and milestone achievement, as both have compounding effects on shareholder value.

To address the above, Mesoblast's remuneration framework comprises:

- competitive fixed remuneration
- annual incentives payments contingent on intensive research, approvals and trials being undertaken on time and budget
- longer term milestone-based incentive payments
- payment delivered, in part, as options, which conserves cash, aligns with shareholder interests, and focuses executives on strategy, risk management, and execution that optimizes shareholder value.

Mesoblast generally sets cash-based STIs at a lower quantum than option-based LTIs to conserve cash flow, focus executives on value creation, and align executives with shareholders.

The current average tenure of our executive team of 6.1 years suggests that the framework works well to attract and retain appropriate executive leadership.

Executive Remuneration Framework

Further details on the Mesoblast Executive Remuneration Framework is provided in Table 4 – Executive Remuneration Framework.

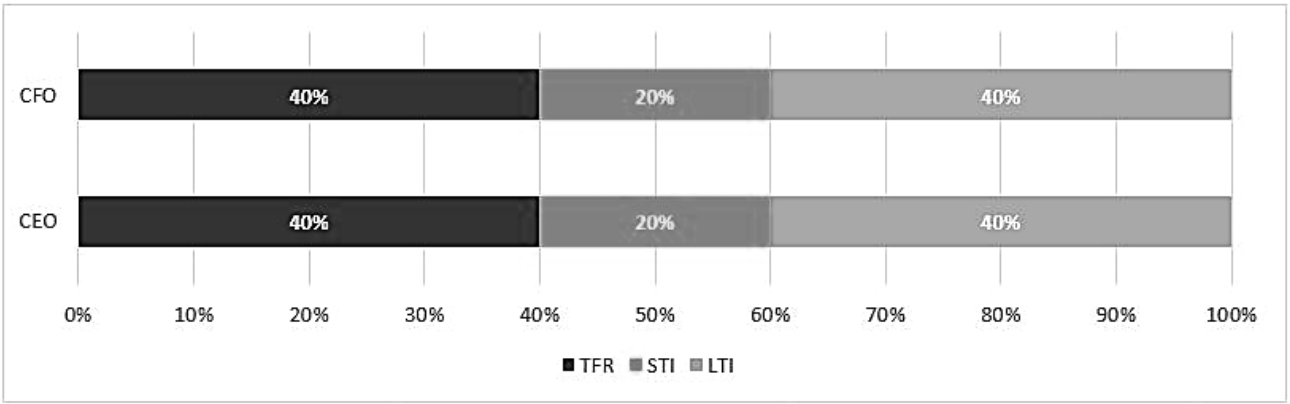
Table 4 – Executive Remuneration Framework

		Performance-based Remuneration	
	Fixed Pay	**Short-term Incentives**	**Long-term Incentives**
Strategic Rationale	Attract and retain key personnel on a global basis via competitive remuneration. Comply with regional statutory and customary benefits (e.g., superannuation in Australia; medical insurance in the US.)	Focuses attention on key KPIs (in areas such as clinical, financial and partnering strategy, manufacturing, commercial, or organizational structure and development) under cost and time constraints that will lead to long-term improvement in patient outcomes and shareholder wealth.	Serves multi-pronged purpose: - Aligns remuneration outcomes with shareholder wealth creation. - Provides a framework for wealth creation by prioritizing key objectives that are critical for long-term profitability. - Rewards speed of achievement, that can have long term compounding effects - Retains employees via deferral - Provides value only if milestones accumulate for increases in share price, aligning with the shareholder experience. - Conserves cash. - Enables risk management via malus.
Process	Assessed annually on market relativities in relevant markets based on position accountabilities. The Nomination and Remuneration Committee makes specific recommendations to the board on remuneration packages for senior executives for approval.	Paid annually for performance against annual corporate and individual KPIs. The Nomination and Remuneration Committee sets the CEO's KPIs. These are used to measure the company performance, which determines the pool available for other employees. Allocations from that pool for senior management are determined with reference to individual KPIs which have been set by the CEO. Resulting outcomes are approved by the Nomination and Remuneration Committee.	The Nomination and Remuneration Committee assesses vesting for the LTI milestones.
Eligibility	All employees	All employees hired on or before March 31, 2020 are eligible for consideration. Employees hired during the year are recognized on a pro-rata basis.	All eligible participants who are in positions to influence achievement of our long- term outcomes and, where required, for attraction and retention.

Quantum of opportunity	Set according to each position's accountabilities, the incumbent's experience and qualifications, and regional market relativities.	Set as a percentage of fixed pay. Quantum generally lower than LTI to conserve cash. Current CEO and CFO maximum STI: 50% of Fixed Remuneration.	Set using a percentage of fixed pay as a guideline. Current CEO maximum LTI: 100% of fixed remuneration Current CFO maximum LTI: 100% of fixed remuneration The actual grant value may vary year on year from this proportion based on various factors being taken account including: - shareholder dilution - internal relativities - share price volatility While the value may fluctuate on a year-to-year basis, the guideline should stand on a long term basis.
Delivered as	Cash	Cash	Options over ordinary shares in Mesoblast Limited with a 7-year expiry date. Option exercise price will be based on the 5-day VWAP prior to grant date.
Performance and service period	N/A	1 year	Three years with provision for earlier vesting limited to one third per year to (a) encourage speed of achievement, and (b) defer material amounts for better governance and (c) encourage executive focus on achievements that have a longer term impact on shareholder value.
Discretion, malus and clawback	N/A	The board has the authority to use its discretion to amend individual outcomes "in year", including down to zero, prior to any payment.	The board has ultimate discretion in determining vesting outcomes. Until options are exercised, the board may also apply discretion in situations where executives have behaved dishonestly or fraudulently to lapse options (unvested and vested).
Cessation of employment		No award will be made to employees who have ceased employment.	Unvested options are forfeited unless Board exercises discretion. Vested options can be retained subject to being exercised within 60 days of cessation or other timeframe specified by the board.
Hedging	The company's share trading policy prohibits hedging via the company's derivatives.		
Oversight	Individual outcomes are reviewed and approved first by the Nomination & Remuneration Committee and then the Board.		

The target remuneration mix at maximum for the CEO and the CFO is described in Figure 1.

Figure 1 – KMP Remuneration Mix.



The actual grant value year-on-year may vary from the target remuneration mix depending on factors such as:

- Dilution considerations
- Internal relativities
- Date of grant
- Difficulty of milestones

Remuneration Outcomes for FY2020

Mesoblast performance

In the financial year leading up to the turmoil caused by COVID-19, Mesoblast's share price had been increasing steadily and continues to do so, responding to executive team efforts to:

- Complete submission of Biologics License Application (BLA) for remestemcel-L in pediatric GvHD, with the FDA accepting the file for priority review,
- Submit an Investigational New Drug (IND) application for use of remestemcel-L in the treatment of patients with moderate to severe ARDS caused by COVID-19, which was cleared by the FDA. Subsequently initiate a 300-patient Phase 3 randomized controlled trial in patients with moderate to severe ARDS from COVID-19 in up to 30 sites across North America,
- Enter into strategic partnerships for key treatments – commercialization revenues have increased by 32% year-on-year and milestone revenues by 127% year on year,
- Raise funds and make key hires for the commercial launch of remestemcel-L in the US pending FDA approval,
- Realize clinical outcomes to develop Mesoblast's pipeline of clinical therapies and intellectual property,
- Scale up manufacturing for potential commercial launch, meeting stringent international regulatory agency criteria,
- Monitor and manage costs to conserve cash.

In addition, Mesoblast has implemented procedures to ensure staff remain healthy in the midst of the COVID-19 crisis, and the team created and leveraged an opportunity to improve outcomes for COVID-19 sufferers on ventilators. The speed with which the team has moved to realize the potential of remestemcel-L's anti-inflammatory qualities against COVID-19 has been enabled by an intense increase in work hours during a challenging time.

Table 5 provides some share price performance data and selected financial results.

Table 5 – Company share price performance and selected financial results over the last five years.

	Currency	2020	2019	2018	2017	2016
Share price (ASX:MSB)						
– closing at June 30	A$	3.25	1.48	1.48	2.08	1.08
– high for the year	A$	4.45	2.34	2.36	3.44	4.06
– low for the year	A$	1.02	1.04	1.19	1.03	1.01
Market capitalization at June 30 (millions)	A$	1,898	738	714	891	412
– increase/(decrease) – (millions)	A$	1,160	24	(177)	479	(855)
– increase/(decrease) – as %		157%	3%	(20%)	116%	(67%)
Revenue (millions)	US$	32,156	16,722	17,341	2,412	42,548
- increase/(decrease) - as %		92%	(4%)	619%	(94%)	NM
Loss before income tax	US$	(87,355)	(98,754)	(65,977)	(90,215)	(90,821)
Net Assets (millions)	US$	549,326	481,052	546,008	516,766	528,161

* NM = not meaningful.

Remuneration outcomes for the year ended June 30, 2020

Fixed remuneration

The CEO and CFO's fixed remuneration did not change from FY2019 to FY2020. The CEO's fixed remuneration has not changed since 2015.

STI

The quantum of the CEO's STI opportunity has reduced by 50% from FY2019 to FY2020 due to introduction of an LTI into the CEO's remuneration mix in response to investor feedback. This reduced the cash cost of the CEO's total remuneration by 40%.

As a result of the company's timely performance against the prespecified key financial, commercialization, clinical, organizational structure and next phase growth KPIs for the year, the CEO achieved 99% of his maximum STI. Discretion was applied to adjust the CEO STI by +11% for significantly exceeding KPIs in key categories and outstanding leadership during the onset of the COVID-19 pandemic, as a result of which Mesoblast was able to quickly make remestemcel-L available to sufferers of COVID-19 infected patients with ARDS through an expanded access protocol, commence a clinical trial in the same indication while also improving cash reserves and minimizing the impact of COVID-19 on our existing phase 3 programs and operations. The outcome of these achievements was significant accretion in value over the period. Therefore, the CEO achieved 110%[(1)] of his maximum STI. Details are provided in Table 6.

The CFO was awarded 95%[(2)] of his maximum STI for achieving his KPIs for accelerating the development and execution of corporate financings in response to both needs and opportunities arising during the year, associated targeted investor relations outcomes, as well as active control of budget expense when we had to rapidly adapt operations to respond to the pandemic and prioritize adjustments.

(1) No portion was forfeited.

(2) No portion was forfeited.

Table 6 - Performance against FY2020 STI KPIs

KPI Category	KPI	Maximum as % of total STI	Rating	Outcome as % of total STI
Execute on Major Clinical Programs				
Significant progress has been made on our major clinical programs during this year despite the challenges presented by COVID-19. Such clinical programs, if successful, form the basis for achieving approval to commercialize our technology for multiple indications. The Board assessed that this objective was completely achieved.				
Remestemcel-L	• Acute GvHD – Selected to present GvHD data at a major international bone marrow transplantation conference. Clinical outcomes published in three articles in prominent journal the	30%	100%	30%

	Biology of Blood and Marrow Transplantation. • Chronic GvHD – Commenced an investigator-initiated expanded access protocol trial and reported clinically meaningful outcomes.			
Chronic Heart Failure (CHF)	• CHF – Phase 3 trial in advanced Chronic Heart Failure patients surpassed the number of primary end point events for the trial. The data monitoring committee completed their final review of the phase 3 trial • LVAD – Attained FDA guidance on the clinical pathway for LVAD market application and clinical outcomes were presented at a major international cardiovascular scientific session			
Chronic Lower Back Pain (CLBP)	• CLBP – Continued patient visit and patient monitoring as our 404 patient phase 3 clinical trial in CLBP patients continued during the year. Continuation of patient visits, patient monitoring and data collection for our in the 404 patient phase 3 clinical trial.			
Execute on Financing and Partnering Strategy				
There have been substantial achievements during the year in this category. An important partnership was forged with Grünenthal. Additionally, two well executed private placements ensured the Group was well funded and able to continue its important development and commercialization work. These placements were completed at a minimal discount to the market price. The board assessed that this objective was completely achieved with performance exceeding target.				
Finance	• In September 2019, completed a strategic partnership with Grünenthal for Europe and Latin America to develop and commercialize our product candidate for the treatment of CLBP. • Successfully raised US$140 million of capital to fund ongoing operations across two separate raisings with minimal discount to prevailing share price at the time. • Successfully deferred principal repayment terms on our existing structure debt arrangements as a result of achieving key commercial milestones. • Substantial increase in share price of over 200% and market capitalization resulting in our inclusion in the S&P Dow Jones S&P/ASX All Australian 200 in June 2020.	25%	100%[1]	25%
Commercialization				
Substantial progress was made towards the potential granting of BLA approval by the FDA. Approval, if received, allows the company to begin to commercialize the technology for the approved indication. The board assessed that this objective was completely achieved with performance exceeding target.				
	• In January 2020 we completed BLA filing for remestemcel-L in pediatric steroid refractory acute GvHD patients and in March 2020 the United States Food and Drug Administration (FDA) accepted for priority review our BLA filing. • Subsequently the FDA provisionally reviewed the BLA and set an Oncologic Drugs Advisory Committee meeting date, at which there was a positive vote. PDUFA date set for September 30, 2020. • A commercial supply agreement was executed and sufficient commercial supply for a successful launch has been manufactured. • Commercial launch team established and launch plans completed.	30%	100%[1]	30%

Organization Structure and Development				
A critical element to our future success is to have the organizational capabilities to execute on our strategies. Significant achievements occurred during the year with the development of our existing talent and the recruitment of two well-credentialled executives. The board assessed that this objective was completely achieved.				
	• Appointment of a leading pharmaceutical industry executive with commercial experience as CMO. • Appointment of a COO with executive leadership experience in corporate and product strategy, market development and operational execution. • Enhanced external and internal communications of key milestones and program developments, and increased publications in journals and medical literature	10%	100%	10%
Next Phase Growth				
Developing our technologies for future opportunities is viewed by the board as an important element of our overall strategy. The company continued to make good progress in its pursuit of these opportunities – however given the other important priorities the company was dealing with the board assessed that this objective was partially to substantially met.				
	• Championed development of second-generation products. • Identification of early research with potential for development into viable therapy	5%	75%	4%
Total		**100%**	**NA**	**99%**
Discretion				
The board appreciates the additional, unintended work carried out by the company in response to the COVID-19 crisis and because of this, and coupled with the extraordinary performance against prespecified KPIs, has approved a discretionary allocation for this financial year.				
COVID-19 ARDS	• The board believes the company responded to the COVID-19 crisis in an impressive manner. Our people were protected and the company moved with great agility, speed and professionalism in receiving FDA clearance to treat patients suffering from acute respiratory distress syndrome (ARDS) caused by COVID-19, making our technology available through an EAP program that allowed some sufferers to be treated. Additionally, the company initiating an important clinical study in this patient group.			11%
Over achievement on pre-specified KPIs	• The Board has decided to adjust the CEO STI payout by +11% to bring his total STI payment to 110% as the Board believe that the company, through the leadership of the CEO, has performed exceptionally in responding to COVID-19 and has over achieved in many of the prespecified KPIs, including specifically both Commercialization and Execute on Finance and Partnering as outlined above, resulting in substantive value accretion during the period.			
Adjusted Total				**110%**

(1) For Commercialization and Execute on Finance and Partnering the Board rated performance as significantly exceeding target. This over performance has been taken into account in the Extraordinary Allocation.

LTI

Where an LTI milestone remains commercial in confidence it has been described in general terms. Many milestones also have an associated delivery window and/or budget which are taken into account when determining if it was achieved. Some clinical outcomes can be partially met depending on the quality and/or cost of results or extent of patient participation.

Two conditions must be met for milestone options to vest.

- The milestone for that option must be met
- Achievement must be within the performance period

The LTI options that will vest based on FY20 performance are summarized in Table 7, along with the financial year in which those options will vest.

Table 7 – LTI Outcomes of July 2019 grant

	Number of options granted	Milestone	Portion of grant attributed to milestone	Status	FY in which the tranche will vest based on time-based vesting conditions [1]
CEO	• 1,346,667[2]	• Granting of a PDUFA date for remestemcel-L[3].	50%	Achieved	FY21- 66.7% FY22- 33.3%
		• US FDA approval of remestemcel-L[3].	50%	Pending	Pending
CFO	• 500,000	• Completion of capital raisings (September 2019, May 2020).	40%	Achieved	FY21 – 41.7% FY22 – 41.7% FY23 – 16.6%
		• Support and implementation of Grünenthal licensing deal (September 2019).	40%	Achieved	FY21 – 41.7% FY22 – 41.7% FY23 – 16.6%
		• Execute key value accretive business development transactions.	20%	Pending	Pending

(1) Vesting based on milestones achieved as at June 30, 2020.

(2) This grant was approved by the Board on July 20, 2019 and granted on November 27, 2019 after shareholder approval for the grant was received at the AGM. 538,667 of the options granted were not milestone based and have not been included in the above table. The 538,667 options were granted as a substitute for a reduction made to the FY2019 short-term cash bonus to conserve cash.

(3) For the treatment of pediatric SR acute GVHD.

Table 8 represents remuneration paid to each executive KMP during the year as required by Section 300A of the Corporations Act 2001.

Table 8 – Statutory remuneration paid to executive KMP.

			Short-term benefits										
Name	Year	Currency	Base salary $	Short-term cash bonus[1] $	Annual Leave/ Holiday Pay $	Non-monetary benefits $	Health and Other Benefits[2] $	Post-employment benefits Super-annuation $	Long-term benefits Long service leave $	Share-based payments Options[3] $	Other Termi-nation benefits $	Total Statutory Remuneration $	% of performance-based remuneration %
Silviu Itescu - Executive Director													
	2020	A$	1,010,000	555,500	69,931	—	—	21,003	16,926	978,232	—	2,651,591	58%
	2019	A$	1,010,000	808,000	71,867	—	—	20,531	16,880	—	—	1,927,278	42%
Josh Muntner - Executive KMP													
	2020	A$[4]	568,876	306,652	18,245	—	41,066	—	—	339,301	—	1,274,139	51%
	2019	A$[4]	534,042	213,617	23,952	—	39,726	—	—	81,076	—	892,412	33%
	2020	US$	382,000	205,917	12,252	—	27,576	—	—	227,840	—	855,584	51%
	2019	US$	382,000	152,800	17,133	—	28,416	—	—	57,994	—	638,343	33%

(1) The CEO's 2019 Short-term bonus was revised from A$808,000 to A$404,000 upon shareholder approval of an option grant at the November 2019 AGM. The reduction in the short-term bonus was recognized in the Financial Statements in FY2020, this adjustment has not been included in the table above. The CFO bonus amount includes a deferred sign-on payment of US$24,467 in addition to an amount of US$181,450 awarded for achieving 95% of his STI target.

(2) Includes health, dental, vision, life, long and short-term disability insurances.

(3) The CEO's FY2020 share based payment includes A$280,418 related to options approved at the November 2019 AGM as a substitute for the reduction in the Short-term bonus

(4) The A$ results have been determined by calculating the average rate of the exchange rates on the last trading day of each month during the period. An A$:US$ exchange rate of 1:0.6715 has been used for the year ended June 30, 2020 and 1:0.7153 for the year ended June 30, 2019.

Non-Executive Director ("NED") Remuneration

As at June 30, 2020 the Board comprised of six NEDs; two based in Australia, three in the United States and one in Switzerland. These directors are global experts in the biopharmaceutical industry and capital markets, each with relevant experience in biotechnology and/or healthcare industries.

The NED fees (In Table 9) reflect responsibilities and work involved with directing a company of Mesoblast's technological and geographical complexity, our financial position, regulatory and compliance context, and market practice in each directors' domicile. The fee levels and structures reflect what is necessary to recruit and retain directors with global experience in this industry. There have been no changes to NED fees from last year.

Table 9 – NED fees
(exclusive of superannuation where applicable for Australian directors)

		As at June 30, 2020		
Position	Currency	Board of Directors	Audit and Risk Committee	Nomination and Remuneration Committee
Chair	US$	250,000	—	—
Chair	A$	—	20,000	20,000
Vice Chair	A$	175,000	—	—
Member	A$	128,250	10,000	10,000

The NEDs' fixed fees for their services are not to exceed a maximum fee pool of A$1,500,000, as approved by shareholders at the 2018 Annual General Meeting.

NEDs do not receive performance-related remuneration and are not provided with retirement benefits other than statutory superannuation. NEDs are reimbursed for costs directly related to conducting Mesoblast business. The key terms of NED service are documented in a letter of appointment to the Board.

Mesoblast grants options to directors, usually at the start of their tenure. Options in lieu of cash are typical in the biotechnology industry. These options are vest one third each after one, two and three years. The options are only able to be forfeited by the director if they engage in conduct that is adverse to the company or breach the terms of their engagement.

The grants enable Mesoblast to secure directors with global pharmaceutical experience cash-effectively. Governance is not compromised because no performance or service conditions apply. The majority of shareholders voted in favor of the grants made during FY20 at the AGM in November 2019.

Further detail on the number of options and exercise price can be found in section “Terms and conditions of share-based payment arrangements”.

Remuneration Details - NEDs

Details of the remuneration of our NEDs for the years ended June 30, 2020 and June 30, 2019 are in Table 10.

Table 10 – Director Fees

Name	Year	Currency	Base Salary	Super-annuation	Share-based payments Options	Total Statutory Remuneration
Joseph Swedish	2020	A$	370,706	—	175,571	546,278
Joseph Swedish	2019	A$	189,855	—	134,263	324,118
William Burns	2020	A$	185,000	—	62,495	247,495
William Burns	2019	A$	179,516	—	21,748	201,264
Donal O’Dwyer	2020	A$	158,250	15,034	23,241	196,525
Donal O’Dwyer	2019	A$	148,465	14,104	18,124	180,693
Eric Rose	2020	A$	128,250	—	62,495	190,745
Eric Rose	2019	A$	128,250	—	21,748	149,998
Michael Spooner	2020	A$	158,250	15,034	23,241	196,525
Michael Spooner	2019	A$	148,465	14,104	18,124	180,693
Shawn Tomasello	2020	A$	128,250	—	43,489	171,738
Shawn Tomasello	2019	A$	124,802	—	93,533	218,335
Brian Jamieson[1]	2019	A$	187,500	15,399	27,185	230,084
Total non-executive directors	2020	**A$**	**1,128,706**	**30,067**	**390,532**	**1,549,304**
Total non-executive directors	2019	**A$**	**1,106,854**	**43,607**	**334,726**	**1,485,185**
Total non-executive directors [2]	2020	**US$**	**757,926**	**20,190**	**262,242**	**1,040,358**
Total non-executive directors [2]	2019	**US$**	**791,732**	**31,192**	**239,429**	**1,062,353**

(1) Brian Jamieson resigned on March 31, 2019.

(2) The US$ result have been determined by calculating the average rate of the exchange rates on the last trading day of each month during the period. An A$:US$ exchange rate of 1:0.6715 has been used for the year ended June 30, 2020 and 1:0.7153 for the year ended June 30, 2019.

Terms and conditions of option grants and equity holdings

Details of options over ordinary shares provided as remuneration to each director and member of key management personnel for the years ended June 30, 2020 and June 30, 2019 are provided in the tables below.

Table 11 – The value of options granted, exercised and lapsed.

	Number of options granted	Remuneration consisting of options [1]	Value of options granted [2] A$	Value of options exercised [3] A$	Value of options lapsed [4] A$
For the year ended June 30, 2020					
Silviu Itescu	1,885,334	37%	1,950,000	—	—
Joseph Swedish	—	32%	—	—	—
William Burns	100,000	25%	93,500	—	—
Donal O'Dwyer	—	12%	—	—	—
Eric Rose	100,000	33%	93,500	—	—
Michael Spooner	—	12%	—	—	—
Shawn Tomasello	—	25%	—	—	—
Josh Muntner	500,000	27%	544,650	—	—
For the year ended June 30, 2019					
Joseph Swedish	500,000	41%	404,790	—	—
William Burns	120,000	11%	64,584	—	—
Donal O'Dwyer	100,000	10%	53,820	—	—
Eric Rose	120,000	14%	64,584	—	—
Michael Spooner	100,000	10%	53,820	—	—
Shawn Tomasello	200,000	43%	155,080	—	—
Brian Jamieson[5]	150,000	12%	80,730	—	—
Josh Muntner	300,000	9%	173,010	—	—

(1) The percentage of the value of remuneration consisting of options, based on the value of options expensed during the year presented in accordance with IFRS 2 *Share-based Payment*. For details on the assumptions made for each grant, see information in share-based payments section of report.

(2) The accounting value at acceptance date of options that were granted during the year presented as part of remuneration, determined using Black-Scholes valuation model and in accordance with IFRS 2 *Share-based Payment*. The acceptance date is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.

(3) The intrinsic value at exercise date of options that were exercised during the year presented, having been granted as part of remuneration previously.

(4) The intrinsic value at lapse date of options that lapsed during the year.

(5) Brian Jamieson resigned on March 31, 2019.

There have been no modifications to any terms and conditions of share-based payment transactions during the years ended June 30, 2019 and 2020.

Reconciliation of Options held by KMP

The table below shows a reconciliation of options held by each KMP from the beginning to the end of FY2020.

Table 12 – Reconciliation of options held by each KMP during FY2020.

		Balance at the start of the year		Granted during the year	Vested during the year		Exercised during the year	Forfeited / Lapsed during the year		Balance at the end of the year	
Name	Grant Date	Unvested	Vested	Number	Number	%	Number	Number	%	Vested and unexercisable	Unvested
Silviu Itescu	27-Nov-19[1]	—	—	1,885,333	—	—	—	—	—	—	1,885,333
Josh Muntner	20-Jul-19	—	—	500,000	—	—	—	—	—	—	500,000
Josh Muntner	15-Jul-18	300,000	—	—	100,000	33	—	—	—	100,000	200,000
William Burns	27-Nov-19	—	—	100,000	—	—	—	—	27	—	100,000
William Burns	30-Nov-18	120,000	—	—	40,000	33	—	—	—	40,000	80,000
William Burns	25-Nov-14	—	80,000	—	—	—	—	80,000	—	—	—
Donal O'Dwyer	30-Nov-18	100,000	—	—	33,333	33	—	—	—	33,333	66,667
Eric Rose	27-Nov-19	—	—	100,000	—	—	—	—	27	—	100,000
Eric Rose	30-Nov-18	120,000	—	—	40,000	33	—	—	—	40,000	80,000
Eric Rose	25-Nov-14	—	80,000	—	—	—	—	80,000	—	—	—
Michael Spooner	30-Nov-18	100,000	—	—	33,333	33	—	—	—	33,333	66,667
Joseph Swedish	27-Nov-19	—	—	300,000	100,000	33	—	—	—	100,000	200,000
Joseph Swedish	30-Nov-18	133,333	66,667	—	66,667	33	—	—	—	133,334	66,666
Shawn Tomasello	30-Nov-18	200,000	—	—	66,667	33	—	—	—	66,667	133,333

(1) This grant was approved by the Board on July 20, 2019 and granted on November 27, 2019 after shareholder approval for the grant was received at the AGM.

Terms and conditions of share-based payment arrangements

The terms and conditions of each grant of options affecting remuneration in the current or a future reporting period are as follows:

Table 13 – Terms and conditions of share-based payment arrangements

Grant date	Recipients of Grants	Vesting date	Expiry date	Exercise price A$	Value per option at acceptance date A$
27-Nov-19[1]	Silviu Itescu	Vesting in accordance with the following schedule, but only after achievement of performance milestones: one third - 19-Jul-2020 one third - 19-Jul-2021 one third - 19-Jul-2022	19-Jul-26	1.47	1.03
27-Nov-19[1]	Silviu Itescu	one third - 19-Jul-2020 one third - 19-Jul-2021 one third - 19-Jul-2022	19-Jul-26	1.47	1.03
27-Nov-19	William Burns Eric Rose	one third - 17 Nov 2020 one third - 17 Nov 2021 one third - 17 Nov 2022	17-Nov-26	1.83	0.94
27-Nov-19	Joseph Swedish	one third - 4 Apr 2020 one third - 4 Apr 2021 one third - 4 Apr 2022	03-Apr-26	1.48	0.78
20-Jul-19	Josh Muntner	Vesting in accordance with the following schedule, but only after achievement of performance milestones: one third - 19-Jul-2020 one third - 19-Jul-2021 one third - 19-Jul-2022	19-Jul-26	1.47	1.09[2]
30-Nov-18	William Burns Eric Rose Michael Spooner Donal O'Dwyer	one third - 30 Nov 2019 one third - 30 Nov 2020 one third - 30 Nov 2021	29-Nov-25	1.33	0.54
30-Nov-18	Joseph Swedish	one third - 18 Jun 2019 one third - 18 Jun 2020 one third - 18 Jun 2021	17-Jun-25	1.52	0.85
30-Nov-18	Shawn Tomasello	one third - 11 Jul 2019 one third - 11 Jul 2020 one third - 11 Jul 2021	10-Jul-25	1.56	0.78
15-Jul-18	Josh Muntner	one third - 15 Jul 2019 one third - 15 Jul 2020 one third - 15 Jul 2021	14-Jul-25	1.72	0.58[3]
25-Nov-14	William Burns Eric Rose	one third - 25 Nov 2015 one third - 25 Nov 2016 one third - 25 Nov 2017	24-Nov-19	4.00	1.30

(1) This grant was approved by the Board on July 20, 2019 and granted on November 27, 2019 after shareholder approval for the grant was received at the AGM.
(2) The acceptance date on which these options have been valued is December 17, 2019.
(3) The acceptance date on which these options have been valued is January 17, 2019.

Table 14 - Shares provided to KMPs on the exercise of remuneration options

	No. of options exercised during the period	No. of ordinary shares in Mesoblast Limited issued	Exercise Date	Value per share at exercise date (closing price) A$	Exercise price per option A$
For the year ended June 30, 2020					
Nil	—	—	—	—	—
For the year ended June 30, 2019					
Nil	—	—	—	—	—

Options Granted as Remuneration

The following table presents options that have been granted over unissued shares during or since the end of the year ended June 30, 2020, to our Directors and our next 5 most highly remunerated officers.

Table 15 – Options Granted as Remuneration

Name	Issue Date	Exercise Price A$	Number of shares, under option
Directors			
Silviu Itescu	27-Nov-19[1]	1.47	1,885,333
Non-Directors			
Fred Grossman	29-Aug-19	1.47	800,000
Fred Grossman	29-Aug-19	1.62	400,000
Peter Howard	20-Jul-19	1.47	700,000
Josh Muntner	20-Jul-19	1.47	500,000
Michael Schuster	20-Jul-19	1.47	700,000
Eric Strati	20-Jul-19	1.47	700,000

(1) This grant was approved by the Board on July 20, 2019 and granted on November 27, 2019 after shareholder approval for the grant was received at the AGM.

KMP Shareholdings

The table below shows a reconciliation of ordinary shares held by each KMP from the beginning to the end of the 2020 financial year.

Table 16 – KMP Shareholdings

Name	Balance at the start of the year	Received during the year upon exercise of options	Other changes during the year	Balance at the end of the year
Silviu Itescu	68,958,928	—	—	68,958,928
Josh Muntner	—	—	—	—
Joseph Swedish	—	—	—	—
William Burns	30,330	—	32,670	63,000
Donal O'Dwyer	1,149,142	—	85,250	1,234,392
Eric Rose	—	—	—	—
Michael Spooner[1]	1,091,335	—	—	1,091,335
Shawn Tomasello	—	—	—	—

(1) Of this balance, Mr. Spooner has a relevant interest of 1,069,000 ordinary shares.

Employment Agreements

The employment of our CEO and CFO are formalized in employment agreements, the key terms of which are as follows:

Table 17 – KMP Employment Agreements

Name	Term	Notice period	Termination benefit
Silviu Itescu (CEO)	Initial term of 3 years commencing April 1, 2014, and continuing subject to a 12 months' notice period.	12 months	12 months base salary
Josh Muntner (CFO)	An ongoing employment agreement until notice is given by either party.	1 month	12 months base salary

On termination of employment our CEO, who is based in Australia, is entitled to receive his statutory entitlements of accrued annual and long service leave, together with any superannuation benefits.

On termination of employment our CFO, who is based in the United States, is entitled to participate in the Company's healthcare plan during the severance period.

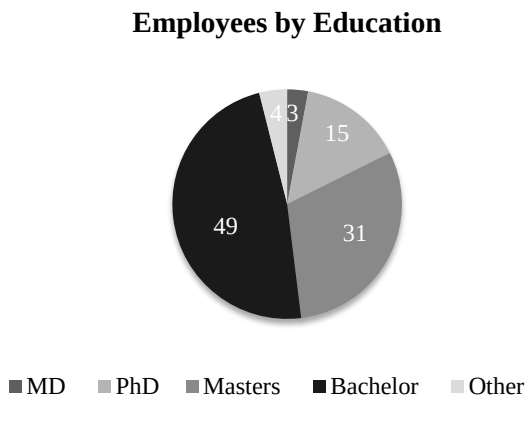
There is no entitlement to a termination payment in the event of resignation (except, in the case of the CFO, if the Company has materially reduced his role or benefits or materially moved office location) or removal for misconduct.

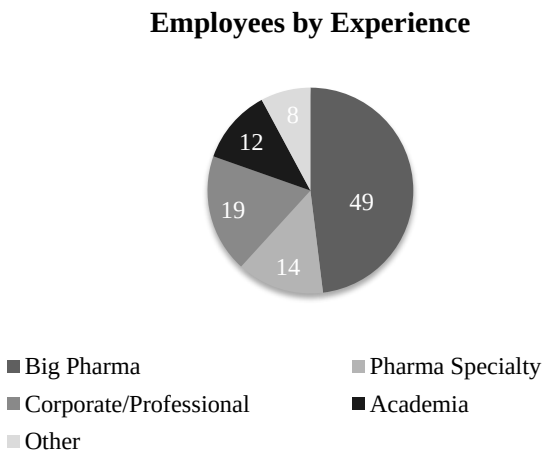
KMP Loans or related transactions

There were no loans or related transactions with KMP during the financial year.

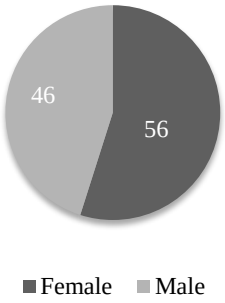
Employee Profile

As of June 30, 2020, we had 102 (2019: 83) employees globally:

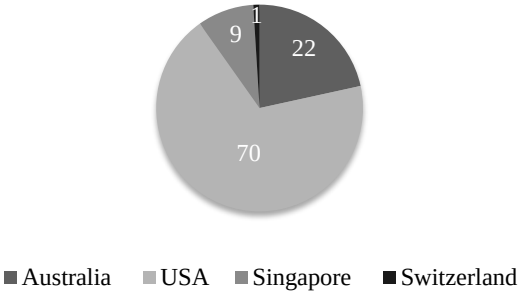




Employees by Gender



Employees by Region



69% of our employees and a majority of our executives are based in the United States where Mesoblast operational activities are concentrated.

Australia is corporate headquarters where 22% of the employees work. This includes the CEO and a portion of the executive team. The remaining 9% of employees are located in Singapore (8%) and 1% in Switzerland where research and development activities are primarily conducted.

(End of Remuneration Report)

Australian Disclosure Requirements

Shares under option

Unissued ordinary shares of Mesoblast Limited under option at the date of this Directors' report are as follows:

Grant date	Exercise price of options A$	Expiry date of options	Number of shares under option
10/07/2015	4.20	30/06/2022	2,268,334
26/08/2015	4.05	16/08/2022	75,000
27/04/2016	2.80	6/03/2023	2,638,334
27/04/2016	2.74	17/04/2023	200,000
30/06/2016	2.20	18/01/2021	900,000
31/10/2016	2.80	6/03/2023	200,000
06/12/2016	1.31	5/12/2023	923,000
06/12/2016	1.19	5/12/2023	2,519,064
13/01/2017	1.65	12/01/2024	300,000
28/06/2017	2.23	27/06/2024	150,000
16/09/2017	1.54	15/09/2024	66,666
16/09/2017	1.40	15/09/2024	150,000
13/10/2017	1.94	12/10/2024	1,655,000
13/10/2017	1.76	12/10/2024	1,302,425
24/11/2017	1.41	23/11/2024	750,000
24/11/2017	1.28	23/11/2024	750,000
18/06/2018	1.52	17/06/2025	200,000
11/07/2018	1.56	10/07/2025	200,000
15/07/2018	1.72	14/07/2025	300,000
18/07/2018	1.87	17/07/2025	5,398,334
18/07/2018	1.87	17/07/2025	350,000
30/11/2018	1.33	29/11/2025	590,000
19/01/2019	1.45	18/01/2026	5,000
19/01/2019	1.45	18/01/2026	150,000
04/04/2019	1.48	3/04/2026	300,000
29/05/2019	1.48	28/05/2026	450,000
20/07/2019	1.62	19/07/2026	4,690,000
20/07/2019	1.47	19/07/2026	5,500,000
20/07/2019	1.47	19/07/2026	1,346,667
20/07/2019	1.47	19/07/2026	538,667
20/07/2019	1.47	19/07/2026	700,000
20/07/2019	1.47	19/07/2026	400,000
29/08/2019	1.47	28/08/2026	150,000
29/08/2019	1.62	28/08/2026	400,000
29/08/2019	1.47	28/08/2026	800,000
18/11/2019	1.83	17/11/2026	200,000
25/11/2019	1.98	24/11/2026	845,000
25/11/2019	1.80	24/11/2026	100,000
25/11/2019	1.98	24/11/2026	450,000
Grand Total			**38,911,491**

No option holder has any right under the options plan to participate in any other of our share issues.

Shares issued on exercise of options during the year

Detail of shares or interests issued as a result of the exercise of options during or since the end of the financial year are:

Grant date	Currency	Number of shares issued	Issue Price	Amount unpaid per share
27-Oct-06	US$	319,892	0.34	—
27-Apr-16	A$	475,000	2.80	—
06-Dec-16	A$	1,527,270	1.19	—
06-Dec-16	A$	720,334	1.31	—
16-Sep-17	A$	33,334	1.54	—
13-Oct-17	A$	297,575	1.76	—
13-Oct-17	A$	310,000	1.94	—
19-Jan-18	A$	600,000	2.20	—
18-Jul-18	A$	389,999	1.87	—
29-Aug-19	A$	150,000	1.47	—
Total		**4,823,404**		—

Indemnification of Officers

During the financial year, we paid premiums in respect of a contract insuring our directors and company secretaries, and all of our executive officers. The liabilities insured are to the extent permitted by the *Corporations Act 2001*. Further disclosure required under section 300(9) of the *Corporations Act 2001* is prohibited under the terms of the insurance contract.

Proceedings on Our Behalf

The *Corporations Act 2001* allows specified persons to bring, or intervene in, proceedings on our behalf. No proceedings have been brought or intervened in on our behalf with leave of the Court under section 237 of the *Corporations Act 2001*.

Non-Audit Services

We may decide to employ the auditor on assignments additional to their statutory audit duties where the auditor's expertise and experience are relevant and considered to be important.

The board of directors has considered the position and in accordance with advice received from the audit committee, is satisfied that the provision of the non-audit services is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001*. The directors are satisfied that the provision of the non-audit services as set out below, did not compromise the auditor independence requirements of the *Corporations Act 2001* because the services are not deemed to undermine the general principles relating to auditor independence as set out in APES 110 Code of Ethics for Professional Accountants.

During both the current and prior financial years, no fees were paid or payable for non-audit services provided by the auditor of the parent entity, its related practices and non-related audit firms.

Auditor's Independence Declaration

A copy of the auditor's independence declaration under Section 307C of the Corporations Act in relation to the audit for the year ended June 30, 2020 is included in Exhibit 99.2 of this annual report on Form 20-F.

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 directors' report. 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.

The components of our directors' report are incorporated in various places within this annual report on the Form 20-F. A table charting these components is included within 'Exhibit 99.1 Appendix 4E'.

Directors' Resolution

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

/s/ Joseph R Swedish	/s/ Silviu Itescu
Joseph R Swedish	Silviu Itescu
Chairman	Chief Executive Officer

Dated: August 27, 2020

6.C Board Practices

Our board of directors currently consists of seven members, including six non-executive directors and one executive director, our Chief Executive Officer.

Our directors are generally elected to serve three-year terms in a manner similar to a "staggered" board of directors under Delaware law. No director, except the Managing Director (currently designated as our Chief Executive Officer, Silviu Itescu), may hold office for a period in excess of three years, or beyond the third annual general meeting following the director's last election, whichever is the longer, without submitting himself or herself for re-election. As a result of the staggered terms, not all of our directors will be elected in any given year. The current term of Mr. O'Dwyer will expire at the annual shareholders' meeting in 2020.

Name	First election at AGM	Last election at AGM	End of current term
William Burns	2014	2019	2022
Donal O'Dwyer	2004	2017	2020
Eric Rose	2013	2019	2022
Michael Spooner	2004	2018	2021
Joseph Swedish	2018	2018	2021
Shawn Cline Tomasello	2018	2018	2021

We believe that each of our directors has relevant industry experience. The membership of our board of directors is directed by the following requirements:

- our Constitution specifies that there must be a minimum of 3 directors and a maximum of 10, and our board of directors may determine the number of directors within those limits;
- we may appoint or remove any director by resolution passed in the general meeting of shareholders;
- our directors may appoint any person to be a director, and that person only holds office until the next general meeting at which time the director may stand for election by shareholders at that meeting;
- it is the intention of our board of directors that its membership consists of a majority of independent directors who satisfy the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations;
- the chairperson of our board of directors should be an independent director who satisfies the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations;
- Australia's Corporations Act requires that at least two of our directors must be resident Australians; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience, and time commitment to properly fulfill its responsibilities or have ready access to such skills where they are not available.

Our board of directors is responsible for, and has the authority to determine, all matters relating to our corporate governance, including the policies, practices, management and operation. The principal roles and responsibilities of our board of directors are to:

- facilitate board of directors and management accountability to our company and its shareholders;
- ensure timely reporting to shareholders;
- provide strategic guidance to us, including contributing to the development of, and approving, the corporate strategy;
- oversee management and ensure there are effective management processes in place;
- monitor:
  - organizational performance and the achievement of our strategic goals and objectives;
  - financial performance including approval of the annual and half-year financial reports and liaison with our auditors;
  - progress of major capital expenditures and other significant corporate projects including any acquisitions or divestments;
  - compliance with our code of conduct;
  - progress in relation to our diversity objectives and compliance with its diversity policy;
- review and approve business plans, the annual budget and financial plans including available resources and major capital expenditure initiatives;

- approve major corporate initiatives;
- enhance and protect the reputation of the organization;
- oversee the operation of our system for compliance and risk management reporting to shareholders; and
- ensure appropriate resources are available to senior management.

Our non-executive directors do not have any service contracts with Mesoblast that provide for benefits upon termination of employment.

Committees

To assist our board of directors with the effective discharge of its duties, it has established a Nomination and Remuneration Committee and an Audit and Risk Management Committee. Each committee operates under a specific charter approved by our board of directors.

Nomination and Remuneration Committee. The members of our Nomination and Remuneration Committee are Messrs. Burns, O'Dwyer (Chairman) and Spooner, all of whom are independent, non-executive directors. The remuneration committee is a committee of our board of directors, and is primarily responsible for making recommendations to our board of directors on:

- board appointments;
- non-executive director fees;
- the executive remuneration framework;
- remuneration of executive directors, including the CEO and other key executives;
- short-term and long-term incentive awards; and
- share ownership plans.

The committee's objective is to ensure remuneration policies are fair and competitive and in line with similar industry benchmarks while aligned with our objectives. The remuneration committee seeks independent advice from remuneration consultants as and when it deems necessary. See "Management—Remuneration."

Audit and Risk Management Committee. The members of our Audit and Risk Management Committee are Messrs. O'Dwyer, Spooner (Chairman) and Swedish, all of whom are independent, non-executive directors. This committee oversees, reviews, acts on and reports on various auditing and accounting matters to our board of directors, including the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices. In addition, the committee oversees, reviews, acts on and reports on various risk management matters to our board of directors.

The effective management of risk is central to our ongoing success. We have adopted a risk management policy to ensure that:

- appropriate systems are in place to identify, to the extent that is reasonably practical, all material risks that we face in conducting our business;
- the financial impact of those risks is understood and appropriate controls are in place to limit exposures to them;
- appropriate responsibilities are delegated to control the risks; and
- any material changes to our risk profile are disclosed in accordance with our continuous disclosure reporting requirements in Australia.

It is our objective to appropriately balance, protect and enhance the interests of all of our shareholders. Proper behavior by our directors, officers, employees and those organizations that we contract to carry out work is essential in achieving this objective.

We have established a code of conduct, which sets out the standards of behavior that apply to every aspect of our dealings and relationships, both within and outside Mesoblast. The following standards of behavior apply:

- patient well-being;
- comply with all laws that govern us and our operations;

- act honestly and with integrity and fairness in all dealings with others and each other;
- avoid or manage conflicts of interest;
- use our assets properly and efficiently for the benefit of all of our shareholders; and
- seek to be an exemplary corporate citizen.

6.D Employees

As of June 30, 2020, we had 102 employees, 70 of whom are based in the United States, 22 of whom are based in Australia, including our CEO and certain executive team members, 9 of whom are based in Singapore, and 1 of whom is based in Switzerland. We had 83 and 81 employees as of June 30, 2019 and 2018, respectively.

The table below sets forth the breakdown of the total year-end number of our employees by main category of activity and geographic area for the past three years:

As of June 30, 2020	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	43	11	3	13	70
Australia	7	—	—	15	22
Singapore	5	—	3	1	9
Switzerland	—	—	—	1	1
Total	**55**	**11**	**6**	**30**	**102**

As of June 30, 2019	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	37	1	3	10	51
Australia	7	—	—	16	23
Singapore	5	—	2	1	8
Switzerland	—	—	—	1	1
Total	**49**	**1**	**5**	**28**	**83**

As of June 30, 2018	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	31	1	4	12	48
Australia	8	—	—	16	24
Singapore	5	—	2	1	8
Switzerland	—	—	—	1	1
Total	**44**	**1**	**6**	**30**	**81**

We have no collective bargaining agreement with our employees. We have not experienced any work stoppages to date and consider our relations with our employees to be good.

See “Item 6.A Directors and Senior Management – Employee Profile”.

6.E Share Ownership

The table below sets forth information regarding the beneficial ownership of our ordinary shares based on 583,949,612 ordinary shares outstanding at June 30, 2020 by each of our directors and key management personnel.

We have determined beneficial ownership in accordance with the rules of the SEC - it generally means that a person has a beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options that are exercisable within 60 days of June 30, 2020. Ordinary shares subject to options currently exercisable or exercisable within 60 days of June 30, 2019 are deemed to be outstanding for computing the percentage ownership of the person holding these options and the percentage ownership of any group of which the holder is a member, however are not deemed outstanding for computing the percentage of any other person.

Unless otherwise indicated, to our knowledge each shareholder possesses sole voting and investment power over the ordinary shares listed. None of our shareholders has different voting rights from other shareholders. Unless otherwise indicated, the principal address of each of the shareholders below is c/o Mesoblast Limited, Level 38, 55 Collins Street, Melbourne 3000, Australia.

	Ordinary Shares beneficially owned	
Name	**Number**	**%**
Directors and key management personnel:		
Silviu Itescu[(1)]	68,958,928	11.8%
Josh Muntner [(2)]	200,000	*
William Burns[(3)]	103,000	*
Donal O'Dwyer[(4)]	1,267,725	*
Eric Rose[(5)]	40,000	*
Michael Spooner[(6)]	1,093,333	*
Joseph Swedish[(7)]	233,334	*
Shawn Tomasello[(8)]	133,334	*
All directors and key management personnel as a group (8 persons)	**72,029,654**	**12.3%**

* Less than 1% of the outstanding ordinary shares.

(1) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu, (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund and (c) 714,286 ordinary shares owned by Tamit Nominees Pty Ltd, an Australian corporation owned by Dr. Itescu.

(2) Includes 200,000 ordinary shares subject to options exercisable at a price of A$1.72 per share until July 14, 2025.

(3) Includes (a) 63,000 ordinary shares owned by Mr. Burns and (b) 40,000 ordinary shares subject to options exercisable at a price of A$1.33 per share until November 29, 2025.

(4) Includes (a) 1,234,392 ordinary shares owned by Dundrum Investments Ltd. as trustee for The O'Dwyer Family Trust. Mr. O'Dwyer and his spouse are the sole shareholders of Dundrum Investments Ltd and (b) 33,333 ordinary shares subject to options exercisable at a price of A$1.33 per share until November 29, 2025.

(5) Includes 40,000 ordinary shares subject to options exercisable at a price of A$1.33 per share until November 29, 2025.

(6) Includes (a) 1,060,000 ordinary shares owned by Mr. Spooner and (b) 33,333 ordinary shares subject to options exercisable at a price of A$1.33 per share until November 29, 2025.

(7) Includes 233,334 ordinary shares subject to options of which; 133,334 are exercisable at a price of A$1.52 per share until June 17, 2025 and 100,000 are exercisable at a price of A$1.48 per share until April 3, 2026.

(8) Includes 133,334 ordinary shares subject to options exercisable at a price of A$1.56 per share until July 10, 2025.

Item 7. Major Shareholders and Related Party Transactions

7.A Major Shareholders

The following table and accompanying footnotes present certain information regarding the beneficial ownership of our ordinary shares based on 583,949,612 ordinary shares outstanding at June 30, 2020 by each person known by us to be the beneficial owner of more than 5% of our ordinary shares. Based upon information known to us, as of June 30, 2020 we had 42 shareholders (ordinary shares) in the United States. These shareholders held an aggregate of 102,177,353 of our ordinary shares, or approximately 22% of our outstanding ordinary shares. None of our shareholders has different voting rights from other shareholders.

	Ordinary Shares beneficially owned	
Name	**Number**	**%**
5% or Greater Shareholders:		
M&G Investment Group[(1)]	70,068,935	12.0%
Silviu Itescu[(2)]	68,958,928	11.8%
Thorney Holdings[(3)]	30,477,834	5.2%

(1) Includes ordinary shares owned indirectly through custodial accounts, over which shares M&G Investment Group retains voting and dispositive power. The address for M&G Investment Group is 5 Laurence Pountney Hill, London EC4R 0HH, United Kingdom.

(2) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu, (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund and (c) 714,286 ordinary shares owned by Tamit Nominees Pty Ltd, an Australian corporation owned by Dr. Itescu.

(3) Includes ordinary shares owned indirectly through custodial accounts, over which shares Thorney Holdings retains voting and dispositive power. The address for Thorney Holdings is 55 Collins Street, Level 39, Melbourne, Victoria 3000, Australia.

To our knowledge, there have not been any significant changes in the ownership of our ordinary shares by major shareholders over the past three years, except as follows (which is based on substantial shareholder notices filed with the ASX and SEC).

- M&G Investment Group reported on September 6, 2017 that it acquired 11,794,313 ordinary shares between July 12, 2017 and September 6, 2017, and that in total it held 65,452,353 ordinary shares (including 1,537,794 ADSs each representing 5 ordinary shares), or 14.19% of the total voting power as of that date. It reported on December 31, 2017 that it acquired 3,845,543 ordinary shares between September 7, 2017 and December 31, 2017, and that in total it held 69,297,896 ordinary shares (including 1,532,843 ADSs, each representing 5 ordinary shares), or 14.73% of the total voting power as of that date. It reported on October 16, 2018 that it disposed of 1,348,839 ordinary shares (including 42,631 ADSs, each representing 5 ordinary shares) between December 13, 2017 and September 11, 2018, and that in total it held 68,041,831 ordinary shares (including 1,490,212 ADSs, each representing 5 ordinary shares), or 13.67% of the total voting power as of that date. It reported on January 30, 2019 that in total it held 67,993,821 ordinary shares or 13.67% of the total voting power as of December 31, 2018. It reported that as of July 10, 2019 in total it held 65,636,115 ordinary shares (including 1,491,414 ADSs, each representing 5 ordinary shares), or 13.15% of the total voting power as of that date. It reported that as of on October 8, 2019 in total it held 70,636,115 ordinary shares (including 1,491,414 ADSs, each representing 5 ordinary shares), or 13.15% of the total voting power as of that date. It reported that as of May 25, 2020 in total it held 70,068,935 ordinary shares (including 1,391,475 ADSs, each representing 5 ordinary shares), or 12.05% of the total voting power as of that date. It reported that as of August 6, 2020 in total it held 64,531,906 ordinary shares (including 1,385,525 ADSs, each representing 5 ordinary shares), or 11.04% of the total voting power as of that date. It reported that as of August 20, 2020 in total it held 58,000,971 ordinary shares (including 1,142,337 ADSs, each representing 5 ordinary shares), or 9.91% of the total voting power as of that date.
- The Capital Group Companies, Inc. reported on 4 December 2019 that it had ceased to be a substantial shareholder.

7.B Related Party Transactions

The Company has not entered into any related party transactions during the year ended June 30, 2020 other than compensation made to Directors and other members of key management personnel, see "Item 6.B Compensation".

7.C Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

8.A Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividend policy

Since our inception, we have not declared or paid any dividends on our shares. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our ordinary shares. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to Australian law.

Any dividend we declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of our ADSs, subject to the terms of the deposit agreement. See "Item 12.D. Description of American Depositary Shares."

8.B Significant Changes

On August 13, 2020, the Oncologic Drugs Advisory Committee ("ODAC") of the United States Food and Drug Administration ("FDA") voted overwhelmingly in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA). Assumptions associated with SR-aGVHD in pediatric patients is included within the total valuation of contingent consideration, Osiris MSC products within in-process research and development and NovaQuest borrowings on the balance sheet.

In August 2020, we amended the terms of the Hercules loan agreement to defer the commencement of principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

There were no other events that have arisen subsequent to June 30, 2020 and prior to the signing of this report that would likely have a material impact on the financial results presented.

Item 9. The Offer and Listing

9.A Offer and Listing Details

Our ordinary shares have been listed in Australia on the Australian Securities Exchange (ASX) since December 2004. Our ordinary shares have been trading under the symbol "MSB".

American Depositary Shares ("ADSs"), each representing five ordinary shares, are available in the US through an American Depositary Receipts ("ADR") program. This program was established under the deposit agreement which we entered into with JP Morgan Chase Bank N.A. as depositary and our ADR holders. Our ADRs have been listed on the Nasdaq Global Select Market since August 2015 and are traded under the symbol "MESO".

9.B Plan of Distribution

Not applicable.

9.C Markets

See “Item 9.A Offer and Listing Details.”

9.D Selling Shareholders

Not applicable.

9.E Dilution

Not applicable.

9.F Expenses of the Issue

Not applicable.

Item 10. Additional Information

10.A Share Capital

Not applicable.

10.B Memorandum and Articles of Association

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of Mesoblast. Our Constitution is subject to the terms of the ASX Listing Rules and the Australian Corporations Act. It may be modified or repealed and replaced by special resolution passed at a meeting of shareholders, which a resolution is passed by at least 75% of the votes cast by shareholders (including proxies and representatives of shareholders) entitled to vote on the resolution.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete nor to constitute a definitive statement of the rights and liabilities of our shareholders, and is qualified in its entirety by reference to the complete text of our Constitution, a copy of which is on file with the SEC.

Directors

Interested Directors

Except as permitted by the Corporations Act and the ASX Listing Rules, a director must not vote in respect of a matter that is being considered at a directors' meeting in which the director has a material personal interest according to our Constitution. Such director must not be counted in a quorum, must not vote on the matter and must not be present at the meeting while the matter is being considered.

Pursuant to our Constitution, the fact that a director holds office as a director, and has fiduciary obligations arising out of that office will not require the director to account to us for any profit realized by or under any contract or arrangement entered into by or on behalf of Mesoblast and in which the director may have an interest.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests and prohibits directors of companies listed on the ASX from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, unless a relevant exception applies, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of financial benefits (including the issue by us of ordinary shares and other securities) to our directors, including entities controlled by them and certain members of their families.

Borrowing Powers Exercisable by Directors

Pursuant to our Constitution, our business is managed by our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or all or any of our uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, and may guarantee or become liable for the payment of money or the performance of any obligation by or of any other person.

Election, Removal and Retirement of Directors

We may appoint or remove any director by resolution passed in a general meeting of shareholders. Additionally, our directors are elected to serve three-year terms in a manner similar to a "staggered" board of directors under Delaware law. No director except the Managing Director (currently designated as our chief executive officer, Silviu Itescu) may hold office for a period in excess of three years, or beyond the third annual general meeting following the director's last election, whichever is the longer, without submitting himself or herself for re-election.

A director who is appointed during the year by the other directors only holds office until the next general meeting at which time the director may stand for election by shareholders at that meeting.

In addition, provisions of the Corporations Act apply where at least 25% of the votes cast on a resolution to adopt our remuneration report (which resolution must be proposed each year at our annual general meeting) are against the adoption of the report at two successive annual general meetings. Where these provisions apply, a resolution must be put to a vote at the second annual general meeting to the effect that a further meeting, or a spill meeting, take place within 90 days. At the spill meeting, the directors in office when the remuneration report was considered at the second annual general meeting (other than the Managing Director) cease to hold office and resolutions to appoint directors (which may involve re-appointing the former directors) are put to a vote.

Voting restrictions apply in relation to the resolutions to adopt our remuneration report and to propose a spill meeting. These restrictions apply to our key management personnel and their closely related parties. See "Rights and Restrictions on Classes of Shares—Voting Rights" below.

Pursuant to our Constitution, a person is eligible to be elected as a director at a general meeting only if:

- the person is in office as a director immediately before the meeting, in respect of an election of directors at a general meeting that is a spill meeting as defined in section 250V(1) of the Corporations Act;
- the person has been nominated by the directors before the meeting;
- where the person is a shareholder, the person has, at least 35 business days but no more than 90 business days before the meeting, given to us a notice signed by the person stating the person's desire to be a candidate for election at the meeting; or
- where the person is not a shareholder, a shareholder intending to nominate the person for election at that meeting has, at least 35 business days but no more than 90 business days before the meeting, given to us a notice signed by the shareholder stating the shareholder's intention to nominate the person for election, and a notice signed by the person stating the person's consent to the nomination.

Share Qualifications

There are currently no requirements for directors to own our ordinary shares in order to qualify as directors.

Rights and Restrictions on Classes of Shares

Subject to the Corporations Act and the ASX Listing Rules, the rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that any of our ordinary shares may be issued with preferential, deferred or special rights, privileges or conditions, with any restrictions in regard to dividends, voting, return of share capital or otherwise as our board of directors may determine from time to time. Subject to the Corporations Act, the ASX Listing Rules and any rights and restrictions attached to a class of shares, we may issue further ordinary shares on such terms and conditions as our board of directors resolve. Currently, our outstanding ordinary share capital consists of only one class of ordinary shares.

Dividend Rights

Our board of directors may from time to time determine to pay dividends to shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

Voting Rights

Under our Constitution, the general conduct and procedures of each general meeting of shareholders will be determined by the chairperson, including any procedures for casting or recording votes at the meeting whether on a show of hands or on a poll. A poll may be demanded by the chairman of the meeting; by at least five shareholders present and having the right to vote on at the meeting; or any shareholder or shareholders representing at least 5% of the votes that may be cast on the resolution on a poll. On a show of hands, each shareholder entitled to vote at the meeting has one vote regardless of the number of ordinary shares held by such shareholder. If voting takes place on a poll, rather than a show of hands, each shareholder entitled to vote has one vote for each ordinary share held and a fractional vote for each ordinary share that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid (not credited) of the total amounts paid and payable, whether or not called (excluding amounts credited), to such date on that ordinary share.

Under Australian law, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present (in person or by proxy) who (being entitled to vote) vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present (in person or by proxy) and entitled to vote at the meeting.

Pursuant to our Constitution, each shareholder entitled to attend and vote at a meeting may attend and vote:

- in person physically or by electronic means;
- by proxy, attorney or by representative; or
- other than in relation to any clause which specifies a quorum, a member who has duly lodged a valid vote delivered to us by post, fax or other electronic means approved by the directors in accordance with the Constitution.

Under Australian law, shareholders of a public listed company are generally not permitted to approve corporate matters by written consent. Our Constitution does not specifically provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depositary to vote the number of deposited ordinary shares their ADSs represent. 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.

There are a number of circumstances where the Corporations Act or the ASX Listing Rules prohibit or restrict certain shareholders or certain classes of shareholders from voting. For example, key management personnel whose remuneration details are included elsewhere in this prospectus are prohibited from voting on the resolution that must be proposed at each annual general meeting to adopt our remuneration report, as well as any resolution to propose a spill meeting. An exception applies to exercising a directed proxy which indicates how the proxy is to vote on the proposed resolution on behalf of someone other than the key management personnel or their closely related parties; or that person is chair of the meeting and votes an undirected proxy where the shareholder expressly authorizes the chair to exercise that power. Key management personnel and their closely related parties are also prohibited from voting undirected proxies on remuneration related resolutions. A similar exception to that described above applies if the proxy is the chair of the meeting.

Right to Share in Our Profits

Subject to the Corporations Act and pursuant to our Constitution, our shareholders are entitled to participate in our profits by payment of dividends. The directors may by resolution declare a dividend or determine a dividend is payable, and may fix the amount, the time for and method of payment.

Rights to Share in the Surplus in the Event of Winding Up

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our winding up.

Redemption Provisions

Under our Constitution and subject to the Corporations Act, the directors have power to issue and allot shares with any preferential, deferred or special rights, privileges or conditions; with any restrictions in regard to the dividend, voting, return of capital or otherwise; and preference shares which are liable to be redeemed or converted.

Sinking Fund Provisions

Our Constitution allows our directors to set aside any amount available for distribution as a dividend such amounts by way of reserves as they think appropriate before declaring or determining to pay a dividend, and may apply the reserves for any purpose for which an amount available for distribution as a dividend may be properly applied. Pending application or appropriation of the reserves, the directors may invest or use the reserves in our business or in other investments as they think fit.

Liability for Further Capital Calls

According to our Constitution, our board of directors may make any calls from time to time upon shareholders in respect of all monies unpaid on partly paid shares respectively held by them, subject to the terms upon which any of the partly paid shares have been issued. Each shareholder is liable to pay the amount of each call in the manner, at the time and at the place specified by our board of directors. Calls may be made payable by instalment.

Provisions Discriminating Against Holders of a Substantial Number of Shares

There are no provisions under our Constitution discriminating against any existing or prospective holders of a substantial number of our ordinary shares.

Variation or Cancellation of Share Rights

The rights attached to shares in a class of shares may only be varied or cancelled by a special resolution of shareholders, together with either:

- a special resolution passed at a separate meeting of members holding shares in the class; or
- the written consent of members with at least 75% of the votes in the class.

General Meetings of Shareholders

General meetings of shareholders may be called by our board of directors or, under the Corporations Act, by a single director. Except as permitted under the Corporations Act, shareholders may not convene a meeting. Under the Corporations Act, shareholders with at least 5% of the votes that may be cast at a general meeting may call and arrange to hold a general meeting. The Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting. Notice of the proposed meeting of our shareholders is required at least 28 days prior to such meeting under the Corporations Act.

No business shall be transacted at any general meeting unless a quorum is present at the time when the meeting proceeds to business. Under our Constitution, the presence, in person or by proxy, attorney or representative, of two shareholders constitutes a quorum, or if we have less than two shareholders, then those shareholders constitute a quorum. If a quorum is not present within 30 minutes after the time appointed for the meeting, the meeting must be either dissolved if it was requested or called by shareholders or adjourned in any other case. A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place, unless otherwise decided by our directors. The reconvened meeting is dissolved if a quorum is not present within 30 minutes after the time appointed for the meeting.

Change of Control

Takeovers of listed Australian public companies, such as Mesoblast, are regulated by the Corporations Act, which prohibits the acquisition of a “relevant interest” in issued voting shares in a listed company if the acquisition will lead to that person’s or someone else’s voting power in Mesoblast increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90% (“Takeovers Prohibition”), subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities or the holder of an ADS over the shares;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct power or control)

If, at a particular time:-

- a person has a relevant interest in issued securities; and
- the person has:
  - entered or enters into an agreement with another person with respect to the securities;
  - given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities; or
  - granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; and
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised,

then, the other person is taken to already have a relevant interest in the securities.

There are a number of exceptions to the above Takeovers Prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder during the bid period for a full takeover bid that is unconditional or only conditional on certain 'prescribed' matters set out in the Corporations Act;
- when the acquisition has been previously approved by resolution passed at general meeting by shareholders of Mesoblast;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other person has had voting power in Mesoblast of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in Mesoblast more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a pro rata rights issue;
- when the acquisition results from the issue of securities under a dividend reinvestment plan or bonus share plan;
- when the acquisition results from the issue of securities under certain underwriting arrangements;
- when the acquisition results from the issue of securities through a will or through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another company listed on the ASX or other Australian financial market or a foreign stock exchange approved in writing by ASIC;
- an acquisition arising from an auction of forfeited shares; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

A formal takeover bid may either be a bid for all securities in the bid class or a fixed proportion of such securities, with each holder of bid class securities receiving a bid for that proportion of their holding. Under our Constitution, a proportionate takeover bid must first be approved by resolution of our shareholders in a general meeting before it may proceed.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. In addition, ASIC and, on application by ASIC or an interested party, such as a shareholder, the Australian Takeovers Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders cancelling contracts, freezing transfers of, and rights (including voting rights) attached to, securities, and forcing a party to dispose of securities including by vesting the securities in ASIC for sale. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

Ownership Threshold

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a substantial shareholder to notify us and the ASX once a 5% interest in our ordinary shares is obtained. Further, once a shareholder has (alone or together with associates) a 5% or greater interest in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its interest in our ordinary shares. In addition, the Constitution requires a shareholder to provide information to the Company in relation to its entry into any arrangement restricting the transfer or other disposal of shares, which are of the nature of arrangements that Mesoblast is required to disclose under the ASX Listing Rules. Following our initial public offering in the United States, our shareholders are also subject to disclosure requirements under U.S. securities laws.

Issues of Shares and Change in Capital

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time grant options over unissued shares and issue shares on any terms, with any preferential, deferred or special rights, privileges or conditions; with any restrictions in regard to dividend, voting, return of capital or otherwise, and for the consideration and other terms that the directors determine. Our power to issue shares includes the power to issue bonus shares (for which no consideration is payable to Mesoblast), preference shares and partly paid shares.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole, does not materially prejudice our ability to pay creditors and obtains the necessary shareholder approval) or buy back our ordinary shares including under an equal access buy-back or on a selective basis. Under the Constitution, the directors may do anything required to give effect to any resolution altering or approving the reduction of our share capital.

Access to and Inspection of Documents

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our share registers on the payment of a prescribed fee. Shareholders are not required to pay a fee for inspection of our share registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

10.C Material Contracts

Manufacturing Service Agreements with Lonza Bioscience Singapore Pte. Ltd.

In September 2011, we entered into a manufacturing services agreement, or MSA, with Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., collectively referred to as Lonza, a global leader in biopharmaceutical manufacturing. Under the MSA, we pay Lonza on a fee for service basis to provide us with manufacturing process development capabilities for our product candidates, including formulation development, establishment and maintenance of master cell banks, records preparation, process validation, manufacturing and other services.

We have agreed to order a certain percentage of our clinical requirements and commercial requirements for MPC products from Lonza. Lonza has agreed not to manufacture or supply commercially biosimilar versions of any of our product candidates to any third party, during the term of the MSA, subject to our meeting certain thresholds for sales of our products.

We can trigger a process requiring Lonza to construct a purpose-built manufacturing facility exclusively for our product candidates. In return if we exercise this option, we will purchase agreed quantities of our product candidates from this facility. We also have a right to buy out this manufacturing facility at a pre-agreed price two years after the facility receives regulatory approval.

The MSA will expire on the three-year anniversary of the date of the first commercial sale of product supplied under the MSA, unless it is sooner terminated. We have the option of extending the MSA for an additional 10 years, followed by the option to extend for successive three-year periods subject to Lonza's reasonable consent. We may terminate the MSA with two years prior written notice, and Lonza may terminate with five years prior written notice. The MSA may also terminate for other reasons, including if the manufacture or development of a product is suspended or abandoned due to the results of clinical trials or guidance from a regulatory authority. In the event we request that Lonza construct the manufacturing facility described above, neither we nor Lonza may terminate before the third anniversary of the date the facility receives regulatory approval to manufacture our product candidates, except in certain limited circumstances. Upon expiration or termination of the MSA, we have the right to require Lonza to transfer certain technologies and lease the Singapore facility or the portion of such facility where our product candidates are manufactured, subject to good faith negotiations.

We currently rely, and expect to continue to rely, on Lonza for the manufacture of our MPC product candidates for preclinical and clinical testing, as well as for commercial manufacture of our MPC product candidates if marketing approval is obtained.

In October 2019, we entered into an agreement with Lonza for commercial manufacture of RYONCIL for pediatric SR-aGVHD. This agreement will facilitate inventory build ahead of the planned US market launch of RYONCIL and commercial supply to meet Mesoblast's long-term market projections. The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

Under the agreement, we agree to order a certain percentage of our commercial requirements for RYONCIL from Lonza. The agreement is subject to standard provisions for termination and its effects, including termination by either party for uncured, material breach of the other, by us in the event of FDA rejects our BLA filing for RYONCIL and after a specified minimum period following the initiation date by either party, on advance notice to the other, which in the case Lonza is the terminating party is intended to provide us sufficient time to transfer the manufacture of the product to an alternative manufacturer.

License Agreement with Grünenthal GmbH

In September 2019, we entered into a strategic partnership with Grünenthal GmbH (Grünenthal) to develop and commercialize MPC-06-ID, the Company's Phase 3 allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. We may receive up to $150.0 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. Cumulative milestone payments could exceed $1.0 billion depending on the final outcome of Phase 3 studies and patient adoption. We will also receive tiered double-digit royalties on product sales. There cannot be any assurance as to the total amount of future milestone and royalty payments that Mesoblast will receive nor when they will be received.

Both parties have agreed on an overall development plan for MPC-06-ID to meet European regulatory requirements. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase 3 trial in Europe. The results of the two Phase 3 trials are expected to support both FDA and European Medicines Agency ("EMA") regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

Grünenthal is able to terminate the agreement with a specified period of notice without cause, or on shorter notice in the case of certain clinical, regulatory and commercial events. We have termination rights with respect to certain patent challenges by Grünenthal. Either party may terminate the agreement on material breach of the agreement if such breach is not cured within the specified cure period or if certain events related to bankruptcy of the other party occurs. For more information, see "Item 18. Financial Statements - Note 3 – Revenue recognition."

Agreements with JCR Pharmaceuticals Co., Ltd.

In October 2013, we acquired all of Osiris Therapeutics, Inc.'s business and assets related to culture expanded MSCs. These assets included assumption of a collaboration agreement with JCR ("JCR Agreement"), which will continue in existence until the later of 15 years from the first commercial sale of any product covered by the agreement and expiration of the last Osiris patent covering any such product. JCR is a research and development oriented pharmaceutical company in Japan. Under the JCR Agreement we assumed from Osiris, 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 HSCs 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. Under the JCR Agreement, JCR obtained rights in Japan to our MSCs, for the treatment of aGVHD. JCR also has a right of first negotiation to obtain rights to commercialize MSC-based products for additional orphan designations in Japan. We retain all rights to those products outside of Japan.

JCR received full approval in September 2015 for its MSC-based product for the treatment of children and adults with aGVHD, TEMCELL. TEMCELL is the first culture-expanded allogeneic stem cell product to be approved in Japan. It was launched in Japan in February 2016.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. With respect to the First JCR Field, we are entitled to future payments of up to $1.0 million in the aggregate 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, we are entitled to a double digit profit share in the fifties.

Intellectual property is licensed both ways under the JCR Agreement, with JCR receiving exclusive and non-exclusive rights as described above from us and granting us non-exclusive, royalty-free rights (excluding in the First JCR Field and Second JCR Field in

Japan) under the intellectual property arising out of JCR's development or commercialization of MSC-based products licensed in Japan.

JCR has the right to terminate the JCR Agreement for any reason, and we have a limited right to terminate the JCR Agreement, including a right to terminate in the event of an uncured material breach by JCR. In the event of a termination of the JCR Agreement other than for our breach, JCR must provide us with its owned product registrations and technical data related to MSC-based products licensed in Japan and all licenses of our intellectual property rights will revert to us.

We have expanded our partnership with JCR in Japan for two new indications: for wound healing in patients with EB in October 2018, and for neonatal HIE, a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. We will receive royalties on TEMCELL product sales for EB and HIE, if and when such indications receive marketing approval in Japan. JCR filed to extend marketing approval of TEMCELL in Japan for EB in March 2019.

We have the right to use all safety and efficacy data generated by JCR in Japan to support our development and commercialization plans for our MSC product candidate remestemcel-L in the United States and other major healthcare markets, including for GVHD, EB and HIE.

Loan Agreement with Hercules

In March 2018, we entered into a loan and security agreement with Hercules for a $75.0 million non-dilutive, secured four-year credit facility with an initial interest rate of 9.45%. We drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019. An additional $25.0 million may be drawn, subject to certain conditions. The loan matures in March 2022. Principal repayments are due to commence in March 2021. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied. Interest on the loan is payable monthly in arrears on the 1st day of the month. The interest rate is floating. It is computed daily based on the actual number of days elapsed and it is the greater of either 9.45% or the prime rate as reported in the Wall Street Journal plus a certain margin. At June 30, 2019, in line with increases in the U.S. prime rate, the interest rate was 10.45%. On August 1, September 19 and October 31, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20%, 9.95% and 9.70%, respectively and remains at 9.70% at June 30, 2020 in line with the amended terms of the loan agreement. The loan agreement contains certain covenants, see "Item 5.B Liquidity and Capital Resource – Borrowings."

Loan Agreement with NovaQuest

In June 2018, we entered into a non-dilutive secured loan with NovaQuest for $40.0 million. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum. The loan agreement contains certain covenants, see "Item 5.B Liquidity and Capital Resource – Borrowings."

All interest and principal payments will be deferred until after the first commercial sale of our allogeneic product candidate MSC-100-IV in pediatric patients with steroid refractory aGVHD, in the United States and other geographies excluding Asia ("pediatric aGVHD"). We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and will accrue further interest. At maturity date, any unpaid loan balances are repaid.

Agreements with Tasly Pharmaceutical Group

In July 2018, we entered into a Development and Commercialization Agreement with Tasly.

The Development and Commercialization Agreement provides Tasly with exclusive rights to develop, manufacture and commercialize in China 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. Tasly will fund all development, manufacturing and commercialization activities in China for MPC-150-IM and MPC-25-IC. On closing, we received a $20.0 million upfront technology access fee. Further, we will receive $25.0 million on product regulatory approvals in China. Mesoblast will receive double-digit escalating royalties on net product sales.

Mesoblast is eligible to receive six escalating milestone payments upon the product candidates reaching certain sales thresholds in China.

The Development and Commercialization Agreement provides that Tasly can terminate this agreement with a specified amount of notice, on the later of (a) third anniversary of the agreement coming into effect and (b) receipt of marketing approval in China for each of MPC-150-IM or MPC-25-IC. Mesoblast has termination rights with respect to certain patent challenges by Tasly and if certain competing activities are undertaken by Tasly. Either party may terminate the agreement on material breach of the agreement if such breach in not cured within the specified cure period or if certain events related to bankruptcy of the other party occurs.

TiGenix NV – patent license for treatment of fistulae

In December 2017, we entered into a Patent License Agreement with TiGenix NV, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell product Alofisel®, previously known as Cx601, a product candidate of Takeda, 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, we received $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment and a further payment of $5.9 million (€5.0 million) before withholding tax 12 months after the patent license agreement date. We are entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

The agreement will continue in full force in each country (other than the United States) until the date upon which the last issued claim of any licensed patent covering Alofisel® expires in such country (currently expected to be 2029) or, with respect to the United States, until the later of (i) the date upon which the last issued claim of any licensed patent covering Alofisel® in the United States expires (currently expected to be around 2031) or (ii) the expiration of the regulatory exclusivity period in the United States with an agreed maximum term.

Either we or Takeda may terminate the agreement for any material breach that is not cured within 90 days after notice. We also have the right to terminate the agreement with a written notice in the event that Takeda file a petition in bankruptcy or insolvency or Takeda makes an assignment of substantially all of its assets for the benefit of its creditors.

Takeda has the right to terminate its obligation to pay royalties for net sales in a specific country if it is of the opinion that there is no issued claim of any licensed patent covering Alofisel® in such country, subject to referral of the matter to the joint oversight/cooperation committee established under the agreement if we disagree.

10.D Exchange Controls

The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Transaction Reports and Analysis Centre (“AUSTRAC”), which monitors such transaction, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

Regulation of acquisition by foreign entities

Under Australian law, in certain circumstances foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without approval from the Australian Treasurer. These limitations are set forth in the Australian Foreign Acquisitions and Takeovers Act 1975. These limitations are in addition to the more general overarching Takeovers Prohibition of an acquisition of more than a 20% interest in a public company (in the absence of an applicable exception) under the takeovers provisions of Australia's Corporations Act by any person whether foreign or otherwise.

Under the Foreign Acquisitions and Takeovers Act, as currently in effect, any foreign person, together with associates, or parties acting in concert, is prohibited from acquiring 20% or more of the shares in any company having consolidated total assets of or that is valued at A$266.0 million or more (or A$1,154.0 million or more in case of U.S. investors or investors from certain other countries). No asset threshold applies in the case of foreign government investors. Different rules apply to sensitive industries (such as media, telecommunications, and encryption and security technologies), companies owning land or that are agribusinesses. “Associates” is a broadly defined term under the Foreign Acquisitions and Takeovers Act and includes in relation to any person:

- any relative of the person;
- any person with whom the person is acting or proposes to act in concert;
- any person with whom the person carries on a business in partnership;
- any entity of which the person is a 'senior officer' (such as a director or executive);
- if the person is an entity, any holding entity or any senior officer of the entity;
- any entity whose senior officers are accustomed or obliged to act in accordance with the directions, instructions or wishes of the person or if the person is an entity, its senior officers or vice versa;
- any corporation in which the person holds a 'substantial interest' (i.e., 20%) or any person holding a substantial interest in the person if a corporation;
- a trustee of a trust in which the person holds a substantial interest or if the person is the trustee of a trust, a person who holds a substantial interest in the trust;
- if the person is a foreign government, a separate government entity or a foreign government investor in relation to a foreign country, any other person that is a foreign government, a separate government entity or foreign government investor, in relation to that country.

The Australian Treasurer also has power in certain circumstances to make an order specifying that two or more persons are associates.

In addition, a foreign person may not acquire shares in a company having consolidated total assets of or that is valued at A$266 million or more (or A$1,154 million or more in case of U.S. investors or investors from certain other countries) if, as a result of that acquisition, the total holdings of all foreign persons and their associates will exceed 40% in aggregate without the approval of the Australian Treasurer. If the necessary approvals are not obtained, the Treasurer may make an order requiring the acquirer to dispose of the shares it has acquired within a specified period of time. The same rule applies if the total holdings of all foreign persons and their associates already exceeds 40% and a foreign person (or its associate) acquires any further shares, including in the course of trading in the secondary market of the ADSs. Different rules apply to government investors, and acquisitions of interests in sensitive business acquisitions, agribusiness and land owning entities.

Each foreign person seeking to acquire holdings in excess of the above caps (including their associates, as the case may be) would need to complete an application form setting out the proposal and relevant particulars of the acquisition/shareholding and pay the relevant application fees. The Australian Treasurer then has 30 days to consider the application and make a decision. However, the Australian Treasurer may extend the period by up to a further 90 days by publishing an interim order. The Australian Foreign Investment Review Board, an Australian advisory board to the Australian Treasurer has provided a guideline titled *Australia’s Foreign Investment Policy* which provides an outline of the policy. As for the risk associated with seeking approval, the policy provides, among other things, that the Treasurer will reject an application if it is contrary to the national interest.

If the level of foreign ownership in Mesoblast exceeds 40% at any time, we would be considered a foreign person under the Foreign Acquisitions and Takeovers Act. In such event, we would be required to obtain the approval of the Australian Treasurer for our company, together with our associates, to acquire (i) more than 20% of an Australian company or business having total assets of, or that is valued at, A$266 million or more; or (ii) any direct or indirect ownership in Australian land; or (iii) any 'direct interest' in any agribusiness.

The percentage of foreign ownership in our company may also be included in determining the foreign ownership of any Australian company or business in which we may choose to invest. Since we have no current plans for any such acquisition and do not own any property, any such approvals required to be obtained by us as a foreign person under the Takeovers Act will not affect our current or future ownership or lease of property in Australia.

Our Constitution does not contain any additional limitations on the right to hold or vote our securities by reason of being a non-resident.

Australian law requires the transfer of shares in our company to be made in writing or electronically through the Clearing House Electronic Sub-register System.

10.E Taxation

The following summary of the material Australian and U.S. federal income tax consequences of an investment in our ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this Form 20-F, all of which are subject to change, possibly with retroactive effect. This summary does not deal with all possible tax consequences relating to an investment in our ADSs or ordinary shares, such as the tax consequences under U.S. state, local and other tax laws other than Australian and U.S. federal income tax laws.

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following summary describes certain material U.S. federal income tax consequences to U.S. holders (as defined below) of the ownership and disposition of our ordinary shares and ADSs as of the date hereof. Except where noted, this summary deals only with our ordinary shares or ADSs acquired and held as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This section does not discuss the tax consequences to any particular holder, nor any tax considerations that may apply to holders subject to special tax rules, such as:

- banks, insurance companies, regulated investment companies and real estate investment trusts;
- financial institutions;
- individual retirement and other tax-deferred accounts;
- certain former U.S. citizens or long-term residents;
- brokers or dealers in securities or currencies;
- traders that elect to use a mark-to-market method of accounting;
- partnerships and other entities treated as partnership or pass through entities for U.S. federal income tax purposes, and partners or investors in such entities;
- tax-exempt organizations (including private foundations);
- persons that may have been subject to the alternative minimum tax;
- persons that hold or dispose of ordinary shares or ADSs as a position in a straddle or as part of a hedging, constructive sale, conversion or other integrated transaction;
- persons that have a functional currency other than the U.S. dollar;
- persons that own (directly, indirectly or constructively) 10% or more of the vote or value of our equity;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to ordinary shares or ADSs being taken into account in an applicable financial statement;
- persons who acquire ordinary shares or ADSs pursuant to the exercise of any employee share option or otherwise as compensation; or
- persons that are not U.S. holders (as defined below).

In this section, a "U.S. holder" means a beneficial owner of ordinary shares or ADSs, other than a partnership or other entity treated as a partnership for U.S. federal income tax purposes, that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a court in the United States and for which one or more U.S. persons have the authority to control all substantial decisions or (ii) that has an election in effect under applicable U.S. income tax regulations to be treated as a U.S. person.

The discussion below is based upon the provisions of the Code, and the U.S. Treasury regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be replaced, revoked or modified, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon the terms of the deposit agreement and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes acquires, owns or disposes of ordinary shares or ADSs, the U.S. federal income tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. Partners of partnerships that acquire, own or dispose of ordinary shares or ADSs should consult their tax advisors.

You are urged to consult your own tax advisor with respect to the U.S. federal, as well as state, local and non-U.S., tax consequences to you of acquiring, owning and disposing of ordinary shares or ADSs in light of your particular circumstances, including the possible effects of changes in U.S. federal income and other tax laws and the effects of any tax treaties.

ADSs

Assuming the deposit agreement and all other related agreements will be performed in accordance with their terms, a U.S. holder of ADSs will be treated as the beneficial owner for U.S. federal income tax purposes of the underlying shares represented by the ADSs. The U.S. Treasury has expressed concerns that parties to whom American depositary shares are released before shares are delivered to the depositary, or intermediaries in the chain of ownership between holders of American depositary shares and the issuer of the security underlying the American depositary shares, may be taking actions that are inconsistent with claiming foreign tax credits by holders of American depositary shares. These actions would also be inconsistent with claiming the reduced rate of tax, described below, applicable to dividends received by certain non-corporate holders. Accordingly, the creditability of any foreign taxes and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. holders, each described below, could be affected by actions taken by such parties or intermediaries.

Distributions

Subject to the passive foreign investment company, or PFIC, rules discussed below, U.S. holders generally will include as dividend income the U.S. dollar value of the gross amount of any distributions of cash or property (without deduction for any withholding tax), other than certain pro rata distributions of ordinary shares, with respect to ordinary shares or ADSs to the extent the distributions are made from our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. A U.S. holder will include the dividend income on the day actually or constructively received: (i) by the holder, in the case of ordinary shares, or (ii) by the depositary, in the case of ADSs. To the extent, if any, that the amount of any distribution by us exceeds our current and accumulated earnings and profits, as so determined, the excess will be treated first as a tax-free return of the U.S. holder's tax basis in the ordinary shares or ADSs and thereafter as capital gain. Notwithstanding the foregoing, we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles. Consequently, any distributions generally will be reported as dividend income for U.S. information reporting purposes. See "—Backup Withholding Tax and Information Reporting Requirements" below. Dividends paid by us will not be eligible for the dividends-received deduction generally allowed to U.S. corporate shareholders.

The U.S. dollar amount of dividends received by an individual, trust or estate with respect to the ordinary shares or ADSs will be subject to taxation at preferential rates if the dividends are "qualified dividends." Dividends paid on ordinary shares or ADSs will be treated as qualified dividends if (i)(a) we are eligible for the benefits of a comprehensive income tax treaty with the United States that the Secretary of the Treasury of the United States determines is satisfactory for this purpose and includes an exchange of information program or (b) the dividends are with respect to ordinary shares (or ADSs in respect of such shares) which are readily tradable on a U.S. securities market; (ii) certain holding period requirements are met; and (iii) we are not classified as a PFIC for the taxable year in which the dividend is paid or for the preceding taxable year. The Agreement between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, or the Treaty, has been approved for the purposes of the qualified dividend rules, and we expect to qualify for benefits under the Treaty. In addition, our ADSs are listed on the Nasdaq Global Select Market, and as such U.S. Treasury Department guidance indicates that our ADSs will be readily tradable on an established U.S. securities market. Thus, we believe that as long as we are not a PFIC, dividends we pay generally should be eligible for the preferential tax rates on qualified dividends. However, the determination of whether a dividend qualifies for the preferential tax rates must be made at the time the dividend is paid. U.S. holders should consult their own tax advisors regarding the availability of the preferential tax rates on dividends.

Includible distributions paid in Australian dollars, including any Australian withholding taxes, will be included in the gross income of a U.S. holder in a U.S. dollar amount calculated by reference to the spot exchange rate in effect on the date of actual or constructive receipt, regardless of whether the Australian dollars are converted into U.S. dollars at that time. If Australian dollars are converted into U.S. dollars on the date of actual or constructive receipt, the tax basis of the U.S. holder in those Australian dollars will be equal to their U.S. dollar value on that date and, as a result, a U.S. holder generally should not be required to recognize any foreign currency exchange gain or loss. If Australian dollars so received are not converted into U.S. dollars on the date of receipt, the U.S. holder will have a basis in the Australian dollars equal to their U.S. dollar value on the date of receipt. Any foreign currency exchange gain or loss on a subsequent conversion or other disposition of the Australian dollars generally will be treated as ordinary income or loss to such U.S. holder and generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

Dividends received by a U.S. holder with respect to ordinary shares (or ADSs in respect of such shares) will be treated as foreign source income, which may be relevant in calculating the holder's foreign tax credit limitation. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to ADSs or ordinary shares will generally constitute "passive category income" but could, in the case of certain U.S. holders, constitute "general category income."

Subject to certain complex limitations, including the PFIC rules discussed below, a U.S. holder generally will be entitled, at such holder's option, to claim either a credit against such holder's U.S. federal income tax liability or a deduction in computing such holder's U.S. federal taxable income in respect of any Australian taxes withheld. If a U.S. holder elects to claim a deduction, rather than a foreign tax credit, for Australian taxes withheld for a particular taxable year, the election will apply to all foreign taxes paid or accrued by or on behalf of the U.S. holder in the particular taxable year.

The availability of the foreign tax credit and the application of the limitations on its availability are fact specific and are subject to complex rules. You are urged to consult your own tax advisor as to the consequences of Australian withholding taxes and the availability of a foreign tax credit or deduction. See "—Australian Tax Considerations Australian—Income Tax—Taxation of Dividends" below.

Sale, Exchange or Other Disposition of Ordinary Shares or ADSs

Subject to the PFIC rules discussed below, a U.S. holder generally will, for U.S. federal income tax purposes, recognize capital gain or loss, if any, on a sale, exchange or other disposition of ordinary shares or ADSs equal to the difference between the amount realized on the disposition and the U.S. holder's tax basis (in U.S. dollars) in the ordinary shares or ADSs. This recognized gain or loss will generally be long-term capital gain or loss if the U.S. holder has held the ordinary shares or ADSs for more than one year. Generally, for U.S. holders who are individuals (as well as certain trusts and estates), long-term capital gains are subject to U.S. federal income tax at preferential rates. For foreign tax credit limitation purposes, gain or loss recognized upon a disposition generally will be treated as from sources within the United States. The deductibility of capital losses is subject to limitations for U.S. federal income tax purposes.

You should consult your own tax advisor regarding the tax consequences if a foreign tax is imposed on a disposition of ADSs or ordinary shares, including availability of a foreign tax credit or deduction in respect of any Australian tax imposed on a sale or other disposition of ordinary shares or ADSs. See "—Australian Tax Considerations—Australian Income Tax—Tax on Sales or Other Dispositions of Shares—Capital Gains Tax."

Passive Foreign Investment Company

As a non-U.S. corporation, we will be a PFIC for any taxable year if either: (i) 75% or more of our gross income for the taxable year is passive income (such as certain dividends, interest, rents or royalties and certain gains from the sale of shares and securities or commodities transactions, including amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares or ADSs); or (ii) the average quarterly value of our gross assets during the taxable year that produce passive income or are held for the production of passive income is at least 50% of the value of our total assets. For purposes of the PFIC asset test, 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. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC income and asset tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income.

We do not believe that we were a PFIC for the taxable year ending June 30, 2020. However, if there is a change in the type or composition of our gross income, or our actual business results do not match our projections, it is possible that we may become a PFIC in future taxable years. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of Australian research and development tax incentive credits and other revenue, and there can be no assurances that such tax incentive credit programs will not be revoked or modified, that we will continue to conduct our operations in the manner necessary to be eligible for such incentives or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. The value of our assets for purposes of the PFIC asset test will generally be determined by reference to our market capitalization, which may fluctuate. The composition of our income and assets will also be affected by how, and how quickly, we spend the cash raised in offerings of our ordinary shares or ADSs. Under circumstances where our gross income from activities that produce passive income significantly increases relative to our gross income from activities that produce non-passive income or where we decide not to deploy significant amounts of cash for active purposes, our risk of becoming classified as a PFIC may substantially increase. Since a separate factual determination as to whether we are or have become a PFIC must be made each year (after the close of such year), we cannot assure you that we will not be or become a PFIC in the current year or any future taxable year. There can be no assurance that we will not be a PFIC for any taxable year, as PFIC status is determined each year and depends on the composition of our income and assets and the value of our assets in such year. If we are a PFIC for any taxable year, upon request, we intend to provide U.S. holders with the information necessary to make and maintain a "Qualified Electing Fund" election, as described below.

Default PFIC Rules

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, unless you make the mark-to-market election or the Qualified Electing Fund election described below, you will generally be (and remain) subject to additional taxes and interest charges, regardless of whether we remain a PFIC in any subsequent taxable year, (i) on certain "excess distributions" we may make; and (ii) on any gain realized on the disposition or deemed disposition of your ordinary shares or ADSs. Distributions in respect of your ordinary shares (or ADSs in respect of such shares) during the taxable year will generally constitute "excess" distributions if, in the aggregate, they exceed 125% of the average amount of distributions in respect of your ordinary shares (or ADSs) over the three preceding taxable years or, if shorter, the portion of your holding period before such taxable year.

To compute the tax on "excess" distributions or any gain: (i) the "excess" distribution or the gain will be allocated ratably to each day in your holding period for the ADSs or the ordinary shares; (ii) the amount allocated to the current taxable year and any taxable year before we became a PFIC will be taxed as ordinary income in the current year; (iii) the amount allocated to other taxable years will be taxable at the highest applicable marginal rate in effect for that year; and (iv) an interest charge at the rate for underpayment of taxes will be imposed with respect to any portion of the "excess" distribution or gain described under (iii) above that is allocated to such other taxable years. In addition, if we are a PFIC or, with respect to a particular U.S. holder, we are treated as a PFIC for the taxable year in which the distribution was paid or the prior taxable year, no distribution that you receive from us will qualify for taxation at the preferential rate for non-corporate holders discussed in "—Distributions" above. You should consult with your own tax advisor regarding the application of the default PFIC rules based on your particular circumstances.

If we are a PFIC for any taxable year during which a U.S. holder holds our ADSs or ordinary shares and any of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and our disposition of shares of the lower-tier PFIC, even though such U.S. holder would not receive the proceeds of those distributions or dispositions. You should consult with your own tax advisor regarding the application to you of the PFIC rules to any of our subsidiaries if we are a PFIC.

Mark-to-Market Election

If we are a PFIC for any taxable year during which you own our ADSs or ordinary shares, you will be able to avoid the rules applicable to "excess" distributions or gains described above if the ordinary shares or ADSs are "marketable" and you make a timely "mark-to-market" election with respect to your ordinary shares or ADSs. The ordinary shares or ADSs will be "marketable" stock as long as they remain regularly traded on a national securities exchange, such as the Nasdaq Global Select Market, or a foreign securities exchange regulated by a governmental authority of the country in which the market is located and which meets certain requirements, including that the rules of the exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter, but no assurances can be given in this regard. Our ordinary shares are traded on the ASX, which may qualify as an eligible foreign securities exchange for this purpose.

If you are eligible to make a "mark-to-market" election with respect to our ordinary shares or ADSs and you make this election in a timely fashion, you will generally recognize as ordinary income or ordinary loss the difference between the fair market value of your ordinary shares or ADSs on the last day of any taxable year and your adjusted tax basis in the ordinary shares or ADSs. Any ordinary income resulting from this election will generally be taxed at ordinary income rates. Any ordinary losses will be deductible only to the extent of the net amount of previously included income as a result of the mark-to-market election, if any. Your adjusted tax basis in the ordinary shares or ADSs will be adjusted to reflect any such income or loss. Any gain recognized on the sale or other disposition of your ordinary shares or ADSs in a year when we are a PFIC will be treated as ordinary income, and any loss will be treated as an ordinary loss (but only to the extent of the net amount previously included as ordinary income as a result of the mark-to-market election).

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. holder may continue to be subject to the PFIC rules with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including shares in any of our subsidiaries that are treated as PFICs.

You should consult with your own tax advisor regarding the applicability and potential advantages and disadvantages to you of making a "mark-to-market" election with respect to your ordinary shares or ADSs if we are or become a PFIC, including the tax issues raised by lower-tier PFICs that we may own and the procedures for making such an election.

QEF Election

Alternative rules to those set forth under "Default PFIC Rules" above apply if an election is made to treat us as a "Qualified Electing Fund," or QEF, under Section 1295 of the Code. A QEF election is available only if a U.S. holder receives an annual information statement from us setting forth such holder's pro rata share of our ordinary earnings and net capital gains, as calculated for U.S. federal income tax purposes.

Upon request from a U.S. holder, we will endeavor to provide to the U.S. holder within 90 days after the request an annual information statement, in order to enable the U.S. holder to make and maintain a QEF election for us or for any of our subsidiaries that is or becomes a PFIC. However, there is no assurance that we will have timely knowledge of our or our subsidiaries' status as a PFIC in the future or of the required information to be provided. You should consult your own tax advisor regarding the availability and tax consequences of a QEF election with respect to the ordinary shares or ADSs or with respect to any lower-tier PFIC that we may own under your particular circumstances.

Reporting

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, as a U.S. holder, you will generally be required to file IRS Form 8621 on an annual basis, and other reporting requirements may apply. The PFIC rules are complex and you should consult with your own tax advisor regarding whether we or any of our subsidiaries are a PFIC, the tax consequences of any elections that may be available to you, and how the PFIC rules may affect the U.S. federal income tax consequences of the receipt, ownership, and disposition of our ordinary shares or ADSs.

Tax on Net Investment Income

Certain non-corporate U.S. holders will be subject to a 3.8% tax on the lesser of (i) the U.S. holder's "net investment income" for the relevant taxable year; and (ii) the excess of the U.S. holder's modified adjusted gross income for the taxable year over a certain threshold. A U.S. holder's net investment income will generally include dividends received on the ordinary shares or ADSs and net gains from the disposition of ordinary shares or ADSs, unless such dividend income or net gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). A U.S. holder

that is an individual, estate or trust should consult the holder's tax advisor regarding the applicability of the tax on net investment income to the holder's dividend income and gains in respect of the holder's investment in the ordinary shares or ADSs.

Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements generally apply to payments to non-corporate holders of ordinary shares or ADSs. Information reporting will apply to payments of dividends on, and to proceeds from the disposition of, ordinary shares or ADSs by a paying agent within the United States to a U.S. holder, other than U.S. holders that are exempt from information reporting and properly certify their exemption. A paying agent within the United States will be required to withhold at the applicable statutory rate, currently 24%, in respect of any payments of dividends on, and the proceeds from the disposition of, ordinary shares or ADSs within the United States to a U.S. holder (other than U.S. holders that are exempt from backup withholding and properly certify their exemption) if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with applicable backup withholding requirements. U.S. holders who are required to establish their exempt status generally must provide a properly completed IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. holder's U.S. federal income tax liability. A U.S. holder generally may obtain a refund of any amounts withheld under the backup withholding rules in excess of such holder's U.S. federal income tax liability by filing the appropriate claim for refund with the IRS in a timely manner and furnishing any required information.

Certain U.S. holders may be required to report (on IRS Form 8938) information with respect to such holder's interest in "specified foreign financial assets" (as defined in Section 6038D of the Code), including stock of a non-U.S. corporation that is not held in an account maintained by a U.S. "financial institution". Persons who are required to report specified foreign financial assets and fail to do so may be subject to substantial penalties. U.S. holders are urged to consult their own tax advisors regarding foreign financial asset reporting obligations and their possible application to the holding of ordinary shares or ADSs.

The discussion above is a general summary only. It is not intended to constitute a complete analysis of all tax considerations applicable to an investment in our ADSs or ordinary shares. You should consult with your own tax advisor concerning the tax consequences to you of an investment in our ADSs or ordinary shares in light of your particular circumstances.

Australian Tax Considerations

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ordinary shares or ADSs. It is based upon existing Australian tax law as of the date of this annual report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty and goods and services tax. Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the acquisition, ownership and disposition of the shares. This summary is based upon the premise that the holder is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment (referred to as a "Foreign Shareholder" in this summary).

Australian Income Tax

Nature of ADSs for Australian Taxation Purposes

Ordinary shares represented by ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a "bare trust" for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to non-Australian resident holders of ordinary shares which, for Australian taxation purposes, will be the same as to U.S. holders of ADSs.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends payable to non-Australian resident shareholders that are not operating from an Australian permanent establishment, or Foreign Shareholders, will be subject to dividend withholding tax, to the extent the dividends are not foreign (i.e., non-Australian) sourced and declared to be conduit foreign income, or CFI, and are unfranked. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation agreement and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not CFI paid by us to which a resident of the United States is beneficially entitled is limited to 15%.

If a company that is a non-Australian resident shareholder directly owns a 10% or more interest, the Australian tax withheld on unfranked dividends (that are not CFI) paid by us to which a resident of the United States is beneficially entitled is limited to 5%. In limited circumstances the rate of withholding can be reduced to zero.

Tax on Sales or Other Dispositions of Shares—Capital Gains Tax

Foreign Shareholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of our ordinary shares, unless they, together with associates, hold 10% or more of our issued capital, at the time of disposal or for 12 months of the last 2 years prior to disposal.

Foreign Shareholders who own a 10% or more interest would be subject to Australian capital gains tax if more than 50% of our assets held directly or indirectly, determined by reference to market value, consists of Australian real property (which includes land and leasehold interests) or Australian mining, quarrying or prospecting rights. The Double Taxation Convention between the United States and Australia is unlikely to limit the amount of this taxable gain. Australian capital gains tax applies to net capital gains of Foreign Shareholders at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

The 50% capital gains tax discount is not available to non-Australian residents on gains accrued after May 8, 2012. Companies are not entitled to a capital gains tax discount.

Broadly, where there is a disposal of certain taxable Australian property, the purchaser will be required to withhold and remit to the Australian Taxation Office ("ATO") 12.50% of the proceeds from the sale. A transaction is excluded from the withholding requirements in certain circumstances, including where the value of the taxable Australian property is less than A$750,000, the transaction is an on-market transaction conducted on an approved stock exchange, a securities lending, or the transaction is conducted using a broker operated crossing system. There is also an exception to the requirement to withhold where the Commissioner issues a clearance certificate which broadly certifies that the vendor is not a foreign person. The Foreign Shareholder may be entitled to receive a tax credit for the tax withheld by the purchaser which they may claim in their Australian income tax return.

Tax on Sales or Other Dispositions of Shares—Shareholders Holding Shares on Revenue Account

Some Foreign Shareholders may hold ordinary shares on revenue rather than on capital account for example, share traders. These shareholders may have the gains made on the sale or other disposal of the ordinary shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Foreign Shareholders assessable under these ordinary income provisions in respect of gains made on ordinary shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Some relief from Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the United States and Australia.

To the extent an amount would be included in a Foreign Shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

The comments above in "Tax on Sales or Other Dispositions of Shares—Capital Gains Tax" regarding a purchaser being required to withhold 12.5% tax on the acquisition of certain taxable Australian property equally applies where the disposal of the Australian real property asset by a foreign resident is likely to generate gains on revenue account, rather than a capital gain.

Dual Residency

If a shareholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax may be subject to limitation by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

Australian Death Duty

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's ordinary shares. The disposal of inherited ordinary shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax (as discussed above).

Stamp Duty

No Australian stamp duty is payable by Australian residents or non-Australian residents on the issue, transfer and/or surrender of the ADSs or the ordinary shares in Mesoblast, provided that all of the ADSs and ordinary shares in Mesoblast are listed on Nasdaq and ASX and the shares issued, transferred and/or surrendered do not represent 90% or more of the issued shares in Mesoblast.

Goods and Services Tax

The supply of ADSs and/or ordinary shares in Mesoblast will not be subject to Australian goods and services tax.

10.F Dividends and Paying Agents

Not applicable.

10.G Statement by Experts

Not applicable.

10.H Documents on Display

Any statement in this Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Form 20-F the contract or document is deemed to modify the description contained in this Form 20-F. You must review the exhibits themselves for a complete description of the contract or document.

You may review a copy of our filings with the SEC, as well as other information furnished to the SEC, including exhibits and schedules filed with it, at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the SEC maintains a website at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the SEC. These SEC filings are also available to the public from commercial document retrieval services.

We are required to file or furnish reports and other information with the SEC under the Securities Exchange Act of 1934 and regulations under that act. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the form and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short swing profit recovery provisions contained in Section 16 of the Exchange Act.

10.I Subsidiary Information

For information about our subsidiaries, see "Item 18. Financial Statements – Note 12."

Item 11. Quantitative and Qualitative Disclosures about Market Risk

For information about our exposure to market risk and how we manage this risk, see "Item 18. Financial Statements – Note 10."

Item 12. Description of Securities Other than Equity Securities

12.A Debt Securities

Not applicable.

12.B Warrants and Rights

Not applicable.

12.C Other Securities

Not applicable.

12.D American Depositary Shares

Fees Payable by ADR Holders

Holders of our ADRs may have to pay our ADS depositary, JPMorgan Chase Bank N.A. (JPMorgan), fees or charges up to the amounts described in the following table:

Persons depositing or withdrawing ordinary shares or ADS holders must pay:	Description of service
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances pursuant to a deposits of shares, share or rights distributions, stock dividend, stock split, merger or any other transactions affecting the issuance of ADSs • Cancellation of ADSs for the purpose of withdrawal of deposited securities
$0.05 (or less) per ADS	• Cash distribution to ADS holders
$1.50 per ADR	• Transfers of ADRs
$0.05 (or less) per ADS per calendar year	• Administrative services performed by the depositary

Fees Payable by the Depositary to the Issuer

From time to time, the depositary may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. "Disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2020.

Management's Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2020 based on the criteria set forth in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, our management has concluded that its internal control over financial reporting was effective as of June 30, 2020.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Item 16A. Audit Committee Financial Expert

The Board of Directors of Mesoblast Ltd has determined that Michael Spooner possesses specific accounting and financial management expertise and is an Audit Committee Financial Expert as defined by the SEC. The Board of Directors has also determined that Donal O'Dwyer and Joseph Swedish, members of the Audit and Risk Management Committee, have sufficient experience and ability in finance and compliance matters to enable them to adequately discharge their responsibilities. All members of the Audit and Risk Management Committee are "independent" according to the listing standards of the Nasdaq Global Select Market.

Item 16B. Code of Ethics

Our Code of Conduct covers conflicts of interest, confidentiality, fair dealing, protection of assets, compliance with laws and regulations, whistle blowing, security trading and commitments to stakeholders. In summary, the code requires that at all times all Company personnel act with the utmost integrity, objectivity and in compliance with the letter and the spirit of the law and Company policies. This document is accessible on our internet website at: http://www.mesoblast.com/company/corporate-governance/code-of-conduct.

Item 16C. Principal Accountant Fees and Services

Pre-Approval of Audit and Non-Audit Services

The Audit and Risk Management Committee's pre-approval is required for all services provided by PwC. These services may include audit services, audit-related services, tax services and permissible non-audit services, and are subject to a specific budget. The Audit and Risk Management Committee uses a combination of two approaches – general pre-approval and specific pre-approval – in considering whether particular services or categories of services are consistent with the SEC's rules on auditor independence. Under general pre-approval proposed services may be pre-approved without consideration of specific case-by-case services.

Audit and Non-Audit Services Fees

See "Item 18. Financial Statements – Note 18". For the purpose of SEC classification, there were no audit-related, tax or other fees that were paid or payable to PwC that were not pre-approved by the Audit and Risk Management Committee during the years ended June 30, 2020 and 2019.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. 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 bylaws do 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 five 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.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

See “Item 18. Financial Statements”.

Item 18. Financial Statements

The following financial statements are filed as part of this annual report on Form 20-F.

Australian Disclosure Requirements

All press releases, financial reports and other information are available on our website: www.mesoblast.com

Auditor's Independence Declaration

As lead auditor for the audit of Mesoblast Limited for the year ended 30 June 2020, 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 audit; and

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

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

Sam Lobley
Partner
PricewaterhouseCoopers

Melbourne
27 August 2020

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Index to Financial Statements

Consolidated Income Statement 155
Consolidated Statement of Comprehensive Income 156
Consolidated Statement of Changes in Equity 157
Consolidated Balance Sheet 158
Consolidated Statement of Cash Flows 159
Notes to Consolidated Financial Statements 160

Mesoblast Limited
Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Note	Year Ended June 30, 2020	2019	2018
Revenue	3	32,156	16,722	17,341
Research & development		(56,188)	(59,815)	(65,927)
Manufacturing commercialization		(25,309)	(15,358)	(5,508)
Management and administration		(25,609)	(21,625)	(21,907)
Fair value remeasurement of contingent consideration	3	1,380	(6,264)	10,541
Other operating income and expenses	3	(455)	(1,086)	1,312
Finance costs	3	(13,330)	(11,328)	(1,829)
Loss before income tax	3	**(87,355)**	**(98,754)**	**(65,977)**
Income tax benefit	4	9,415	8,955	30,687
Loss attributable to the owners of Mesoblast Limited		**(77,940)**	**(89,799)**	**(35,290)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**	**Cents**
Basic - losses per share		(14.74)	(18.16)	(7.58)
Diluted - losses per share		(14.74)	(18.16)	(7.58)

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

Mesoblast Limited
Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Note	Year Ended June 30, 2020	2019	2018
Loss for the period		**(77,940)**	**(89,799)**	**(35,290)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Financial assets at fair value through other comprehensive income	7(b)	(446)	(4)	324
Exchange differences on translation of foreign operations	7(b)	1,146	(137)	(903)
Other comprehensive (loss)/income for the period, net of tax		**700**	**(141)**	**(579)**
Total comprehensive losses attributable to the owners of Mesoblast Limited		**(77,240)**	**(89,940)**	**(35,869)**

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

Mesoblast Limited
Consolidated Statement of Changes in Equity

(in U.S. dollars, in thousands)	Note	Issued Capital	Share Option Reserve	Investment Revaluation Reserve	Foreign Currency Translation Reserve	Retained Earnings/ (accumulated losses)	Total
Balance as of 1 July 2017		**830,425**	**69,919**	**(303)**	**(38,373)**	**(344,902)**	**516,766**
Loss for the period		—	—	—	—	(35,290)	(35,290)
Other comprehensive income/(loss)		—	—	324	(903)	—	(579)
Total comprehensive profit/(loss) for the period		**—**	**—**	**324**	**(903)**	**(35,290)**	**(35,869)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		49,358	—	—	—	—	49,358
Contributions of equity for unissued ordinary shares, net of transaction costs		9,660	—	—	—	—	9,660
		59,018	**—**	**—**	**—**	**—**	**59,018**
Transfer exercised options		38	(38)	—	—	—	—
Fair value of share-based payments	17	—	5,959	—	—	—	5,959
Reclassification of modified options from liability		—	134	—	—	—	134
		38	**6,055**	**—**	**—**	**—**	**6,093**
Balance as of June 30, 2018	7(a)	**889,481**	**75,974**	**21**	**(39,276)**	**(380,192)**	**546,008**
Balance as of July 1, 2018		**889,481**	**75,974**	**21**	**(39,276)**	**(380,192)**	**546,008**
Loss for the period		—	—	—	—	(89,799)	(89,799)
Other comprehensive income/(loss)		—	—	(4)	(137)	—	(141)
Total comprehensive profit/(loss) for the period		**—**	**—**	**(4)**	**(137)**	**(89,799)**	**(89,940)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		19,441	—	—	—	—	19,441
		19,441	**—**	**—**	**—**	**—**	**19,441**
Transfer of services rendered in shares		1,170	(1,170)	—	—	—	—
Transfer of exercised options		313	(313)	—	—	—	—
Fair value of share-based payments	17	—	5,533	—	—	—	5,533
Reclassification of modified options to liability		—	10	—	—	—	10
		1,483	**4,060**	**—**	**—**	**—**	**5,543**
Balance as of June 30, 2019	7(a)	**910,405**	**80,034**	**17**	**(39,413)**	**(469,991)**	**481,052**
Balance as of June 30, 2019		**910,405**	**80,034**	**17**	**(39,413)**	**(469,991)**	**481,052**
Adjustment on adoption of IFRS 16 (net of tax)		—	—	—	—	(827)	(827)
Adjusted balance as of July 1, 2019		**910,405**	**80,034**	**17**	**(39,413)**	**(470,818)**	**480,225**
Loss for the period		—	—	—	—	(77,940)	(77,940)
Other comprehensive income/(loss)		—	—	(446)	1,146	—	700
Total comprehensive profit/(loss) for the period		**—**	**—**	**(446)**	**1,146**	**(77,940)**	**(77,240)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		137,840	—	—	—	—	137,840
		137,840	**—**	**—**	**—**	**—**	**137,840**
Tax credited / (debited) to equity		—	979	—	—	—	979
Transfer of exercised options		3,205	(3,205)	—	—	—	—
Fair value of share-based payments	17	—	7,522	—	—	—	7,522
		3,205	**5,296**	**—**	**—**	**—**	**8,501**
Balance as of June 30, 2020	7(a)	**1,051,450**	**85,330**	**(429)**	**(38,267)**	**(548,758)**	**549,326**

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

Mesoblast Limited
Consolidated Balance Sheet

(in U.S. dollars, in thousands)	Note	As of June 30, 2020	2019
Assets			
Current Assets			
Cash & cash equivalents	5(a)	129,328	50,426
Trade & other receivables	5(b)	1,574	4,060
Prepayments	5(b)	5,646	8,036
Total Current Assets		**136,548**	**62,522**
Non-Current Assets			
Property, plant and equipment	6(a)	2,293	826
Right-of-use assets	6(b)	7,978	—
Financial assets at fair value through other comprehensive income	5(c)	1,871	2,317
Other non-current assets	5(d)	3,311	3,324
Intangible assets	6(c)	581,601	583,126
Total Non-Current Assets		**597,054**	**589,593**
Total Assets		**733,602**	**652,115**
Liabilities			
Current Liabilities			
Trade and other payables	5(e)	24,972	13,060
Provisions	6(d)	29,197	7,264
Borrowings	5(f)	32,455	14,007
Lease liabilities	6(b)	3,519	—
Deferred consideration	6(f)	—	10,000
Total Current Liabilities		**90,143**	**44,331**
Non-Current Liabilities			
Deferred tax liability	6(e)	730	11,124
Provisions	6(d)	27,563	48,329
Borrowings	5(f)	57,023	67,279
Lease liabilities	6(b)	6,317	—
Deferred consideration	6(f)	2,500	—
Total Non-Current Liabilities		**94,133**	**126,732**
Total Liabilities		**184,276**	**171,063**
Net Assets		**549,326**	**481,052**
Equity			
Issued Capital	7(a)	1,051,450	910,405
Reserves	7(b)	46,634	40,638
(Accumulated losses)/retained earnings		(548,758)	(469,991)
Total Equity		**549,326**	**481,052**

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

Mesoblast Limited
Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Note	Year ended June 30, 2020	2019	2018
Cash flows from operating activities				
Commercialization revenue received		7,676	4,359	3,019
Upfront and milestone payments received		17,500	26,409	7,125
Government grants and tax incentives received		1,577	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)		(77,710)	(86,294)	(84,682)
Interest received		546	726	367
Interest and other costs of finance paid		(5,947)	(4,641)	(816)
Income taxes (paid)		(7)	(3)	(25)
Net cash (outflows) in operating activities	8(b)	**(56,365)**	**(57,790)**	**(75,012)**
Cash flows from investing activities				
Investment in fixed assets		(2,096)	(279)	(201)
Payments for contingent consideration		(1,027)	(721)	(952)
Payments for licenses		(150)	—	—
Net cash (outflows) in investing activities		**(3,273)**	**(1,000)**	**(1,153)**
Cash flows from financing activities				
Proceeds from borrowings		512	43,572	31,704
Repayment of borrowings		(512)	—	—
Payments of transaction costs from borrowings		—	(1,614)	(392)
Proceeds from issue of shares		144,946	30,258	40,566
Payments for share issue costs		(6,277)	(608)	(3,265)
Payments for lease liabilities		(1,625)	—	—
Net cash inflows by financing activities		**137,044**	**71,608**	**68,613**
Net increase/(decrease) in cash and cash equivalents		77,406	12,818	(7,552)
Cash and cash equivalents at beginning of period		50,426	37,763	45,761
FX gain/(losses) on the translation of foreign bank accounts		1,496	(155)	(446)
Cash and cash equivalents at end of period	8(a)	**129,328**	**50,426**	**37,763**

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

Mesoblast Limited ("the Company") and its subsidiaries ("the Group") are primarily engaged in the development of regenerative medicine products. The Group'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 and notes 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$").

1. Basis of preparation

The general purpose financial statements of Mesoblast Limited and its subsidiaries have been prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board and Australian equivalent International Financial Reporting Standards, as issued by the Australian Accounting Standards Board. Mesoblast Limited is a for-profit entity for the purpose of preparing the financial statements.

The financial statements cover Mesoblast Limited and its subsidiaries. The financial statements were authorized for issue by the board of directors on August 27, 2020. The directors have the power to amend and reissue the financial statements.

(i) Going concern

The Group has incurred losses from operations since our inception in 2004 and as of June 30, 2020, the Group had an accumulated deficit of $548.8 million. The Group had cash and cash equivalents of $129.3 million as of June 30, 2020 and incurred net cash outflows from operations of $56.4 million for the year ended June 30, 2020.

The Group has an overarching strategy to fund operations predominately through sales of RYONCIL and non-dilutive strategic and commercial transactions. In addition to increasing cash inflows through sales of RYONCIL, the Group intends to enter into new strategic partnerships for our Phase 3 product candidates, drawing on up to $67.5 million additional funds from existing strategic and financing partnerships, subject to certain conditions, or through equity-based financing. Over the next 12 months some or all of these cash inflows will be required for us to meet our forecast expenditure and continue as a going concern, although there is uncertainty related to our ability to access these cash inflows.

Management and the directors believe that the Group will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on our ability to continue as a going concern and that the Group may be unable to realize our assets and discharge our liabilities in the normal course of business.

References to matters that may cast significant doubt about the Group's ability to continue as a going concern also raise substantial doubt as contemplated by the Public Company Accounting Oversight Board ("PCAOB") standards.

(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

Leases

The Group adopted IFRS 16 *Leases* on July 1, 2019. Our principal accounting policy from July 1, 2019, are that leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. For principal accounting policies relating to the comparative year, refer to our annual report on Form 20-F for the year ended June 30, 2019. In accordance with the transition provisions in IFRS 16 the new rules have been adopted retrospectively with the cumulative effect of initially applying the new standard recognized on July 1, 2019. Comparatives have not been restated as permitted under the specific transition provisions in the standard.

On adoption of IFRS16, the Group recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 *Leases*. These liabilities were measured at the present value of the remaining lease payments, discounted using the incremental borrowing rate as of July 1, 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on July 1, 2019 was 6.52%. A reconciliation between the operating lease commitments disclosed applying IAS 17 at June 30, 2019 and the lease liabilities recognized at July 1, 2019 is described in Note 22(a).

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate;
- amounts expected to be payable by the lessee under residual value guarantees;
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

Variable lease payments that are not based on an index or a rate are not included in the initial measurement of the lease liability and are expensed in the Income Statement when incurred. There were no variable lease payments that were expensed in the Income Statement for the year ended June 30, 2020.

For certain contracts that contain lease and non-lease components, the Group accounts for each lease component within the contract as a lease separately from non-lease components of the contract. The Group identifies a separate lease component if there is an explicit or implicit identified asset in the contract and if the Group controls use of the identified asset.

The lease payments are discounted using the interest rate implicit in the lease, if that rate can be determined, or the Group's incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability;
- any lease payments made at or before the commencement date, less any lease incentives received;
- any initial direct costs; and
- restoration costs.

Payments associated with short-term leases with a lease term of 12 months or less, contracts that contain lease and non-lease components that are cancellable within 12 months and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Low-value assets comprise IT-equipment and small items of office furniture.

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

There were no new accounting standards and interpretations not yet adopted by the Group for the June 30, 2020 reporting period.

2. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was affected by the following events during the year ended June 30, 2020:

- On September 10, 2019, the Group announced that it had entered into a strategic partnership with Grünenthal, to develop and commercialize MPC-06-ID, a Phase 3 allogeneic product candidate for the treatment of chronic low back pain due to degenerative disc disease. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. The Group has recognized revenue of $15.0 million and deferred revenue of $2.5 million in the current reporting period.
- On October 3, 2019, the Group announced completion of a A$75.0 million (US$50.7 million) capital raise through the placement of 37.5 million new fully-paid ordinary shares at a price of A$2.00 per share to existing and new institutional investors.
- On October 17, 2019, the Group announced that it had entered into a manufacturing service agreement with Lonza Bioscience Singapore Pte. Ltd. for the supply of commercial product for the potential approval and launch of RYONCIL™ ("RYONCIL") for the treatment of pediatric acute graft versus host disease in the US market. A right-of-use asset and lease liability was recognized in relation to the lease component within this agreement.
- In October 2019, February 2020 and May 2020, the Group was able to defer the commencement of principal repayments under the Hercules loan agreement to April 2020, July 2020 and October 2020, respectively. In August 2020, as disclosed in Note 15, the Group amended the terms of the loan agreement to defer commencement of principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million were recognized as a currently liability, given that the terms of the loan agreement to defer the principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.
- On May 13, 2020, the Group announced completion of a A$138.0 million (US$88.8 million) capital raise through the placement of 43.0 million new fully-paid ordinary shares at a price of A$3.20 per share to existing and new institutional investors.

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Year Ended June 30, 2020	2019	2018
Revenue				
Commercialization revenue		6,614	5,003	3,641
Milestone revenue		25,000	11,000	13,334
Interest revenue		542	719	366
Total Revenue		**32,156**	**16,722**	**17,341**
Clinical trial and research & development		**(24,565)**	**(37,927)**	**(42,863)**
Manufacturing production & development		**(23,944)**	**(10,912)**	**(3,640)**
Employee benefits				
Salaries and employee benefits		(25,100)	(19,504)	(19,343)
Defined contribution superannuation expenses		(327)	(339)	(374)
Equity settled share-based payment transactions[(1)]		(7,522)	(4,368)	(6,199)
Total Employee benefits		**(32,949)**	**(24,211)**	**(25,916)**
Depreciation and amortization of non-current assets				
Plant and equipment depreciation		(585)	(562)	(909)
Right of use asset depreciation		(1,508)	—	—
Intellectual property amortization		(1,574)	(1,577)	(1,741)
Total Depreciation and amortization of non-current assets		**(3,667)**	**(2,139)**	**(2,650)**
Other Management & administration expenses				
Overheads & administration		(8,276)	(11,356)	(8,477)
Consultancy		(5,168)	(3,360)	(3,295)
Legal, patent and other professional fees		(5,854)	(4,098)	(3,436)
Intellectual property expenses (excluding the amount amortized above)		(2,683)	(2,795)	(3,065)
Total Other Management & administration expenses		**(21,981)**	**(21,609)**	**(18,273)**
Fair value remeasurement of contingent consideration				
Remeasurement of contingent consideration	5(g)(iii)	1,380	(6,264)	10,541
Total Fair value remeasurement of contingent consideration		**1,380**	**(6,264)**	**10,541**
Other operating income and expenses				
Remeasurement of borrowing arrangements		(779)	(752)	—
Research & development tax incentive		—	(74)	1,807
Government grant revenue		78	—	—
Foreign exchange gains/(losses)		246	(208)	161
Foreign withholding tax paid		—	(52)	(656)
Total Other operating income and expenses		**(455)**	**(1,086)**	**1,312**
Finance (costs)/gains				
Remeasurement of borrowing arrangements		1,386	376	—
Interest expense		(14,716)	(11,704)	(1,829)
Total Finance costs		**(13,330)**	**(11,328)**	**(1,829)**
Total loss before income tax		**(87,355)**	**(98,754)**	**(65,977)**

(1) Share-based payment transactions

For the years ended June 30, 2020, 2019 and 2018, share-based payment transactions have been reflected in the Consolidated Statement of Comprehensive Income functional expense categories as follows:

	Year Ended June 30,		
(in U.S. dollars)	**2020**	**2019**	**2018**
Research and development	3,194,695	2,283,646	3,638,310
Manufacturing and commercialization	434,403	329,718	558,928
Management and administration	3,892,647	1,755,027	2,001,349
Equity settled share-based payment transactions	**7,521,745**	**4,368,391**	**6,198,587**
Legal, patent and other professional fees	—	620,000	—
Total equity settled share-based payment transactions in the profit and loss	**7,521,745**	**4,988,391**	**6,198,587**

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. The Group may receive up to an additional $132.5 million in payments if certain milestones are satisfied in relation to clinical, manufacturing, regulatory and reimbursement approval prior to product launch. The Group is further entitled to receive milestones payments based on regulatory and cumulative product sales milestones, as well as tiered double-digit royalties on product sales.

The strategic partnership with Grünenthal includes a license of IP and the provision of development services. Under IFRS 15 *Revenue from contracts with customers*, the Group have identified three distinct performance obligations in the strategic partnership with Grünenthal. The three performance obligations identified are the right of use license of IP, research & development and chemistry, manufacturing and controls ("R&D and CMC") services and other development services. The license of IP was considered distinct from the development services as it is capable of being granted separately and the development services do not significantly modify or customize the license nor are the license and development services significantly interrelated or interdependent. The Group also evaluated the promises in the development services and determined the R&D and CMC services were distinct from the other development services as they are not significantly interrelated or interdependent.

The standalone selling price for each performance obligation is not directly observable, so the Group have estimated the standalone selling price through the most appropriate method to ensure the estimate represents the price the Group would charge for the goods or services if they were sold separately. The Group considered the application and results of a combination of methods and utilized the cost plus a margin approach as the primary method. For R&D and CMC services, the Group estimated the standalone selling price to be $85.0 million. For the other development services the Group estimated the standalone selling price to be $10.0 million. Significant judgement was applied in determining the standalone selling price and the variable consideration that was allocated to each performance obligation. Based on this analysis, the $15.0 million upfront payment was allocated to the license of IP performance obligation. Upon signing of this strategic partnership in September 2019, the Group recognized $15.0 million in revenue for the right of use license of IP as this performance obligation was considered completely satisfied at this date.

The Group evaluated the constraint over the remaining variable consideration under the contract and determined that all of the milestone payments relating to the R&D and CMC services and other development services were considered constrained as at June 30, 2020. As part of this evaluation, the Group considered a variety of factors, including whether the receipt of the milestone payments is outside of the Group's control or contingent on the outcome of clinical trials and the impact of certain repayment clauses. The Group will continue to evaluate the constraint over variable consideration in future periods. Additionally, the Group applies the sales-based and usage-based royalty exception for licenses of intellectual property and therefore will recognize royalties and sales-based milestone payments as revenue when the subsequent sale or usage occurs.

The $2.5 million milestone payment received in December 2019 from Grünenthal was considered constrained and resulted in deferred consideration as of June 30, 2020. In future periods, additional milestone payments from Grünenthal may result in deferred consideration as revenue recognition of R&D and CMC services and other development services will be dependent upon the assessment of the constraint over variable consideration as well as the percentage of progress towards meeting the development service performance obligations over time.

There was no milestone revenue recognized in relation to this strategic partnership with Grünenthal in the year ended June 30, 2019.

See Note 22(e) for further details about the Group's revenue recognition policies.

4. Income tax benefit/(expense)

(in U.S. dollars, in thousands)	Year Ended June 30, 2020	2019	2018
(a) Reconciliation of income tax to prima facie tax payable			
Loss from continuing operations before income tax	(87,355)	(98,754)	(65,977)
Tax benefit at the Australian tax rate of 30% (2019: 30%)	(26,207)	(29,626)	(19,793)
Tax effect of amounts which are not deductible/(exempt) in calculating taxable income:			
Share-based payments expense	1,367	1,221	1,544
Research and development tax concessions	(876)	(1,486)	537
Foreign exchange translation gains/(losses)	129	(15)	(242)
Contingent consideration	(414)	1,880	(3,162)
Other sundry items	97	91	1,011
Current year tax expense/(benefit)	**(25,904)**	**(27,935)**	**(20,105)**
Adjustments for current tax of prior periods[(1)]	283	(18,412)	(3,616)
Differences in overseas tax rates	9,397	24,458	5,259
Tax benefit not recognized	6,809	12,934	11,065
Change in tax rate on Deferred tax assets	(3,412)	—	27,471
Change in tax rate on Deferred tax liability	3,412	—	(50,761)
Previously unrecognized tax losses now recouped to reduce deferred tax expense/(benefit)	—	—	—
Income tax expense/(benefit) attributable to loss before income tax	**(9,415)**	**(8,955)**	**(30,687)**

(1) In the year ended June 30, 2019, the adjustments for current tax of prior periods includes a benefit of $18.2 million relating to a change in estimate in our current tax provision arising from a tax ruling obtained from Inland Revenue Authority of Singapore on November 15, 2018. This ruling allows the Group to claim additional deductions in relation to earn-out payments arising from the acquired MSC assets from Osiris. The Group expects to settle the related tax losses within the tax jurisdiction of Singapore at a future date. The difference in the Australian tax rate of 30% and the tax rate we expect to settle these deferred tax assets at in Singapore, under the tax incentives granted to the Group by the Singapore Economic Development Board, resulted in $14.0 million being recorded in differences in overseas tax rates for the year.

(in U.S. dollars, in thousands)	Year Ended June 30, 2020	2019	2018
(b) Income tax expense/(benefit)			
Current tax			
Current tax	—	—	—
Total current tax expense/(benefit)	—	—	—
Deferred tax			
(Increase)/decrease in deferred tax assets	(12,687)	(8,856)	20,183
(Decrease)/increase in deferred tax liabilities	3,272	(99)	(50,870)
Total deferred tax expense/(benefit)	**(9,415)**	**(8,955)**	**(30,687)**
Income tax expense/(benefit)	**(9,415)**	**(8,955)**	**(30,687)**

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.

In the year ended June 30, 2019, the adjustments for current tax of prior periods includes a benefit of $18.2 million relating to a change in estimate in our current tax provision arising from a tax ruling obtained from Inland Revenue Authority of Singapore on November 15, 2018. This ruling allows the Group to claim additional deductions in relation to earn-out payments arising from the acquired MSC assets from Osiris. The Group expects to settle the related tax losses within the tax jurisdiction of Singapore at a future date. The difference in the Australian tax rate of 30% and the tax rate we expect to settle these deferred tax assets at in Singapore, under the tax incentives granted to the Group by the Singapore Economic Development Board, resulted in $14.0 million being recorded in differences in overseas tax rates for the year.

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 December 22, 2017, the United States signed into law the Tax Act, which changed many aspects of U.S. corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%. The Group recognized the tax effects of the Tax Act in the year ended June 30, 2018, the most significant of which was a tax benefit resulting from the remeasurement of deferred tax balances to 21%.

	Year Ended June 30,		
(in U.S. dollars, in thousands)	**2020**	**2019**	**2018**
(c) Amounts that would be recognized directly in equity if brought to account			
Aggregate current and deferred tax arising in the reporting period and not recognized in net loss or other comprehensive income but which would have been directly applied to equity had it been brought to account:			
Current tax recorded in equity (if brought to account)	(2,293)	(390)	(1,059)
Deferred tax recorded in equity (if brought to account)	1,266	879	877
	(1,027)	**489**	**(182)**

	Year Ended June 30,		
(in U.S. dollars, in thousands)	**2020**	**2019**	**2018**
(d) Amounts recognized directly in equity			
Aggregate current and deferred tax arising in the reporting period and not recognized in net loss or other comprehensive income but debited/credited to equity			
Current tax recorded in equity	—	—	—
Deferred tax recorded in equity	(979)	—	—
	(979)	—	—

	As of June 30,		
(in U.S. dollars, in thousands)	**2020**	**2019**	**2018**
(e) Deferred tax assets not brought to account			
Unused tax losses			
Potential tax benefit at local tax rates	55,573	51,807	41,501
Other temporary differences			
Potential tax benefit at local tax rates	6,782	3,130	3,704
Other tax credits			
Potential tax benefit at local tax rates	3,220	3,220	3,220
	65,575	**58,157**	**48,425**

As of June 30, 2020, 2019 and 2018, the Group has deferred tax assets not brought to account of $65.6 million, $58.2 million and $48.4 million, respectively. Deferred tax assets have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities.

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 June 30, 2020					
Cash & cash equivalents	5(a)	—	—	129,328	129,328
Trade & other receivables	5(b)	—	—	1,574	1,574
Financial assets at fair value through other comprehensive income	5(c)	1,871	—	—	1,871
Other non-current assets	5(d)	—	—	3,311	3,311
		1,871	**—**	**134,213**	**136,084**
As of June 30, 2019					
Cash & cash equivalents	5(a)	—	—	50,426	50,426
Trade & other receivables	5(b)	—	—	4,060	4,060
Financial assets at fair value through other comprehensive income	5(c)	2,317	—	—	2,317
Other non-current assets	5(d)	—	—	3,324	3,324
		2,317	**—**	**57,810**	**60,127**

(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 June 30, 2020					
Trade and other payables	5(e)	—	—	24,972	24,972
Borrowings	5(f)	—	—	89,478	89,478
Contingent consideration	5(g)(iii)	—	45,166	—	45,166
		—	**45,166**	**114,450**	**159,616**
As of June 30, 2019					
Trade and other payables	5(e)	—	—	13,060	13,060
Borrowings	5(f)	—	—	81,286	81,286
Contingent consideration	5(g)(iii)	—	47,534	—	47,534
		—	**47,534**	**94,346**	**141,880**

(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 10. 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 June 30, 2020	2019
Cash at bank	128,916	50,005
Deposits at call[(1)]	412	421
	129,328	**50,426**

(1) As of June 30, 2020 and June 30, 2019, 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 receivables

(in U.S. dollars, in thousands)	As of June 30, 2020	2019
Trade debtors	678	1,739
Income tax and tax incentives recoverable[(1)]	—	1,511
Foreign withholding tax recoverable	471	471
Security deposit	252	250
Sundry debtors	—	2
Other recoverable taxes (Goods and services tax and value-added tax)	173	86
Interest receivables	—	1
Trade and other receivables	**1,574**	**4,060**

(1) The Group's research and development activities are not eligible for the refundable tax offset under an Australian Government tax incentive as a result of the Group earning revenues in excess of A$20.0 million for the years ended June 30, 2020 and 2019. For the year ended June 30, 2020, the Group has recognized $Nil income from research and development tax incentives. The $1.5 million recognized as a receivable at June 30, 2019 related to revenue from research and development tax incentives for the year ended June 30, 2018, and was received in July 2019.

(ii) Prepayments

(in U.S. dollars, in thousands)	As of June 30, 2020	2019
Clinical trial research and development expenditure	3,304	6,042
Prepaid insurance and subscriptions	1,337	1,095
Other	1,005	899
Prepayments	**5,646**	**8,036**

(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) Other receivables

These amounts generally arise from transactions outside the usual operating activities of the Group.

(v) 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.

(vi) 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 10(a) and (b).

c. Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income include the following classes of financial assets:

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Unlisted securities:		
Equity securities	1,871	2,317
	1,871	**2,317**

(i) Classification of financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income comprises equity securities which are not held for trading, and which the Group has irrevocably elected at initial recognition to recognize in this category. These are strategic investments and the Group considers this classification to be more relevant.

The financial assets are presented as non-current assets unless they mature, or management intends to dispose of them within 12 months of the end of the reporting period.

(ii) Impairment indicators for financial assets at fair value through other comprehensive income

Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value. See Note 22(m)(iv) for further details about the Group's impairment policies for financial assets.

(iii) Amounts recognized in other comprehensive income

For the years ended June 30, 2020, 2019 and 2018, the Group recognized in statement of comprehensive income a loss of $0.4 million, a loss of $0.4 thousand and a gain of $0.3 million respectively, for change in fair value of the financial assets through other comprehensive income.

(iv) Fair value, impairment and risk exposure

Information about the methods and assumptions used in determining fair value is provided in Note 5(g). None of the financial assets through other comprehensive income are either past due or impaired.

All financial assets at fair value through other comprehensive income are denominated in USD.

d. Other non-current assets

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Bank Guarantee	660	673
Letter of Credit	1,178	1,178
U.S. Tax credits	1,473	1,473
	3,311	**3,324**

(i) Classification of financial assets as other non-current assets

Bank guarantee

These funds are held in an account named Mesoblast Limited at National Australia Bank according to the terms of a Bank Guarantee which is security for the sublease agreement for our occupancy of Level 38, 55 Collins Street, Melbourne, Victoria, Australia. The Bank Guarantee is security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The Bank Guarantee continues in force until it is released by the lessor.

Letter of credit

These funds held in an account named Mesoblast, Inc. at the Bank of America according to the terms of an irrevocable standby letter of credit which is security for the sublease agreement for our occupancy of 505 Fifth Avenue, New York, New York, United States of America. The letter of credit is security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The letter of credit is deemed to automatically extend without amendment for a period of one year at each anniversary but will not automatically extend beyond the final expiration of July 31, 2021.

U.S. Tax credits

These funds are receivable from the Internal Revenue Service ("IRS") as a result of the changes in the U.S. corporate income tax legislation with the Tax Act. Tax credits arising from the Alternative Minimum Tax ("AMT") regime become refundable in 2021.

(ii) Impairment and risk exposure

No other non-current assets are either past due or impaired.

e. Trade and other payables

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Trade payables and other payables	24,972	13,060
Trade and other payables	**24,972**	**13,060**

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

f. Borrowings

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Borrowings		
Secured liabilities:		
Borrowing arrangements	80,000	80,000
Less: transaction costs	(6,738)	(6,738)
Amortization of carrying amount, net of payments made	16,216	8,024
	89,478	**81,286**

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Borrowings		
Current	32,455	14,007
Non-current	57,023	67,279
	89,478	**81,286**

(i) Borrowing arrangements

Hercules

In March 2018, the Group entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. The Group drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019. An additional $25.0 million may be drawn, subject to certain conditions. The loan matures in March 2022.

In August 2020, as disclosed in Note 15, the Group amended the terms of the loan to defer the commencement of principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45% per annum. At June 30, 2019, in line with increases in the U.S. prime rate, the interest rate was 10.45%. On August 1, September 19 and October 31, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20%, 9.95% and 9.70%, respectively, and remains at 9.70% at June 30, 2020 in line with the amended terms of the loan agreement. As at June 30, 2020, the Group recognized $3.6 million in interest payable within twelve months as a current liability.

In the years ended June 30, 2020 and 2019, the Group recognized gains of $1.3 million and $0.4 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurement gains relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility.

NovaQuest

On June 29, 2018, the Group drew the first tranche of $30.0 million of the principal amount from the $40.0 million loan and security agreement with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of RYONCIL for the treatment in pediatric SR-aGVHD. The Group can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of RYONCIL for pediatric SR-aGVHD are significantly higher than current forecasts.

If there are no net sales of RYONCIL for pediatric SR-aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD is less than the 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 as we approach the potential approval of RYONCIL for pediatric SR-aGVHD (Prescription Drug User Fee Act ("PDUFA") date of September 30, 2020) may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment 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 other operating income and expenses and finance costs in the period the revision is made.

As of June 30, 2020, management have assumed that RYONCIL for pediatric SR-aGVHD will obtain Biologics License Application ("BLA") approval at the PDUFA action date of September 30, 2020. In August 2020, as disclosed in Note 15, the Oncologic Drugs Advisory Committee ("ODAC") of the United States Food and Drug Administration ("FDA") voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. An FDA decision could lead to a remeasurement of the carrying value of the NovaQuest borrowings as management update net sales forecasts and other key assumptions.

As at June 30, 2020, the Group has recognized a current liability of $4.5 million which represents the present value of interest payable of $4.2 million and $0.3 million loan administration fee which is payable annually in June.

In the years ended June 30, 2020 and 2019, the Group recognized losses of $0.8 million and $0.7 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within other operating income. In the years ended June 30, 2020 and 2019, the Group recognized gains of $0.1 million and $Nil, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurements relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility with NovaQuest.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group's floating rate loan with the senior creditor, Hercules.

(ii) Compliance with loan covenants

Our loan facilities with Hercules 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. In addition, under our loan and security agreement with Hercules, the Group are obliged to maintain certain levels of cash in the United States and a minimum unrestricted cash balance across the Group.

The Group has complied with the financial and other restrictive covenants of its borrowing facilities during the year ended June 30, 2020 and during the year ended June 30, 2019.

(iii) Net debt reconciliation

(in U.S. dollars, in thousands)	As of June 30, 2020	As of June 30, 2019
Cash and cash equivalents	129,328	50,426
Borrowings Repayable within one year [1]	(35,974)	(14,007)
Borrowings Repayable after one year	(63,340)	(67,279)
Net Debt[2]	**30,014**	**(30,860)**
Cash and cash equivalents	129,328	50,426
Gross debt - fixed interest rates	(49,414)	(33,060)
Gross debt - variable interest rates	(49,900)	(48,226)
Net Debt[2]	**30,014**	**(30,860)**

(1) In August 2020, as disclosed in Note 15, the Group amended the terms of the Hercules loan agreement to defer principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

(2) Net debt amount includes leases and borrowing arrangements

		Liabilities from financing activities			Other assets	
(in U.S. dollars, in thousands)	Notes	Borrowings	Leases	Sub-total	Cash and cash equivalents	Total
Net Debt as at June 30, 2019		(81,286)	—	(81,286)	50,426	(30,860)
Recognized on adoption of IFRS 16	22 (a)	—	(5,775)	(5,775)	—	(5,775)
		(81,286)	**(5,775)**	**(87,061)**	**50,426**	**(36,635)**
Cash Flows[1]		5,443	2,078	7,521	77,406	84,927
Remeasurement of borrowing arrangements		607	—	607	—	607
Other Changes[2]		(14,242)	(2,057)	(16,299)	—	(16,299)
Acquisition - leases		—	(4,083)	(4,083)	—	(4,083)
Foreign exchange adjustments		—	1	1	1,496	1,497
Net Debt as at June 30, 2020		**(89,478)**	**(9,836)**	**(99,314)**	**129,328**	**30,014**

(1) Cash flows include the interest payments for borrowings and leases and payments of lease liabilities which are presented as operating and financing cash flows in the statement of cash flows, respectively.

(2) Other changes include accrued interest expense which will be presented as operating cash flows in the statement of cash flows when paid.

(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.

g. Recognized fair value measurements

(i) Fair value hierarchy

The following table presents the Group's financial assets and financial liabilities measured and recognized at fair value as of June 30, 2020 and June 30, 2019 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of June 30, 2020 (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	5(c)	—	—	1,871	1,871
Total Financial Assets		**—**	**—**	**1,871**	**1,871**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(g)(iii)	—	—	45,166	45,166
Total Financial Liabilities		**—**	**—**	**45,166**	**45,166**

As of June 30, 2019 (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	5(c)	—	—	2,317	2,317
Total Financial Assets		**—**	**—**	**2,317**	**2,317**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(g)(iii)	—	—	47,534	47,534
Total Financial Liabilities		**—**	**—**	**47,534**	**47,534**

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, and trading and financial assets at fair value through other comprehensive income) 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) and equity securities (unlisted).

(ii) Valuation techniques used.

The Group used the discounted cash flow analysis to determine the fair value measurements of level 3 instruments.

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

The following table presents the changes in level 3 instruments for the years ended June 30, 2020 and June 30, 2019:

(in U.S. dollars, in thousands)	**Contingent consideration provision**
Opening balance - July 1, 2018	42,070
Amount used during the period	(800)
Charged/(credited) to consolidated income statement:	
Remeasurement[(1)]	6,264
Closing balance - June 30, 2019	**47,534**
Opening balance - July 1, 2019	47,534
Amount used during the period	(988)
Charged/(credited) to consolidated income statement:	
Remeasurement[(2)]	(1,380)
Closing balance - June 30, 2020	**45,166**

(1) In the year ended June 30, 2019 a loss of $6.3 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, developmental timelines, product pricing 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 year ended June 30, 2020 a gain of $1.3 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, 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.

(iv) Valuation inputs and relationship to fair value

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) Description	Fair value as of June 30, 2020	Fair value as of June 30, 2019	Valuation technique	Unobservable inputs[1]	Range of inputs (weighted average) Year Ended June 30, 2020	Range of inputs (weighted average) Year Ended June 30, 2019	Relationship of unobservable inputs to fair value
Contingent consideration provision	45,166	47,534	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.4%. Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2020: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 3%. Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Year ended June 30, 2020: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 3%. Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

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

(v) Valuation processes

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

For the years ended June 30, 2020 and 2019, 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 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. The remeasurement charged to the consolidated income statement was a net result of changes to key assumptions such as developmental timelines, market penetration, market population, product pricing, probability of success and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

As of June 30, 2020, management have assumed that RYONCIL will obtain BLA approval at the PDUFA action date of September 30, 2020. In August 2020, as disclosed in Note 15, the ODAC of the FDA voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy

and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. An FDA decision could lead to a remeasurement of contingent consideration as management update key assumptions to reflect that decision.

The fair value of contingent consideration (in U.S. dollars, in thousands)	As of June 30, 2020	2019
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	28,801	28,005
Fair value of royalty payments from commercialization of the intellectual property acquired	16,365	19,529
	45,166	**47,534**

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 revenues: 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.

6. Non-financial assets and liabilities

a. Property, plant and equipment

(in U.S. dollars, in thousands)	Plant and Equipment	Office Furniture and Equipment	Computer Hardware and Software	Total
Year Ended June 30, 2019				
Opening net book amount	306	414	364	1,084
Additions	114	102	107	323
Exchange differences	1	(5)	(13)	(17)
Disposals	—	(2)	—	(2)
Depreciation charge	(217)	(133)	(212)	(562)
Closing net book value	**204**	**376**	**246**	**826**
As of June 30, 2019				
Cost	4,207	1,304	3,023	8,534
Accumulated depreciation	(4,003)	(928)	(2,777)	(7,708)
Net book value	**204**	**376**	**246**	**826**
Year Ended June 30, 2020				
Opening net book amount	204	376	246	826
Additions	1,393	458	152	2,003
Exchange differences	(2)	9	43	50
Disposals	—	—	(1)	(1)
Depreciation charge	(259)	(136)	(190)	(585)
Closing net book value	**1,336**	**707**	**250**	**2,293**
As of June 30, 2020				
Cost	5,598	1,766	3,182	10,546
Accumulated depreciation	(4,262)	(1,059)	(2,932)	(8,253)
Net book value	**1,336**	**707**	**250**	**2,293**

(i) Depreciation methods and useful lives

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over the estimated useful lives. The estimated useful lives are:

- Plant and equipment 3 – 15 years
- Office furniture and equipment 3 – 10 years
- Computer hardware and software 3 – 4 years

See Note 22(o) for other accounting policies relevant to property, plant and equipment.

b. Leases

(i) Amounts recognized on the balance sheet

Right-of-use assets

(in U.S. dollars, in thousands)	Buildings	Manufacturing	Total
Year Ended June 30, 2020			
Opening net book amount	—	—	—
Initial recognition under IFRS 16 adoption	4,897	—	4,897
Additions	—	3,844	3,844
Reassessment	321	998	1,319
Exchange differences	51	—	51
Depreciation charge	(1,509)	(624)	(2,133)
Closing net book value	**3,760**	**4,218**	**7,978**
As of June 30, 2020			
Cost	5,269	4,842	10,111
Accumulated depreciation	(1,509)	(624)	(2,133)
Net book value	**3,760**	**4,218**	**7,978**

Lease liabilities

(in U.S. dollars, in thousands)	As of June 30, 2020	As of June 30, 2019
Current	3,519	—
Non-current	6,317	—
Lease liabilities included in the statement of financial position	**9,836**	**—**

The lease liability is measured at the present value of the fixed and variable lease payments net of cash lease incentives that are not paid at the balance date. Lease payments are apportioned between the finance charges and reduction of the lease liability using the incremental borrowing rate to achieve a constant rate of interest on the remaining balance of the liability. Lease payments for buildings exclude service fees for cleaning and other costs. The interest expense (included in finance costs) for leases is $0.5 million for the year ended June 30, 2020.

Payments associated with short-term leases with a lease term of 12 months or less, contracts that contain lease and non-lease components that are cancellable within 12 months and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. The expense relating to short term leases was $0.6 million for the year ended June 30, 2020.

In the year ended June 30, 2020, total payments associated with lease liabilities was $2.4 million.

(ii) Depreciation methods and useful lives of right-of use assets

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over the estimated useful lives. Depreciation for leases for the years ended June 30, 2020 and 2019 was $1.5 million and $Nil, respectively.

(iii) Extension and termination options

Extension options and termination options may be included in the right-of-use asset leases across the Group. These are used to maximize operational flexibility in terms of managing the assets used in the Group's operations.

In determining the lease term, management considers all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options and periods after termination options are only included in the lease term if the lease is reasonably certain to be extended or not terminated.

A right-of-use asset and lease liability has been recognized in relation to the manufacturing service agreement entered into with Lonza in October 2019 for the supply of commercial product for the potential approval and launch of RYONCIL for the treatment of pediatric acute graft versus host disease in the US market. Management has determined that this agreement has a non-cancellable lease term of 4.5 years, at which time the Group has the option to exercise an extension or terminate the agreement. Additionally, if during

the initial 4.5 year lease term there is a significant delay in the expected approval date of the BLA for RYONCIL by the FDA then the lease term can be reduced at the Group's discretion.

As of June 30, 2020, the anticipated future contractual cash flows relating to the lease component of the Lonza agreement are $5.3 million, as included within lease liabilities in Note 10(c) on an undiscounted basis. The anticipated future contractual cash flows exclude cashflows beyond the initial non-cancellable lease term of 4.5 years as it is not reasonably certain the Group will extend the agreement. If there is a significant delay in the expected approval date of the BLA for RYONCIL by the FDA then the anticipated future contractual cash flows relating to the lease component will reduce by $2.0 million.

See Note 1(iii) and Note 22a(i) for other accounting policies relevant to lease accounting.

c. **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, 2019					
Opening net book amount	134,453	1,770	427,779	20,604	584,606
Additions	—	100	—	—	100
Exchange differences	—	(4)	—	1	(3)
Amortization charge	—	(122)	—	(1,455)	(1,577)
Closing net book amount	**134,453**	**1,744**	**427,779**	**19,150**	**583,126**
As of June 30, 2019					
Cost	134,453	2,822	489,698	23,999	650,972
Accumulated amortization	—	(1,078)	—	(4,849)	(5,927)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,744**	**427,779**	**19,150**	**583,126**
Year Ended June 30, 2020					
Opening net book amount	134,453	1,744	427,779	19,150	583,126
Additions	—	50	—	—	50
Exchange differences	—	(2)	—	1	(1)
Amortization charge	—	(119)	—	(1,455)	(1,574)
Closing net book amount	**134,453**	**1,673**	**427,779**	**17,696**	**581,601**
As of June 30, 2020					
Cost	134,453	2,862	489,698	24,000	651,013
Accumulated amortization	—	(1,189)	—	(6,304)	(7,493)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,673**	**427,779**	**17,696**	**581,601**

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

	As of June 30,	
(in U.S. dollars, in thousands)	2020	2019
Cardiovascular products [1]	254,351	254,351
Intravenous products for metabolic diseases and inflammatory/immunologic conditions [2]	70,730	70,730
Osiris MSC products [3]	102,698	102,698
	427,779	**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 RYONCIL for the treatment of children with SR-aGVHD and remestemcel-L for the treatment of Crohn's disease

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

(ii) Amortization methods and useful lives

The Group amortizes intangible assets with a finite useful life using the straight-line method over the following periods:

- Acquired licenses to patents 7 – 16 years
- Current marketed products 15 – 20 years

See Note 22(p) for the other accounting policies relevant to intangible assets and Note 22(j) for the Group's policy regarding impairments.

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

The Group tests annually whether goodwill and its assets with indefinite useful lives have suffered any impairment in accordance with its accounting policy stated in Note 22(j). 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 certain assumptions. A full annual impairment assessment was performed at March 31, 2020 and no impairment of the in-process research and development and goodwill was identified.

(iv) Impairment tests for goodwill and intangible assets with and 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 22(p)(iii)). 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 adult stem cell technology platform for commercialization. The carrying value of goodwill has been allocated to the appropriate operating segment for the purpose of impairment testing.

The recoverable amount of both goodwill and in-process research and development was assessed as of March 31, 2020 based on the fair value less costs to dispose. Management assess for indicators of impairment as at June 30, 2020 including considering events up to the date of the approval financial statements. No impairment as at June 30, 2020, was identified.

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

In determining the fair value less costs to dispose we have 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 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. 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 valuation of the Group that was applicable to the July 10, 2018 equity placement undertaken with NovaQuest through issuing of the Group's securities on the ASX;

- the valuation of the Group that was applicable to the October 12, 2018 equity placement undertaken with Tasly Pharmacetuicals through issuing of the Group's securities on the ASX;
- the market capitalization of the Group on the ASX (ASX:MSB) on the impairment testing date of March 31, 2020; and
- the valuation of the Group's assets from an independent valuation as of March 31, 2020.

Costs of disposal were assumed to be immaterial at March 31, 2020.

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 patent expiry.

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.

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

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 assessment showed that the recoverable amount of each product exceeds the carrying amount and therefore there is no impairment.

(vi) 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 at June 30, 2020 to exceed its recoverable amount.

In August 2020, as disclosed in Note 15, the ODAC of the FDA voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the PDUFA. Assumptions associated with SR-aGVHD in pediatric patients are included within the total valuation of Osiris MSC products within in-process research and development. As of June 30, 2020, management have assumed that RYONCIL for pediatric SR-aGVHD will obtain BLA approval at the PDUFA action date of September 30, 2020.

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

d. Provisions

	As of June 30, 2020			As of June 30, 2019		
(in U.S. dollars, in thousands)	**Current**	**Non-current**	**Total**	**Current**	**Non-current**	**Total**
Contingent consideration	19,699	25,467	45,166	1,033	46,501	47,534
Employee benefits	5,748	83	5,831	4,231	86	4,317
Provision for license agreements	3,750	2,013	5,763	2,000	1,742	3,742
	29,197	**27,563**	**56,760**	**7,264**	**48,329**	**55,593**

(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(g)(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 of June 30, 2020 and 2019, the entire amount of the accrual was $0.8 million and $0.7 million respectively, and is presented as current, since the Group does not have an unconditional right to defer settlement for any of these obligations.

(ii) Movements

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements. Refer to Note 5(g)(iii) for movements in contingent consideration for the years ended June 30, 2020 and 2019.

e. Deferred tax balances

(i) Deferred tax balances

(in U.S. dollars, in thousands)	As of June 30, 2020	2019
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	72,899	61,742
Other temporary differences	6,196	3,687
Total deferred tax assets	**79,095**	**65,429**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	79,825	76,553
Total deferred tax liabilities	**79,825**	**76,553**
Net deferred tax liabilities	**730**	**11,124**
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	79,095	65,429
Deferred tax liabilities expected to be settled within 12 months	99	99
Deferred tax liabilities expected to be settled after 12 months	79,726	76,454

(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, 2018	**(55,904)**	**(669)**	**76,652**	**20,079**
Charged/(credited) to:				
- profit or loss	(5,838)	(3,018)	(99)	(8,955)
As of June 30, 2019	**(61,742)**	**(3,687)**	**76,553**	**11,124**
Charged/(credited) to:				
- profit or loss	(10,727)	(1,960)	3,272	(9,415)
- directly to equity	(430)	(549)	—	(979)
As of June 30, 2020	**(72,899)**	**(6,196)**	**79,825**	**730**

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

f. Deferred consideration

(in U.S. dollars, in thousands)	As of June 30, 2020	2019
Opening balance[(1)]	10,000	—
Milestone consideration received during the period[(2)]	2,500	20,000
Amount recognized as revenue during the period[(1)]	(10,000)	(10,000)
Balance as of the end of the period	**2,500**	**10,000**

(1) The $10.0 million opening balance in deferred consideration represents the portion of the $20.0 million up-front technology access fee received from Tasly that had not been recognized as revenue. In accordance with the Group's accounting policy, revenue related to the licensing of intellectual property is only recognized to the extent that control has been transferred to the customer. In the year ended June 30, 2020, the Group recognized the remaining $10.0 million of the up-front technology access fee received in revenue as the control for this portion of revenue was transferred to Tasly based on our decision regarding the exercise of our rights in the terms and conditions of the agreement.

(2) The $2.5 million milestone payment received in December 2019 from Grünenthal was considered constrained and resulted in deferred consideration as of June 30, 2020.

7. Equity

a. Contributed equity

(i) Share capital

	As of June 30,					
	2020	2019	2018	2020	2019	2018
	Shares No.			(U.S. dollars, in thousands)		
Contributed equity						
(i) Share capital						
Ordinary shares	583,949,612	498,626,208	482,639,654	1,051,450	910,405	889,481
Less: Treasury Shares	(3,500,000)	(3,500,000)	(3,500,000)	—	—	—
Total Contributed Equity	**580,449,612**	**495,126,208**	**479,139,654**	**1,051,450**	**910,405**	**889,481**

(ii) Movements in ordinary share capital

	As of June 30,			As of June 30,		
	2020	2019	2018	2020	2019	2018
	Shares No.			(U.S. dollars, in thousands)		
Opening balance	498,626,208	482,639,654	428,221,398	910,405	889,481	830,425
Issues of ordinary shares during the period						
Exercise of share options[1]	4,223,404	313,108	289,245	4,364	258	116
Share based compensation for services rendered	600,000	1,209,187	540,051	864	1,170	662
Payment for contingent consideration	—	—	6,029,545	—	—	10,000
Entitlement offer to existing eligible shareholders	—	—	36,191,982	—	—	40,449
Placement of shares under an equity facility agreement	—	—	2,000,000	—	—	—
Placement of shares under a share placement agreement[2]	80,500,000	14,464,259	—	139,483	20,000	—
Placement of shares under a license agreement	—	—	892,857	—	—	1,000
Transaction costs arising on share issue	—	—	—	(6,871)	(817)	(2,869)
	85,323,404	15,986,554	45,943,680	137,840	20,611	49,358
Unissued ordinary shares during the period						
Placement of shares under a share placement agreement	—	—	8,474,576	—	—	10,000
Transaction costs arising on share issue	—	—	—	—	—	(340)
	—	—	8,474,576	—	—	9,660
Total contributions of equity during the period	85,323,404	15,986,554	54,418,256	137,840	20,611	59,018
Share options reserve transferred to equity on exercise of options	—	—	—	3,205	313	38
Ending balance	**583,949,612**	**498,626,208**	**482,639,654**	**1,051,450**	**910,405**	**889,481**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Options Plan ("ESOP"). The shares issued and share capital received upon the exercise of options are recorded above.

(2) In October 2019, the Group completed a A$75.0 million (US$50.7 million) capital raise through the placement of 37.5 million new fully-paid ordinary shares at a price of A$2.00 per share to existing and new institutional investors, representing a 3.15% discount to the 10 day volume weighted average price calculated at the close of trading. In May 2020, the Group completed a A$138.0 million (US$88.8 million) capital raise through the placement of 43.0 million new fully-paid ordinary shares at a price of A$3.20 per share to existing and new institutional investors, representing a 7% discount to the 5 day volume weighted average price calculated at the close of trading May 8, 2020. During the year ended June 30, 2019, a $20.0 million equity purchase of Mesoblast Limited was completed at A$1.86 per share, representing a 20% premium to a blended volume weighted average price calculated over three months, one month and one day.

(iii) Ordinary shares

Ordinary shares participate in dividends and the proceeds on winding up of the Group in equal proportion to the number of shares held. At shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands. Ordinary shares have no par value and the Company does not have a limited amount of authorized capital.

(iv) Employee share options

Information relating to the Group's employee share option plan, including details of shares issued under the scheme, is set out in Note 17.

b. Reserves

(i) Reserves

(in U.S. dollars, in thousands)	As at June 30, 2020	2019
Share-based payments reserve	85,330	80,034
Investment revaluation reserve	(429)	17
Foreign currency translation reserve	(38,267)	(39,413)
	46,634	**40,638**

(ii) Reconciliation of reserves

(in U.S. dollars, in thousands)	As at June 30,
Share-based payments reserve	2020	2019
Opening balance	80,034	75,974
Tax credited / (debited) to equity	979	—
Transfer to ordinary shares on exercise of options	(3,205)	(313)
Share option expense for the year	7,522	4,363
Reclassification of modified options to/(from) liability	—	10
Closing Balance	**85,330**	**80,034**
Investment revaluation reserve		
Opening balance	17	21
Changes in the fair value of financial assets through other comprehensive income	(446)	(4)
Closing Balance	**(429)**	**17**
Foreign currency translation reserve		
Opening balance	(39,413)	(39,276)
Currency gain/(loss) on translation of foreign operations net assets	1,146	(137)
Closing Balance	**(38,267)**	**(39,413)**

(iii) Nature and purpose of reserves

Share-based payment reserve

The share-based payments reserve is used to recognize:

- the fair value(1) of options issued but not exercised; and
- the fair value(1) of deferred shares granted but not yet vested.

(1) The fair value recognized is determined at the acceptance date, which is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.

Foreign currency translation reserve

Exchange differences arising on translation of a foreign controlled entity are recognized in other comprehensive income and accumulated in a separate reserve within equity. The cumulative amount is reclassified to profit or loss when the net investment is disposed of.

8. Cash flow information

(in U.S. dollars, in thousands) (a) Reconciliation of cash and cash equivalents	As of June 30, 2020	 2019	 2018
Cash at bank	128,916	50,005	37,221
Deposits at call	412	421	542
	129,328	**50,426**	**37,763**

(in U.S. dollars, in thousands) (b) Reconciliation of net cash flows used in operations with loss after income tax	Year Ended June 30, 2020	 2019	 2018
Loss for the period	(77,940)	(89,799)	(35,290)
Add/(deduct) net loss for non-cash items as follows:			
Depreciation and amortization	3,667	2,139	2,650
Foreign exchange (gains)/losses	(302)	(154)	(160)
Finance costs	8,800	6,914	725
Remeasurement of borrowing arrangements	(607)	376	—
Remeasurement of contingent consideration	(1,380)	6,264	(10,541)
Payment under a license agreement paid in shares	—	—	1,000
Payment for services rendered in shares	—	620	—
Equity settled share-based payment	7,522	4,368	6,199
Deferred tax benefit	(9,415)	(8,955)	(30,664)
Change in operating assets and liabilities:			
Decrease/(increase) in trade and other receivables	890	4,974	(6,093)
Decrease/(increase) in prepayments	2,292	5,237	1,503
Decrease/(increase) in tax assets	1,499	1,729	(1,807)
Increase/(decrease) in trade creditors and accruals	12,508	(3,972)	(4,464)
Increase/(decrease) in provisions	3,601	2,469	1,930
(Decrease)/increase in deferred consideration	(7,500)	10,000	—
Net cash outflows used in operations	**(56,365)**	**(57,790)**	**(75,012)**

9. Significant estimates, judgments and errors

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgment in applying the Group's accounting policies.

This note provides an overview of the areas that involved a higher degree of judgment or complexity, and of items which are more likely to be materially adjusted due to estimates and assumptions turning out to be wrong. Detailed information about each of these estimates and judgments is included in Notes 1 to 8 together with information about the basis of calculation for each affected line item in the financial statements. In addition, this note also explains where there have been actual adjustments this year as a result of an error and of changes to previous estimates.

Significant estimates and judgments

The areas involving significant estimates or judgments are:

- recognition of revenue (Note 3 and Note 22(e));
- fair value of contingent liabilities and contingent purchase consideration in a business combination (Note 5(g) and 12);
- fair value of goodwill and other intangible assets including in-process research and development (Note 6(c));
- useful life of intangible assets (Note 6(c));
- recognition of deferred tax assets and deferred tax liabilities (Note 4(b));
- accrued research and development and manufacturing commercialization expenses (Note 5(e));
- fair value of share-based payments (Note 17);

- fair value of borrowings (Note 5(f)); and
- recognition of pre-launch inventory costs (Note 22(f)).

The preparation of these 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.

Impact of COVID-19

Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that COVID-19 could have on the Group's significant accounting estimates. COVID-19 has not led to a material deterioration in the Group's financial circumstances, nor required the Group to utilize government support.

The Group is facing some challenges from the pandemic. The Group's clinical trials that aren't treating COVID-19 infected patients are experiencing some delays given reduced capacity at hospitals for completing activities and impacts on patient mobility for treatments or final visits. In addition, health regulators may rate other treatments as higher priorities due to the crisis.

On the other hand, COVID-19 has presented potentially significant opportunities for the Group. At the initial onset of the pandemic, the Group was able to offer rememstemcel-L to sufferers of COVID-19 after the FDA cleared it for expanded access protocol ("EAP") for compassionate use.

The Group's future assessments of the impact of COVID-19 could result in material impacts to the Group's consolidated financial statements in future periods.

10. 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	Long-term borrowings at floating rates	Sensitivity analysis	The facility can be refinanced and/or repaid. Interest rate swaps can be entered into to convert the floating interest rate to a fixed interest rate as required.
	Term deposits at fixed 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.

Credit risk	Cash and cash equivalents, and trade and other receivables	Aging analysis Credit ratings	Only transact with the best risk rated banks available in each region giving consideration to the products required.
Liquidity risk	Cash and cash equivalents Borrowings	Rolling cash flow forecasts	Future cash flows 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 primarily in the Group's Australian based entity, whose functional currency is the A$ relating to clinical, regulatory and overhead activities. 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 June 30, 2020, the Group held 86% of its cash in USD, and 14% in AUD. As of June 30, 2019 the Group held 97% of its cash in USD, and 3% in AUD.

The balances held at the end of the year that give rise to currency risk exposure are presented in USD in the following table, together with a sensitivity analysis which assesses the impact that a change of +/-20% in the exchange rate as of June 30, 2020 and June 30, 2019 would have had on the Group's reported net profits/(losses) and/or equity balance.

		+20%	-20%
(in U.S. dollars, in thousands) **As of June 30, 2020**	**Foreign currency balance held**	**Profit/(Loss) USD**	**Profit/(Loss) USD**
Bank accounts - USD	USD 402	$ 80	$ (80)
Bank accounts - CHF	CHF 87	$ 18	$ (18)
Bank accounts - SGD	SGD 112	$ 16	$ (16)
Bank accounts - EUR	EUR 46	$ 10	$ (10)
Trade and other receivables - SGD	SGD 141	$ 20	$ (20)
Trade and other receivables - CHF	CHF 2	$ 0	$ (0)
Trade and other receivables - EUR	EUR 43	$ 10	$ (10)
Trade payables and accruals - USD	(USD 4,872)	$ (974)	$ 974
Trade payables and accruals - AUD	(AUD 731)	$ (100)	$ 100
Trade payables and accruals - SGD	(SGD 124)	$ (18)	$ 18
Trade payables and accruals - GBP	(GBP 60)	$ (15)	$ 15
Trade payables and accruals - EUR	(EUR 124)	$ (28)	$ 28
Trade payables and accruals - CHF	(CHF 37)	$ (8)	$ 8
Provisions - USD	(USD 0)	$ (350)	$ 350
Provisions - SGD	(SGD 98)	$ (14)	$ 14
		$ (1,353)	**$ 1,353**

(in U.S. dollars, in thousands) As of June 30, 2019	Foreign currency balance held	+20% Profit/(Loss) USD	-20% Profit/(Loss) USD
Bank accounts - USD	USD 383	$ 77	$ (77)
Bank accounts - CHF	CHF 49	$ 10	$ (10)
Bank accounts - SGD	SGD 83	$ 12	$ (12)
Bank accounts - EUR	EUR 4	$ 1	$ (1)
Trade and other receivables - SGD	SGD 30	$ 4	$ (4)
Trade and other receivables - CHF	CHF 2	$ 0	$ (0)
Trade and other receivables - EUR	EUR 8	$ 2	$ (2)
Trade payables and accruals - USD	(USD 490)	$ (98)	$ 98
Trade payables and accruals - AUD	(AUD 280)	$ (39)	$ 39
Trade payables and accruals - SGD	(SGD 193)	$ (28)	$ 28
Trade payables and accruals - GBP	(GBP 30)	$ (8)	$ 8
Trade payables and accruals - EUR	(EUR 86)	$ (19)	$ 19
Trade payables and accruals - CHF	(CHF 55)	$ (11)	$ 11
Provisions - SGD	(SGD 70)	$ (10)	$ 10
		$ (107)	**$ 107**

(ii) Cash flow and fair value interest rate risk

The Group's main interest rate risk arises from long-term borrowings with a floating interest rate, which exposes the Group to cash flow interest rate risk. As interest rates fluctuate, the amount of interest payable on financing where the interest rate is not fixed will also fluctuate. This interest rate risk can be managed by interest rate swaps which can be entered into to convert the floating interest rate to a fixed interest rate as required. Additionally, the Group can repay its loan facility at its discretion and can also refinance if the terms are suitable in the marketplace or from the existing lender.

The Group did not enter into any interest rate swaps during the year ended June 30, 2020.

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

	As of June 30, 2020		As of June 30, 2019	
(in U.S. dollars, in thousands, except percent data)	Total	% of total loans	Total	% of total loans
Financial liabilities				
Current borrowings				
Variable rate borrowings - Hercules	27,949	31%	13,607	17%
Non-current borrowings				
Variable rate borrowings - Hercules	21,951	25%	34,619	43%
	49,900	**56%**	**48,226**	**60%**

An analysis by maturities is provided in Note 10(c) below. The percentage of total loans shows the proportion of loans that are currently at variable rates in relation to the total amount of borrowings.

The borrowings which expose the Group to interest rate risk are described in the table below, together with the maximum and minimum interest rates being earned as of June 30, 2020 and June 30, 2019. The effect on profit is shown if interest rates change by 5%, in either direction, is as follows:

	As of June 30, 2020			As of June 30, 2019		
(in U.S. dollars, in thousands, except percent data)	Low	High	USD	Low	High	USD
Borrowings - USD	9.70%	9.70%	49,900[(1)]	10.45%	10.45%	48,226[(1)]
Rate increase by 5%	10.19%	10.19%	243	10.97%	10.97%	261
Rate decrease by 5%	9.22%	9.22%	(243)	9.93%	9.93%	(261)

(1) Effect on profit/loss of interest rate changes is based on the loan principal amount of $50.0 million as of June 30, 2020 and June 30, 2019.

The Group is also exposed to interest rate movements which impacts interest income earned on its deposits and at call accounts. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by periodically reviewing interest rates available for suitable interest bearing accounts to ensure we earn interest at market rates. 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 June 30, 2020 and June 30, 2019. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

	As of June 30, 2020			As of June 30, 2019		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Funds invested - USD	0.03%	0.03%	102,925	1.76%	1.76%	46,051
Rate increase by 10%	0.03%	0.03%	3	1.94%	1.94%	81
Rate decrease by 10%	0.03%	0.03%	(3)	1.58%	1.58%	(81)
AUD	**Low**	**High**	**AUD**	**Low**	**High**	**AUD**
Funds invested - AUD	0.86%	0.86%	600	2.23%	2.23%	600
Rate increase by 10%	0.95%	0.95%	1	2.45%	2.45%	1
Rate decrease by 10%	0.77%	0.77%	(1)	2.01%	2.01%	(1)

(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 the financing arrangement will also fluctuate, resulting in an adjustment to the carrying amount of financial liability. The adjustment is recognized in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses in the period the revision is made.

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

	As of June 30, 2020		As of June 30, 2019	
(in U.S. dollars, in thousands, except percent data)	**Total**	**% of total loans**	**Total**	**% of total loans**
Financial liabilities				
Current borrowings				
Borrowings - NovaQuest	4,506	5%	400	0%
Non-current borrowings				
Borrowings - NovaQuest	35,072	39%	32,660	40%
	39,578	**44%**	**33,060**	**40%**

As at June 30, 2020, all other factors held constant, a 20% increase in the forecast net sales of MSC-100-IV for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia would increase non-current borrowing and decrease profit by $5.3 million, whereas a 20% decrease in the net sales of MSC-100-IV for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia would decrease non-current borrowings and increase profit by $3.1 million.

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 June 30, 2020, 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.

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 Group does not generally have trade receivables. The Group's receivables are tabled below.

(in U.S. dollars, in thousands)	As of June 30, 2020	2019
Cash and cash equivalents		
Deposits at call (Note 5(a)) - minimum A rated	412	421
Cash at bank (Note 5(a)) - minimum A rated	128,916	50,005
Trade and other receivables		
Receivable from other parties (non-rated)	801	1,740
Receivable from the Australian Government (Income Tax)	—	1,511
Receivable from the Australian Government (Foreign Withholding Tax)	400	400
Receivable from minimum A rated bank deposits (interest)	250	252
Receivable from the Australian Government (Goods and Services Tax)	171	84
Receivable from the United States Government (Income Tax)	—	71
Receivable from the Swiss Government (Value-Added Tax)	2	2
Other non-current assets		
Receivable from the United States Government (U.S. tax credits)	1,473	1,467

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 June 30, 2020 and June 30, 2019 are non-interest bearing and mature within 6 months. The total contractual cash flows associated with these liabilities equate to the carrying amount disclosed within the financial statements.

As of June 30, 2020, the maturity profile of the anticipated future contractual cash flows, on an undiscounted basis 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)(3)]	(35,995)	(35,915)	(51,218)	(17,510)	(140,638)	(89,478)
Trade payables	(24,972)	—	—	—	(24,972)	(24,972)
Lease liabilities	(4,026)	(2,377)	(4,204)	(593)	(11,200)	(9,836)
	(64,993)	**(38,292)**	**(55,422)**	**(18,103)**	**(176,810)**	**(124,286)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at June 30, 2020 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 pediatric SR-aGVHD**.**

(3) In August 2020, as disclosed in Note 15, the Group amended the terms of the Hercules loan agreement to defer principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability and are included in the contractual cash flows due within one year, on an undiscounted basis, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

11. Capital management

The Group's objective when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders. See Note 5(a) for the cash reserves of the Group as at the end of the financial reporting period.

12. Interests in other entities

The Group's subsidiaries as of June 30, 2020 and 2019 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also their principal place of business, aside from BeiCell Ltd, which was incorporated on November 15, 2018 in the Cayman Islands however operates in Hong Kong.

	Country of incorporation	Class of shares	Equity holding	
			As of June 30,	
			2020	2019
			%	%
Mesoblast, Inc.	USA	Ordinary	100	100
Mesoblast International Sàrl (includes Mesoblast International Sàrl Singapore Branch)	Switzerland	Ordinary	100	100
Mesoblast Australia Pty Ltd	Australia	Ordinary	100	100
Mesoblast UK Ltd	United Kingdom	Ordinary	100	100
Mesoblast International (UK) Ltd	United Kingdom	Ordinary	100	100
BeiCell Ltd	Cayman Islands	Ordinary	100	100

13. Contingent assets and liabilities

a. Contingent assets

The Group did not have any contingent assets outstanding as of June 30, 2020 and June 30, 2019.

b. Contingent liabilities

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

The Group 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 its use of the Medvet IP, on completion of certain milestones the Group 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.

(ii) Other contingent liabilities

The Group has entered into a number of other 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. As of June 30, 2020, the Group has assessed these contingent liabilities to be remote and specific disclosure is not required.

14. Commitments

a. Capital commitments

The Group did not have any commitments for future capital expenditure outstanding as of June 30, 2020 and June 30, 2019.

b. Purchase commitments

In the year ended June 30, 2020, the Group entered into a manufacturing service agreement with Lonza for the supply of commercial product for the potential approval and launch of RYONCIL for the treatment of pediatric acute graft versus host disease in

the US market. This agreement contains lease and non-lease components with a non-cancellable term of 4.5 years. The agreement contains a minimum financial commitment of $49.5 million. The Group has accounted for the lease component within the agreement as a lease liability separately from the non-lease components. As of June 30, 2020, the minimum financial commitment of the lease component is $5.3 million, disclosed within the total contractual cash flows on an undiscounted basis as lease liabilities. The minimum financial commitment of the non-lease component in the agreement is $44.2 million. If there is a significant delay in the expected approval date of the BLA for RYONCIL by the FDA then the minimum financial commitment under this manufacturing services agreement will reduce by $28.3 million, with $2.0 million of this reduction relating to the lease component and $26.3 million relating to the non-lease component of the agreement.

The Group did not have any other purchase commitments as of June 30, 2020.

15. Events occurring after the reporting period

On August 13, 2020, the ODAC of the FDA voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. RYONCIL has been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the PDUFA. Assumptions associated with SR-aGVHD in pediatric patients is included within the total valuation of contingent consideration, Osiris MSC products within in-process research and development and NovaQuest borrowings on the balance sheet.

In August 2020, the Group amended the terms of the Hercules loan agreement to defer principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result $24.3 million of the borrowings were recognized as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.

There were no other events that have occurred after June 30, 2020 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

16. Related party transactions

a. Parent entity

The parent entity within the Group is Mesoblast Limited.

b. Subsidiaries

Details of interests in subsidiaries are disclosed in Note 12 to the financial statements.

c. Key management personnel compensation

The aggregate compensation made to Directors and other members of key management personnel of the Group is set out below

	Year Ended June 30,	
(in U.S. dollars)	**2020**	**2019**
Short-term employee benefits	2,483,862	2,723,902
Long-term employee benefits	11,366	12,074
Post-employment benefits	34,294	45,878
Share based payments	1,146,965	297,423
	3,676,487	**3,079,277**

d. Transactions with other related parties

Accounts receivable from revenues, accounts payable to expenses and loans from subsidiaries as at the end of the fiscal year have been eliminated on consolidation of the Group.

e. Terms and conditions

All other transactions were made on normal commercial terms and conditions and at market rates, except that there are no fixed terms for the repayment of loans between the parties.

Outstanding balances are unsecured and are repayable in cash.

17. Share-based payments

The Company has adopted an Employee Share Option Plan ("ESOP") and a Loan Funded Share Plan ("LFSP") (together, "the Plans") to foster an ownership culture within the Company and to motivate senior management and consultants to achieve performance targets. Selected directors, employees and consultants may be eligible to participate in the Plans at the absolute discretion of the board of directors, and in the case of directors, upon approval by shareholders. The Company has not issued new securities under the LFSP since July 1, 2015, as of December 16, 2019 all LFSP grants had reach their expiry date.

Grant policy

In accordance with the Company's policy, options and loan funded shares are typically issued in three equal tranches. For issues granted prior to July 1, 2015 the length of time from grant date to expiry date was typically 5 years. Grants since July 1, 2015, are issued with a seven year term.

Options issued to employees generally vest based on performance or time conditions, or both. In the year ended June 30, 2020, senior executives were issued options that vest based on performance and time conditions. These options are required to satisfy certain pre-specified performance conditions and time-based vesting conditions prior to vesting. Time-based conditions restrict vesting to a maximum of one third at 12 months, two thirds at 24 months and full grant at 36 months, but only if the pre-specified performance conditions have been met. For time-based vesting options, the first tranche typically vests 12 months after grant date, the second tranche 24 months after grant date, and the third tranche 36 months after grant date.

The exercise price is determined by reference to the Company policy. Generally the exercise price is determined based on the market price calculated as the greater of the volume weighted market price of a share sold on the ASX on the 5 trading days up to and including the Board approval date, or the closing price on that day. In the case of options that have time-based vesting conditions only, the board of directors adds a 10% premium to the market price. Options with performance based vesting conditions are issued with no premium. The board of directors' policy is not to issue options at a discount to the market price.

The aggregate number of options which may be issued pursuant to the ESOP must not exceed 10,000,000 with respect to US incentive stock options, and with respect to Australian residents, the limit imposed under the Australian Securities and Investments Commission Class Order 14/1000.

In addition, the LFSP which has not been issued since July 1, 2015 and as of December 16, 2019 all LFSP grants had reach their expiry date, has the following characteristics:

On grant date, the Company issues new equity (rather than purchasing shares on market), and the loan funded shares are placed in a trust which holds the shares on behalf of the employee. The trustee issues a limited recourse, interest free, loan to the employee which is equal to the number of shares multiplied by the price. A limited-recourse loan means that the repayment amount will be the lesser of the outstanding loan value (the loan value less any amounts that may have already been repaid) and the market value of the shares that are subject to the loan. The price is the amount the employee must pay for each loan funded share if exercised.

The trustee continues to hold the shares on behalf of the employee until the employee chooses to settle the loan pertaining to the shares and all vesting conditions have been satisfied, at which point ownership of the shares is fully transferred to the employee.

Any dividends paid by the Company, while the shares are held by the trustee, are applied as a repayment of the loan at the after-tax value of the dividend.

a. Reconciliation of outstanding share based payments

Series	Grant Date[1]	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	07-Dec-10	26-Oct-19	USD 0.340	319,892	—	(319,892)	—	—	—
25b	12-Dec-14	31-Oct-19	AUD 4.49	50,000	—	—	(50,000)	—	—
28/LF13	09-Oct-14	08-Oct-19	AUD 4.52	75,000	—	—	(75,000)	—	—
29	25-Nov-14	24-Nov-19	AUD 4.00	240,000	—	—	(240,000)	—	—
LF14	06-Jan-15	16-Dec-19	AUD 4.66	150,000	—	—	(150,000)	—	—
31b	12-May-15	16-Feb-20	AUD 4.28	200,000	—	—	(200,000)	—	—
32	10-Jul-15	30-Jun-22	AUD 4.20	2,308,334	—	—	(40,000)	2,268,334	2,268,334
33	26-Aug-15	16-Aug-22	AUD 4.05	75,000	—	—	—	75,000	75,000
34	27-Apr-16	06-Mar-23	AUD 2.80	3,193,334	—	(475,000)	(70,000)	2,638,334	2,638,334
34	27-Apr-16	06-Mar-23	AUD 2.80				(10,000) *		
34a	27-Apr-16	17-Apr-23	AUD 2.74	200,000	—	—	—	200,000	200,000
34b	31-Oct-16	06-Mar-23	AUD 2.80	200,000	—	—	—	200,000	200,000
35	30-Jun-16	18-Jan-21	AUD 2.20	1,500,000	—	(600,000)	—	900,000	900,000
36	06-Dec-16	05-Dec-23	AUD 1.31	1,670,000	—	(720,334)	(26,666)	923,000	923,000
36a	06-Dec-16	05-Dec-23	AUD 1.19	4,188,000	—	(1,527,270)	(141,666)	2,519,064	2,023,232
36b	13-Jan-17	12-Jan-24	AUD 1.65	300,000	—	—	—	300,000	300,000
37	28-Jun-17	27-Jun-24	AUD 2.23	150,000	—	—	—	150,000	150,000
38	16-Sep-17	15-Sep-24	AUD 1.54	100,000	—	(33,334)	—	66,666	33,334
38a	16-Sep-17	15-Sep-24	AUD 1.40	150,000	—	—	—	150,000	150,000
39	13-Oct-17	12-Oct-24	AUD 1.94	1,978,333	—	(310,000)	(13,333)	1,655,000	999,994
39a	13-Oct-17	12-Oct-24	AUD 1.76	1,900,000	—	(297,575)	(300,000)	1,302,425	1,302,425
40	24-Nov-17	23-Nov-24	AUD 1.41	750,000	—	—	—	750,000	500,000
40a	24-Nov-17	23-Nov-24	AUD 1.28	750,000	—	—	—	750,000	—
41	18-Jun-18	17-Jun-25	AUD 1.52	200,000	—	—	—	200,000	133,334
42	11-Jul-18	10-Jul-25	AUD 1.56	200,000	—	—	—	200,000	66,667
43	18-Jul-18	17-Jul-25	AUD 1.87	5,845,000	—	(389,999)	(9,999)	5,398,334	1,544,992
43	18-Jul-18	17-Jul-25	AUD 1.87				(46,668) *		
43b	18-Jul-18	17-Jul-25	AUD 1.87	—	350,000	—	—	350,000	116,667
44	15-Jul-18	14-Jul-25	AUD 1.72	300,000	—	—	—	300,000	100,000
45	30-Nov-18	29-Nov-25	AUD 1.33	590,000	—	—	—	590,000	196,666
46	19-Jan-19	18-Jan-26	AUD 1.45	5,000	—	—	—	5,000	1,667
47	19-Jan-19	18-Jan-26	AUD 1.45	150,000	—	—	—	150,000	150,000
48	04-Apr-19	03-Apr-26	AUD 1.48	—	300,000	—	—	300,000	100,000
49	20-Jul-19	19-Jul-26	AUD 1.62	—	4,810,000	—	(120,000) *	4,690,000	—
49a	20-Jul-19	19-Jul-26	AUD 1.47	—	5,500,000	—	—	5,500,000	—
49b	20-Jul-19	19-Jul-26	AUD 1.47	—	1,346,667	—	—	1,346,667	—
49c	20-Jul-19	19-Jul-26	AUD 1.47	—	538,667	—	—	538,667	—
50	20-Jul-19	19-Jul-26	AUD 1.47	—	700,000	—	—	700,000	—
50a	20-Jul-19	19-Jul-26	AUD 1.47	—	400,000	—	—	400,000	—
51	29-Aug-19	28-Aug-26	AUD 1.47	—	300,000	(150,000)	—	150,000	—
52	29-Aug-19	28-Aug-26	AUD 1.62	—	400,000	—	—	400,000	—
53	29-Aug-19	28-Aug-26	AUD 1.47	—	800,000	—	—	800,000	—
54	25-Nov-19	24-Nov-26	AUD 1.98	—	845,000	—	—	845,000	—
55	29-May-19	28-May-26	AUD 1.48	—	450,000	—	—	450,000	300,000
56	18-Nov-19	17-Nov-26	AUD 1.83	—	200,000	—	—	200,000	—
57	25-Nov-19	24-Nov-26	AUD 1.80	—	100,000	—	—	100,000	—
58	25-Nov-19	24-Nov-26	AUD 1.98	—	450,000	—	—	450,000	—
June 30, 2020				**27,737,893**	**17,490,334**	**(4,823,404)**	**(1,493,332)**	**38,911,491**	**15,373,646**
Weighted average share purchase price				AUD 2.06	AUD 1.57	AUD 1.60	AUD 2.80	AUD 1.86	AUD 2.25

(1) The dates presented in the grant date column represent the date on which board approval was obtained. For valuation dates per IFRS 2, refer to Note 17(c).

Series	Grant Date[1]	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	07-Dec-10	26-Oct-18	USD 0.305	26,108	—	(26,108)	—	—	—
INC	07-Dec-10	26-Oct-19	USD 0.340	319,892	—	—	—	319,892	319,892
17/LF3	09-Jul-12	08-Jul-18	AUD 6.67	150,000	—	—	(150,000)	—	—
22/LF8	04-Sep-13	27-Aug-18	AUD 6.26	225,000	—	—	(225,000)	—	—
25a (i&ii)	01-Jan-14	31-Dec-18	AUD 6.36	650,000	—	—	(650,000)	—	—
25b	12-Dec-14	31-Oct-19	AUD 4.49	50,000	—	—	—	50,000	50,000
27/LF12	05-Sep-14	30-Jun-19	AUD 4.71	2,045,000	—	—	(1,790,000)		
27/LF12	05-Sep-14	30-Jun-19	AUD 4.71		—	—	(255,000) *	—	—
28/LF13	09-Oct-14	08-Oct-19	AUD 4.52	75,000	—	—	—	75,000	75,000
29	25-Nov-14	24-Nov-19	AUD 4.00	240,000	—	—		240,000	240,000
30c[2]	25-Mar-15	20-Jan-19	AUD 4.98	135,000	—	—	(135,000)	—	—
30d[2]	25-Mar-15	25-Jan-19	AUD 4.98	300,000	—	—	(300,000)	—	—
30f[2]	25-Mar-15	25-Jan-19	AUD 4.98	200,000	—	—	(200,000)	—	—
30h[2]	25-Mar-15	30-Jun-19	AUD 4.69	400,000	—	—	(400,000)	—	—
30i[2]	25-Mar-15	30-Jun-19	AUD 4.44	600,000	—	—	(600,000)	—	—
LF14	06-Jan-15	16-Dec-19	AUD 4.66	150,000	—	—	—	150,000	150,000
31b	12-May-15	16-Feb-20	AUD 4.28	200,000	—	—	—	200,000	200,000
32	10-Jul-15	30-Jun-22	AUD 4.20	2,458,334	—	—	(150,000) *	2,308,334	2,308,334
33	26-Aug-15	16-Aug-22	AUD 4.05	75,000	—	—	—	75,000	75,000
34	27-Apr-16	06-Mar-23	AUD 2.80	3,380,000	—	—	(186,666) *	3,193,334	3,193,334
34a	27-Apr-16	17-Apr-23	AUD 2.74	200,000	—	—	—	200,000	200,000
34b	31-Oct-16	06-Mar-23	AUD 2.80	200,000	—	—	—	200,000	200,000
35	30-Jun-16	18-Jan-21	AUD 2.20	1,500,000	—	—	—	1,500,000	1,500,000
36	06-Dec-16	05-Dec-23	AUD 1.31	1,885,000	—	(75,000)	(140,000) *	1,670,000	1,116,666
36a	06-Dec-16	05-Dec-23	AUD 1.19	4,400,000	—	(212,000)	—	4,188,000	3,000,502
36b	13-Jan-17	12-Jan-24	AUD 1.65	300,000	—	—	—	300,000	300,000
37	28-Jun-17	27-Jun-24	AUD 2.23	300,000	—	—	(150,000) *	150,000	100,000
38	16-Sep-17	15-Sep-24	AUD 1.54	100,000	—	—	—	100,000	33,334
38a	16-Sep-17	15-Sep-24	AUD 1.40	150,000	—	—	—	150,000	150,000
39	13-Oct-17	12-Oct-24	AUD 1.94	2,215,000	—	—	(236,667) *	1,978,333	668,330
39a	13-Oct-17	12-Oct-24	AUD 1.76	1,900,000	—	—	—	1,900,000	1,300,000
40	24-Nov-17	23-Nov-24	AUD 1.41	750,000	—	—	—	750,000	250,000
40a	24-Nov-17	23-Nov-24	AUD 1.28	750,000	—	—	—	750,000	—
41	18-Jun-18	17-Jun-25	AUD 1.52		200,000	—	—	200,000	66,667
42	11-Jul-18	10-Jul-25	AUD 1.56		200,000	—	—	200,000	—
43	18-Jul-18	17-Jul-25	AUD 1.87		5,970,000	—	(125,000) *	5,845,000	—
44	15-Jul-18	14-Jul-25	AUD 1.72		300,000	—	—	300,000	—
45	30-Nov-18	29-Nov-25	AUD 1.33		590,000	—	—	590,000	—
46	19-Jan-19	18-Jan-26	AUD 1.45		5,000	—	—	5,000	—
47	19-Jan-19	18-Jan-26	AUD 1.45		150,000	—	—	150,000	75,000
June 30, 2019				**26,329,334**	**7,415,000**	**(313,108)**	**(5,693,333)**	**27,737,893**	**15,572,059**
Weighted average share purchase price				AUD 2.68	AUD 1.79	AUD 1.16	AUD 4.58	AUD 2.06	AUD 2.35

(1) The dates presented in the grant date column represent the date on which board approval was obtained. For valuation dates per IFRS 2, refer to Note 17(c).

(2) 30a to 30i were granted as remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended 30 June 2015 (see Note 17(b)).

Series	Grant Date[1]	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	07-Dec-10	26-Oct-18	USD 0.305	154,064	—	(127,956)	—	26,108	26,108
INC	07-Dec-10	26-Oct-19	USD 0.340	447,848	—	(127,956)	—	319,892	319,892
17/LF3	09-Jul-12	08-Jul-18	USD 6.690	150,000	—	—	—	150,000	150,000
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2018	USD 6.290	50,000	—	—	(50,000)	—	—
20/LF6	24-May-13	23-May-18	USD 6.360	425,000	—	—	(325,000)		
20/LF6	24-May-13	23-May-18	AUD 6.36		—	—	(100,000) *	—	—
21/LF7	03-Sep-13	30-Jun-18	AUD 5.92	1,865,000	—	—	(1,615,000)		
22/LF8	04-Sep-13	27-Aug-18	AUD 6.28	225,000	—	—	—	225,000	225,000
25a (i&ii)	01-Jan-14	31-Dec-18	AUD 6.38	650,000	—	—	—	650,000	650,000
25b	12-Dec-14	31-Oct-19	AUD 4.51	50,000	—	—	—	50,000	50,000
27/LF12	05-Sep-14	30-Jun-19	AUD 4.71	2,070,000	—	—	(25,000) *	2,045,000	2,045,000
27(iv)	25-Aug-14	24-Aug-19	AUD 4.67	75,000	—	—	(75,000) *	—	—
28/LF13	09-Oct-14	08-Oct-19	AUD 4.54	85,000	—	—	(10,000) *	75,000	75,000
29	25-Nov-14	24-Nov-19	AUD 4.02	240,000	—	—	—	240,000	240,000
30a[2]	25-Mar-15	30-Jun-18	AUD 5.00	650,000	—	—	(650,000)	—	—
30b[2]	25-Mar-15	25-Jan-18	AUD 5.00	235,000	—	—	(235,000)	—	—
30c[2]	25-Mar-15	25-Jan-19	AUD 5.00	135,000	—	—	—	135,000	135,000
30d[2]	25-Mar-15	30-Jun-19	AUD 5.00	300,000	—	—	—	300,000	300,000
30e[2]	25-Mar-15	23-Jul-19	AUD 5.00	165,000	—	—	(165,000)	—	—
30f[2]	25-Mar-15	23-Jul-19	AUD 5.00	200,000	—	—	—	200,000	200,000
30g[2]	25-Mar-15	20-Jan-19	AUD 4.71	300,000	—	—	(300,000) *	—	—
30h[2]	25-Mar-15	25-Jan-18	AUD 4.71	400,000	—	—	—	400,000	400,000
30i[2]	25-Mar-15	25-Jan-19	AUD 4.46	600,000	—	—	—	600,000	600,000
30j	25-Mar-15	30-Jun-19	AUD 4.71	150,000	—	—	(150,000) *	—	—
LF14	06-Jan-15	16-Dec-19	AUD 4.66	150,000	—	—	—	150,000	150,000
31b	12-May-15	16-Feb-20	AUD 4.30	200,000	—	—	—	200,000	200,000
32	10-Jul-15	30-Jun-22	AUD 4.22	2,620,000	—	—	(161,666) *	2,458,334	1,683,336
33	26-Aug-15	16-Aug-22	AUD 4.07	91,667	—	—	(16,667) *	75,000	50,000
34	27-Apr-16	06-Mar-23	AUD 2.82	3,621,667	—	—	(241,667) *	3,380,000	2,299,982
34a	27-Apr-16	17-Apr-23	AUD 2.76	200,000	—	—	—	200,000	133,334
34b	31-Oct-16	06-Mar-23	AUD 2.82	200,000	—	—	—	200,000	200,000
35	30-Jun-16	30-Jun-19	AUD 2.20	1,500,000	—	—	—	1,500,000	1,500,000
36	06-Dec-16	05-Dec-23	AUD 1.33	2,045,000	—	(33,333)	(126,667) *	1,885,000	611,666
36a	06-Dec-16	05-Dec-23	AUD 1.21	4,400,000	—	—	—	4,400,000	1,495,002
36b	13-Jan-17	12-Jan-24	AUD 1.67	450,000	—	—	(150,000) *	300,000	300,000
37	28-Jun-17	27-Jun-24	AUD 2.23	—	300,000	—	—	300,000	100,000
38	16-Sep-17	15-Sep-24	AUD 1.54	—	100,000	—	—	100,000	—
38a	16-Sep-17	15-Sep-24	AUD 1.40	—	150,000	—	—	150,000	—
39	13-Oct-17	12-Oct-24	AUD 1.94	—	2,310,000	—	(95,000) *	2,215,000	—
39a	13-Oct-17	12-Oct-24	AUD 1.76	—	2,000,000	—	(100,000) *	1,900,000	200,000
40	24-Nov-17	23-Nov-24	AUD 1.41	—	750,000	—	—	750,000	—
40a	24-Nov-17	23-Nov-24	AUD 1.28	—	750,000	—	—	750,000	—
June 30, 2018				**25,100,246**	**6,360,000**	**(289,245)**	**(4,841,667)**	**26,329,334**	**14,339,320**
Weighted average share purchase price				AUD 3.35	AUD 1.74	AUD 0.52	AUD 4.97	AUD 2.68	AUD 3.39

(1) The dates presented in the grant date column represent the date on which board approval was obtained. For valuation dates per IFRS 2, refer to Note 17(c).

(2) 30a to 30i were granted as remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended 30 June 2015 (see Note 17(b)).

The weighted average share price at the date of exercise of options exercised during the years ended June 30, 2020, 2019 and 2018 were AUD 3.47, AUD 2.06 and AUD 1.46 respectively. The weighted average remaining contractual life of share options and loan funded shares outstanding as of June 30, 2020, 2019 and 2018 were 4.79 years, 4.53 years and 4.24 years, respectively.

b. Existing share-based payment arrangements

General terms and conditions attached to share based payments

Share options pursuant to the employee share option plan are generally granted in three equal tranches. For issues granted prior to July 1, 2015 the length of time from grant date to expiry date was typically 5 years. Grants since July 1, 2015, are issued with a seven year term. Vesting occurs based on achievement of performance conditions and/or progressively over the life of the option with the first tranche vesting one year from grant date, the second tranche two years from grant date, and the third tranche three years from grant date. On cessation of employment the Company's board of directors determines if a leaver is a bad leaver or not. If a participant is deemed a bad leaver, all rights, entitlements and interests in any unexercised options or shares (pursuant to the loan funded share plan) held by the participant will be forfeited and will lapse immediately. If a leaver is not a bad leaver they may retain vested options and shares (pursuant to the loan funded share plan), however, they must be exercised within 60 days of cessation of employment (or within a longer period if so determined by the Company's board of directors), after which time they will lapse. Unvested options will normally be forfeited and lapse.

This policy applies to all issues shown in the above table with the exception of the following:

25a(i&ii)	Options were granted in two equal tranches and vested on the date that the option holder had direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
INC.	As part of the acquisition of Mesoblast, Inc., Mesoblast, Inc. options were converted to options of the Company at a conversion ratio of 63.978. The Mesoblast, Inc. option exercise price per option was adjusted using the same conversion ratio. All options vested on acquisition date (December 7, 2010), and will expire according to their original expiry dates (with the exception of options held by directors which were limited to an expiry date not exceeding four years from acquisition).
31b	Options were granted in two equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
35	Incentive rights granted pursuant to the Equity Facility Agreement with Kentgrove Capital, dated June 30, 2016, had fully vested on the agreement date and will expire thirty six months after the date of the issue of the incentive right.
36a & 36b	Options were granted in two or three equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
49a, 49b, 50, 50a & 53	Options were granted two or three equal tranches and are required to satisfy certain pre-specified performance conditions and time-based vesting conditions prior to vesting. Time-based conditions restrict vesting to a maximum of one third at 12 months, two thirds at 24 months and full grant at 36 months, but only if the pre-specified performance conditions have been met.
38a, 40a & 57	Options were granted in one tranche and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
39a	Options were granted in one or two equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
51	Options were granted in two equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.

55 Options were granted in five tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.

Modifications to share-based payment arrangements

During the year ended June 30, 2015, the Company repurchased an aggregate amount of $13.9 million (AUD 17.7 million) of loans under LFSP and correspondingly cancelled 2,985,000 of the Company's ordinary shares held in trust for certain employees of the Company. As remuneration for the repurchase of loans and cancellation of these ordinary shares under LFSP, the Company granted options to purchase 2,985,000 of the Company's ordinary shares at exercise prices ranging from AUD 4.44 to AUD 4.98 under ESOP 30a to 30i. As of March 25, 2015 (the "modification date"), the total incremental fair value granted as a result of these modifications was $0.6 million. During the year ended June 30, 2018, as a result of a fully underwritten institutional and retail entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in September 2017, the exercise price of all outstanding options at the time was reduced by AUD0.02 per option subject to the ESOP plan under clause 7.3. There were no modifications made to share-based payment arrangements during the years ended June 30, 2019 and June 30, 2020.

c. Fair values of share based payments

The weighted average fair value of share options granted during the years ended June 30, 2020, 2019 and 2018 were AUD 1.07, AUD 0.95 and AUD 0.61, respectively.

The fair value of all shared-based payments made has been calculated using the Black-Scholes model. This model requires the following inputs:

Share price at acceptance date

The share price used in valuation is the share price at the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement. This price is generally the volume weighted average share price for the five trading days leading up to the date.

Exercise price

The exercise price is a known value that is contained in the agreements.

Share price volatility

The model requires the Company's share price volatility to be measured. In estimating the expected volatility of the underlying shares our objective is to approximate the expectations that would be reflected in a current market or negotiated exchange price for the option. Historical volatility data is considered in determining expected future volatility.

Life of the option

The life is generally the time period from grant date through to expiry. Certain assumptions have been made regarding "early exercise" i.e. options exercised ahead of the expiry date, with respect to option series 14 and later. These assumptions have been based on historical trends for option exercises within the Company and take into consideration exercise trends that are also evident as a result of local taxation laws.

Dividend yield

The Company has yet to pay a dividend so it has been assumed the dividend yield on the shares underlying the options will be 0%.

Risk free interest rate

This has been sourced from the Reserve Bank of Australia historical interest rate tables for government bonds.

Model inputs

The model inputs for the valuations of options approved and granted during the year ended June 30, 2020 are as follows:

Series	Valuation date[1]	Exercise price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life[2]	Dividend yield	Risk-free interest rate
43b	14-May-20	1.87	3.55	60.39%	4.5 yrs	0%	0.37%
48	04-Apr-19	1.48	1.49	54.22%	6.1 yrs	0%	1.50%
49	17-Sep-19	1.62	1.93	54.10%	6.1 yrs	0%	0.89%
49a	15-Mar-20	1.47	1.87	55.48%	5.8 yrs	0%	0.56%
49a	17-Dec-19	1.47	1.93	53.65%	5.9 yrs	0%	0.82%
49b	27-Nov-19	1.47	1.83	53.85%	6.3 yrs	0%	0.73%
49c	27-Nov-19	1.47	1.83	53.85%	6.3 yrs	0%	0.73%
50	13-Sep-19	1.47	1.88	54.02%	6.1 yrs	0%	0.93%
50a	16-Sep-19	1.47	2.03	54.21%	6.1 yrs	0%	0.95%
51	28-Mar-20	1.47	1.17	55.60%	5.7 yrs	0%	0.45%
52	17-Dec-19	1.62	1.93	53.65%	6.0 yrs	0%	0.82%
53	26-Mar-20	1.47	1.17	58.30%	5.8 yrs	0%	0.47%
54	28-Jan-20	1.98	2.86	56.63%	6.1 yrs	0%	0.71%
55	29-May-19	1.48	1.48	53.98%	6.3 yrs	0%	1.18%
56	27-Nov-19	1.83	1.83	53.80%	6.3 yrs	0%	0.73%
57	25-Nov-19	1.80	1.80	53.82%	6.3 yrs	0%	0.82%
58	10-Apr-20	1.98	1.97	57.65%	5.9 yrs	0%	0.45%

(1) Valuation date is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.
(2) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2020 was AUD 3.25.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2019 are as follows:

Series	Valuation date[1]	Exercise price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life[2]	Dividend yield	Risk-free interest rate
41	03-Sep-18	1.52	1.52	52.31%	5.8 yrs	0%	2.16%
42	21-Jun-18	1.56	1.56	52.40%	6.1 yrs	0%	2.36%
43	24-Oct-18	1.87	1.70	52.78%	5.9 yrs	0%	2.27%
44	17-Jan-19	1.72	1.59	54.40%	5.6 yrs	0%	1.91%
45	20-Dec-18	1.33	1.33	54.11%	6.1 yrs	0%	2.01%
46	07-Jun-19	1.45	1.33	53.92%	5.8 yrs	0%	1.14%
47	04-Jun-19	1.45	1.33	53.95%	5.8 yrs	0%	1.19%

(1) Valuation date is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.
(2) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2019 was AUD 1.48.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2018 are as follows:

Series	Valuation date[1]	Exercise price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life[2]	Dividend yield	Risk-free interest rate
37	14-Jul-17	2.23	2.02	52.21%	5.8 yrs	0%	2.22%
38	02-Oct-17	1.54	1.37	52.04%	5.8 yrs	0%	2.41%
38a	14-Dec-17	1.40	1.37	52.56%	5.8 yrs	0%	2.27%
39	06-Nov-17	1.94	1.34	52.49%	5.9 yrs	0%	2.16%
39a	06-Nov-17	1.76	1.34	52.49%	5.9 yrs	0%	2.16%
40	08-Feb-18	1.41	1.32	52.35%	5.8 yrs	0%	2.43%
40a	08-Feb-18	1.28	1.32	52.35%	5.8 yrs	0%	2.43%

(1) Valuation date is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.
(2) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2018 was AUD 2.08.

18. Remuneration of auditors

During the year the following fees were paid or payable for services provided by the auditor of the parent entity, its related practices and non-related audit firms:

(in U.S. dollars)	Year Ended June 30, 2020	2019	2018
a. PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	713,461	690,245	620,837
Other audit services[1]	14,097	—	92,403
Total remuneration of PricewaterhouseCoopers Australia	**727,558**	**690,245**	**713,240**
b. Network firms of PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	108,262	89,038	93,839
Total remuneration of Network firms of PricewaterhouseCoopers Australia	**108,262**	**89,038**	**93,839**
Total auditors' remuneration[2]	**835,820**	**779,283**	**807,079**

(1) Audit and review of financial reports and registration statements in connection with the filings on Form S-8 and F-3.

(2) All services provided are considered audit services for the purpose of SEC classification.

19. Losses per share

	Year Ended June 30, 2020	2019	2018
(Losses) per share			
(in cents)			
(a) Basic (losses) per share			
From continuing operations attributable to the ordinary equity holders of the company	(14.74)	(18.16)	(7.58)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(14.74)**	**(18.16)**	**(7.58)**
(b) Diluted (losses) per share			
From continuing operations attributable to the ordinary equity holders of the company	(14.74)	(18.16)	(7.58)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(14.74)**	**(18.16)**	**(7.58)**
(c) Reconciliation of (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	(77,940)	(89,799)	(35,290)
Diluted (losses) per share			
(Losses) from continuing operations attributable to the ordinary equity holders of the company:			
Used in calculating basic (losses) per share	(77,940)	(89,799)	(35,290)
(Losses) attributable to the ordinary equity holders of the company used in calculating diluted losses per share	(77,940)	(89,799)	(35,290)

	2020 Number	2019 Number	2018 Number
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	528,821,630	494,381,490	465,688,997
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	528,821,630	494,381,490	465,688,997

Options granted to employees (see Note 17) are considered to be potential ordinary shares. These securities have been excluded from the determination of basic losses per shares. They have also been excluded from the calculation of diluted losses per share because they are anti-dilutive for the years ended June 30, 2020, 2019 and 2018. Shares that may be paid as contingent consideration have also been excluded from basic losses per share. They have also been excluded from the calculation of diluted losses per share because they are anti-dilutive for the years ended June 30, 2020, 2019 and 2018

The calculation for the year ended June 30, 2018 has been adjusted to reflect the bonus element in the entitlement offer to existing eligible shareholders which occurred during September 2018.

20. Parent entity financial information

a. Summary financial information

The parent entity financial information disclosure is an Australian Disclosure Requirement as required by *Corporations Regulations 2001*. The individual financial statements for the parent entity show the following aggregate amounts:

	As of June 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Balance Sheet		
Current Assets	22,715	6,723
Total Assets	**775,407**	**643,708**
Current Liabilities	11,765	5,792
Total Liabilities	**17,278**	**5,878**
Shareholders' Equity		
Issued Capital	1,051,450	910,405
Reserves		
Foreign Currency Translation Reserve	(216,440)	(209,207)
Share Options Reserve	69,695	65,379
(Accumulated losses)	(146,576)	(128,747)
	758,129	**637,830**
Loss for the period	**(16,981)**	**(23,094)**
Total comprehensive loss for the period	**(16,981)**	**(23,094)**

b. Contingent liabilities of the parent entity

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

Mesoblast Limited 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 its use of the Medvet IP, on completion of certain milestones Mesoblast Limited 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.

21. 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.

22. Summary of significant accounting policies

This note provides the principal accounting policies adopted in the preparation of these consolidated financial statements as set out below. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the consolidated entity consisting of Mesoblast Limited and its subsidiaries.

a. Change in accounting policies

i. Leases

The Group adopted IFRS 16 *Leases* on July 1, 2019. Our accounting policy from July 1, 2019, is that leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use. For accounting policies relating to the comparative year, refer to our annual report on Form 20-F for the year ended June 30, 2019. Comparatives have not been restated as permitted under the specific transition provisions in the standard.

(in U.S. dollars, in thousands)	2019
Operating lease commitments disclosed as at June 30, 2019	7,460
Discounted using the group's average incremental borrowing rate of 6.52%	6,146
(Less): Short term leases recognized on a straight line basis as expense	(371)
Lease liability recognized as at July 1, 2019	**5,775**

The associated right-of-use assets for property leases were measured on a retrospective basis as if the new rules had always been applied. Right-of-use assets increased by $4.7 million and lease liabilities increased by $5.6 million on July 1, 2019. The net impact on retained earnings on July 1, 2019 was $0.9m.

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics
- the accounting for operating leases with a remaining lease term of less than 12 months as at July 1, 2019 as short term leases
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Group has also elected not to reassess whether a contract is, or contains a lease at the date of initial application. Instead, for contracts entered into before the transition date the group relied on its assessment made applying IAS 17 and Interpretation 4 *Determining whether an Arrangement contains a Lease.*

b. Principles of consolidation

i. Subsidiaries

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Mesoblast Limited ("Company" or "Parent Entity") as of June 30, 2020 and the results of all subsidiaries for the year then ended. Mesoblast Limited and its subsidiaries together are referred to in this financial report as the Group or the consolidated entity.

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the Group.

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

ii. Employee share trust

The Group has formed a trust to administer the Group's employee share scheme. This trust is consolidated, as the substance of the relationship is that the trust is controlled by the Group.

c. Segment reporting

The Group predominately operates in one segment as set out in Note 21.

d. Foreign currency translation

(i) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The functional currency of Mesoblast Limited is the AUD. The consolidated financial statements are presented in USD, which is the Group's presentation currency.

(ii) Translations and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the transaction at period end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in net loss, except when they are deferred in equity as qualifying cash flow hedges and qualifying net investment hedges or attributable to part of the net investment in a foreign operation.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at fair value through profit or loss are recognized in net loss as part of the fair value gain or loss and translation differences on non-monetary assets such as equities classified as financial assets at fair value are recognized in other comprehensive income.

(iii) Group companies

The results and financial position of all the Group entities (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for the balance sheets presented are translated at the closing rate at the date of that balance sheets;
- income and expenses for the statements of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and all resulting exchange differences are recognized in other comprehensive income.

(iv) Other

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to net loss, as part of the gain or loss on sale.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entities and translated at the closing rate.

e. Revenue recognition

The Group adopted IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018, using the modified retrospective approach. Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by the standard.

First, contracts with customers within the scope of IFRS 15 are identified. Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration the Group expect to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

There was no cumulative impact of the adoption of IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018.

Revenues from contracts with customers comprise commercialization and milestone revenue. The Group also have revenue from research and development tax incentives and interest revenue.

(i) Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent upon the achievement of 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 revenue or deferred consideration in our consolidated balance sheets, depending on the nature of arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified within non-current liabilities.

Milestone revenue

The Group applies the five-step method under the standard to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration. The Group estimate the transaction price of the contingent milestone using the most likely amount method. The Group include in the transaction price some or all of the amount of the contingent milestone only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations.

When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of IP (such as cumulative net sales targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Licenses of intellectual property

When licenses of IP are distinct from other goods or services promised in the contract, the Group recognize the transaction price allocated to the license as revenue upon transfer of control of the license to the customer. The Group evaluate all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a “right to access” license. This is when the Group undertake activities that significantly affect the IP to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of our activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a “right to use” license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

Sales-based or usage-based royalties

Licenses of IP can include royalties that are based on the customer’s usage of the IP or sale of products that contain the IP. The Group apply the specific exception to the general requirements of variable consideration and the constraint on variable consideration

for sales-based or usage-based royalties promised in a license of IP. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

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. The Group may receive up to an additional $132.5 million in payments if certain milestones are satisfied in relation to clinical, manufacturing, regulatory and reimbursement approval prior to product launch. The Group is further entitled to receive milestones payments based on regulatory and cumulative product sales milestones, as well as tiered double-digit royalties on product sales.

The strategic partnership with Grünenthal includes a license of IP and the provision of development services. Under IFRS 15 *Revenue from contracts with customers*, the Group have identified three distinct performance obligations in the strategic partnership with Grünenthal. The three performance obligations identified are the right of use license of IP, research & development and chemistry, manufacturing and controls ("R&D and CMC") services and other development services. The license of IP was considered distinct from the development services as it is capable of being granted separately and the development services do not significantly modify or customize the license nor are the license and development services significantly interrelated or interdependent. The Group also evaluated the promises in the development services and determined the R&D and CMC services were distinct from the other development services as they are not significantly interrelated or interdependent.

The standalone selling price for each performance obligation is not directly observable, so the Group have estimated the standalone selling price through the most appropriate method to ensure the estimate represents the price the Group would charge for the goods or services if they were sold separately. The Group considered the application and results of a combination of methods and utilized the cost plus a margin approach as the primary method. For R&D and CMC services, the Group estimated the standalone selling price to be $85.0 million. For the other development services the Group estimated the standalone selling price to be $10.0 million. Significant judgement was applied in determining the standalone selling price and the variable consideration that was allocated to each performance obligation. Based on this analysis, the $15.0 million upfront payment was allocated to the license of IP performance obligation. Upon signing of this strategic partnership in September 2019, the Group recognized $15.0 million in revenue for the right of use license of IP as this performance obligation was considered completely satisfied at this date.

The Group evaluated the constraint over the remaining variable consideration under the contract and determined that all of the milestone payments relating to the R&D and CMC services and other development services were considered constrained as at June 30, 2020. As part of this evaluation, the Group considered a variety of factors, including whether the receipt of the milestone payments is outside of the Group's control or contingent on the outcome of clinical trials and the impact of certain repayment clauses. The Group will continue to evaluate the constraint over variable consideration in future periods. Additionally, the Group applies the sales-based and usage-based royalty exception for licenses of intellectual property and therefore will recognize royalties and sales-based milestone payments as revenue when the subsequent sale or usage occurs.

The $2.5 million milestone payment received in December 2019 from Grünenthal was considered constrained and resulted in deferred consideration as of June 30, 2020. In future periods, additional milestone payments from Grünenthal may result in deferred consideration as revenue recognition of R&D and CMC services and other development services will be dependent upon the assessment of the constraint over variable consideration as well as the percentage of progress towards meeting the development service performance obligations over time.

There was no milestone revenue recognized in relation to this strategic partnership with Grünenthal in the year ended June 30, 2019.

Tasly arrangement

In July 2018, the Group entered into a strategic alliance with 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 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.

Under IFRS 15, upon completion of this strategic alliance in September 2018, the Group recognized $10.0 million in milestone revenue from the $20.0 million up-front technology access fee received in October 2018, as this was the portion of revenue that control was transferred to Tasly, and the remaining $10.0 million from the $20.0 million up-front payment was recognized as deferred consideration on the consolidated balance sheet. In the year ended June 30, 2020, the deferred consideration amount was recognized in revenue as the control for this portion of revenue was transferred to Tasly based on the Group's decision regarding the exercise of the Group's rights in the terms and conditions of the agreement.

TiGenix arrangement

In December 2017, the Group entered into a patent license agreement with TiGenix, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived 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. The Group is entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, the Group will receive single digit royalties on net sales of Alofisel®.

In the year ended June 30, 2020, the Group commenced earning royalty income on sales of Alofisel® in Europe by our licensee Takeda. To date, royalty income earned on sales of Alofisel® in Europe by our licensee Takeda have not been significant.

JCR arrangement

In October 2013, the Group acquired all of Osiris' culture-expanded, MSC-based assets. 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 the Group assumed from Osiris, 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 is entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. 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 is entitled to a double digit 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 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 EB and HIE, if and when JCR begins selling TEMCELL for such indications in Japan. The Group apply the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognize royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the year ended June 30, 2020, the Group recognized $6.6 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $5.0 million for the year ended June 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2019, and 2018, the Group recognized $1.0 million and $1.5 million, respectively, in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan. These amounts were recorded in revenue as there were no further performance obligations required in regard to this items. There was no milestone revenue recognized in year ended June 30, 2020.

(ii) Interest revenue

Interest revenue is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

(iii) Research and development tax incentive

The Australian Government replaced the research and development tax concession with the research and development tax incentive from July 1, 2011. The provisions provide refundable or non-refundable tax offsets.

The research and development tax incentive applies to expenditure incurred and the use of depreciating assets in an income year commencing on or after July 1, 2011. The research and development tax incentive credit is available for our research and development activities in Australia as well as research and development activities outside of Australia to the extent such non-Australian based activities relate to intellectual property owned by our Australian resident entities do not exceed half the expenses for the relevant activities and are approved by the Australian government. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For the years ended June 30, 2020 and 2019, the rate of the refundable tax offset is 43.5%.

The Group anticipates that the combined worldwide turnover of the Mesoblast Group will be in excess of A$20.0 million for the year ended June 30, 2020 making us ineligible for the refundable tax offset for the research and development tax incentive. The Group was ineligible for the refundable tax offset for the research and development tax incentive for the year ended June 30, 2019. Consequently, no income was recognized from the Research and Development Tax Incentive program for the year ended June 30, 2020 and 2019.

The Group's research and development activities are eligible under an Australian government tax incentive for eligible expenditure from July 1, 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. At each period end management estimates and recognizes the refundable tax offset available to the Group based on available information at the time.

The receivable for reimbursable amounts that have not been collected is reflected in trade and other receivables in the Group's consolidated balance sheets. Income associated with the research and development tax incentive is recorded in the Group's other operating income and expenses in the Group's consolidated income statement.

f. Inventories

Inventories are included in the financial statements at the lower of cost (including raw materials, direct labour, 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 37 *Provisions, Contingent Liabilities and Contingent Assets*; 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 will be reversed through Manufacturing Commercialization expenses. As of June 30, 2020, there was $8.8 million of pre-launch inventory recognized on the balance sheet that was fully provided for.

g. Research and development undertaken internally

The Group currently does not have any capitalized development costs. Research expenditure is recognized as an expense as incurred. Costs incurred on development projects, which consist of preclinical and clinical trials, manufacturing development, and general research, are recognized as intangible assets when it is probable that the project will, after considering its commercial and technical feasibility, be completed and generate future economic benefits and its costs can be measured reliably.

The expenditure capitalized comprises all directly attributable costs, including costs of materials, services, direct labor and an appropriate proportion of overheads. Other development costs that do not meet these criteria are expensed as incurred. Development costs previously recognized as expenses, are not recognized as an asset in a subsequent period and will remain expensed. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its useful life.

h. Income tax

The income tax expense or benefit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Group's subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, the deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting, nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses. Deferred tax assets are only recognized to the extent that there are sufficient deferred tax liabilities unwinding.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in controlled entities where the parent entity is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

Current and deferred tax is recognized in net loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

i. Business combinations

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred also includes the fair value of any asset or liability resulting from a contingent consideration arrangement and the fair value of any pre-existing equity interest in the subsidiary. Acquisition-related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. On an acquisition-by-acquisition basis, the Group recognizes any noncontrolling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net identifiable assets.

The excess of the consideration transferred and the amount of any non-controlling interest in the acquiree over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the subsidiary acquired and the measurement of all amounts has been reviewed, the difference is recognized directly in net loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions.

Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

j. Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to dispose and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets (other than goodwill) that have suffered impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

k. Cash and cash equivalents

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term and highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

l. 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.

m. Investments and other financial assets

(i) Classification

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through OCI or through profit or loss); and
- those to be measured at amortized cost

The classification depends on the Group's business model for managing the financial assets and the contractual terms of the cash flow. For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI). See Note 5 for details about each type of financial asset.

(ii) Recognition and derecognition

Regular way purchases and sales of financial assets are recognized on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

(iii) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss. Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Details on how the fair value of financial instruments is determined are disclosed in Note 5(g).

Equity instruments

The group subsequently measures all equity investments at fair value. Where the Group has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss

following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognized in other gains/(losses) in the statement of profit or loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

(iv) Impairment

For trade receivables, the group applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables, see note 5(b) for further details.

n. Derivatives

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently remeasured to their fair value at the end of each reporting period.

Derivatives that do not qualify for hedge accounting

Certain derivative instruments do not qualify for hedge accounting. Changes in the fair value of any derivative instrument that does not qualify for hedge accounting are recognized immediately in profit or loss and are included in other income or other expenses.

o. Property, plant and equipment

Plant and equipment are stated at historical cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item.

Subsequent cost are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associates with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to profit and loss during the reporting period in which they are incurred.

Property, plant and equipment, other than freehold land, are depreciated over their estimated useful lives using the straight line method (see Note 6(a)).

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposal of plant and equipment are taken into account in determining the profit for the year.

p. Intangible assets

(i) Goodwill

Goodwill is measured as described in Note 22(i). Goodwill on acquisition of subsidiaries is included in intangible assets (Note 6(c)). Goodwill is not amortized but it is tested for impairment annually or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash generating units for the purpose of impairment testing. The allocation is made to those cash generating units or groups of cash generating units that are expected to benefit from the business combination in which the goodwill arose, identified according to operating segments (Note 21).

(ii) Trademarks and licenses

Trademarks and licenses have a finite useful life and are carried at cost less accumulated amortization and impairment losses.

(iii) In-process research and development acquired

In-process research and development that has been acquired as part of a business acquisition is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form. Indefinite life intangible assets are not amortized but rather are tested for impairment annually in the third quarter of each year, or whenever events or circumstances present an indication of impairment.

In-process research and development will continue to be tested for impairment until the related research and development efforts are either completed or abandoned. Upon completion of the related research and development efforts, management determines the remaining useful life of the intangible assets and amortizes them accordingly. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and various other relevant factors.

In the case of abandonment, the related research and development efforts are considered impaired and the asset is fully expensed.

(iv) Current marketed products

Current marketed products contain products that are currently being marketed. The assets are recognized on our balance sheet as a result of business acquisitions or reclassifications from In-process research and development upon completion. Upon completion, when assets become available for use, assets are reclassified from in-process research and development to current marketed products at the historical value that they were recognized at within the in-process research and development category.

Upon reclassification to the current market products category management determines the remaining useful life of the intangible assets and amortizes them from the date they become available for use. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and any other relevant factors.

Management have chosen to amortize all intangible assets with a finite useful life on a straight-line basis over the useful life of the asset. Current marketed products are tested for impairment in accordance with IAS 36 Impairment of Assets which requires testing whenever there is an indication that an asset may be impaired.

q. Trade and other payables

Payables represent the principal amounts outstanding at balance date plus, where applicable, any accrued interest. Liabilities for payables and other amounts are carried at cost which approximates fair value of the consideration to be paid in the future for goods and services received, whether or not billed. The amounts are unsecured and are usually paid within 30 to 60 days of recognition.

r. Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. If it is not probable, the fee is deferred until the draw down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred of liabilities assumed, is recognized in profit or loss as other income or finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period

In March 2018, the Group entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. The Group drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019. An additional $25.0 million may be drawn, subject to certain conditions. The loan matures in March 2022.

In August 2020, as disclosed in Note 15, the Group amended the terms of the loan to defer the commencement of principal repayments to March 2021. As at June 30, 2020, principal repayments were due to commence in October 2020 and as a result the Group recognized $24.3 million of the borrowings as a current liability, given that the terms of the loan agreement to defer principal repayments were amended subsequent to the period end. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied. Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45% per annum. At June 30, 2019, in line with increases in the U.S. prime rate, the interest rate was 10.45%. On August 1, September 19 and October 31, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20%, 9.95% and 9.70%, respectively, and remains at 9.70% at June 30, 2020 in line with the amended terms of the loan agreement. As at June 30, 2020, the Group recognized $3.6 million in interest payable within twelve months as a current liability.

In the years ended June 30, 2020 and 2019, the Group recognized gains of $1.3 million and $0.4 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurement gains relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility.

NovaQuest

On June 29, 2018, the Group drew the first tranche of $30.0 million of the principal amount from the $40.0 million loan and security agreement with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of RYONCIL for the treatment in pediatric SR-aGVHD. The Group can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of RYONCIL for pediatric SR-aGVHD are significantly higher than current forecasts.

If there are no net sales of RYONCIL for pediatric SR-aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of RYONCIL for pediatric SR-aGVHD is less than the 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 adjustment 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 other operating income and expenses and finance costs in the period the revision is made.

As of June 30, 2020, management have assumed that RYONCIL for pediatric SR-aGVHD will obtain BLA approval at the PDUFA action date of September 30, 2020. In August 2020, as disclosed in Note 15, the ODAC of the FDA voted in favor that available data support the efficacy of RYONCIL in pediatric patients with SR-aGVHD. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made solely by the FDA, and the recommendations by the panel are non-binding. An FDA decision could lead to a remeasurement of the carrying value of the NovaQuest borrowings as management update net sales forecasts and other key assumptions.

As at June 30, 2020, the Group has recognized a current liability of $4.5 million which represents the present value of interest payable of $4.2 million and $0.3 million loan administration fee which is payable annually in June.

In the years ended June 30, 2020 and 2019, the Group recognized losses of $0.8 million and $0.7 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within other operating income. In the years ended June 30, 2020 and 2019, the Group recognized gains of $0.1 million and $Nil, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurements relate to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility with NovaQuest.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group's floating rate loan with the senior creditor, Hercules.

s. Provisions

Provisions are recognized when the Group has a present legal obligation as a result of a past event, it is probable that the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the end of the reporting period. The discount rate used to determine the present value is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognized as interest expense.

Provisions are recorded on acquisition of a subsidiary, to the extent they relate to a subsidiary's contingent liabilities, if it relates to a past event, regardless of whether it is probable the amount will be paid.

t. Employee benefits

A liability is recognized for benefits accruing to employees in respect of wages and salaries, bonuses, annual leave and long service leave.

Liabilities recognized in respect of employee benefits which are expected to be settled within 12 months after the end of the period in which the employees render the related services are measured at their nominal values using the remuneration rates expected to apply at the time of settlement.

Liabilities recognized in respect of employee benefits which are not expected to be settled within 12 months after the end of the period in which the employees render the related services are measured as the present value of the estimated future cash outflows to be made by the Group in respect of services provided by employees up to reporting date.

The obligations are presented as current liabilities in the balance sheet if the entity does not have an unconditional right to defer settlement for at least twelve months after the reporting period, regardless of when the actual settlement is expected to occur.

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates: when the Group can no longer withdraw the offer of those benefits and when the entity recognizes costs for a restructuring that is within the scope of IAS 37 and involves the payment of termination benefits.

u. Share-based payments

Share-based payments are provided to eligible employees, directors and consultants via the Employee Share Option Plan ("ESOP") and the Australian Loan Funded Share Plan ("LFSP"). The terms and conditions of the LFSP are in substance the same as the employee share options and therefore they are accounted for on the same basis.

Equity-settled share-based payments with employees and others providing similar services are measured at the fair value of the equity instrument at acceptance date. Fair value is measured using the Black-Scholes model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioral considerations. It does not make any allowance for the impact of any service and non-market performance vesting conditions. Further details on how the fair value of equity-settled share-based transactions has been determined can be found in Note 17.

The fair value determined at the acceptance date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on management's estimate of shares that will eventually vest, with a corresponding increase in equity. At the end of each period, the entity revises its estimates of the number of shared-based payments that are expected to vest based on the non-market vesting conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

v. Contributed equity

Ordinary shares are classified as equity.

Transaction costs arising on the issue of equity instruments are recognized separately in equity. Transaction costs are the costs that are incurred directly in connection with the issue of those equity instruments and which would not have been incurred had those instruments not been issued.

w. Loss per share

(i) Basic losses per share

Basic losses per share is calculated by dividing:

- the loss attributable to equity holders of the Group, excluding any costs of servicing equity other than ordinary shares;
- by the weighted average number of ordinary shares outstanding during the fiscal year, adjusted for bonus elements in ordinary shares issued during the year.

(ii) Diluted losses per share

Diluted losses per share adjusts the figures used in the determination of basic earnings per share to take into account

- the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares; and
- the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

x. Goods and services tax ("GST")

Revenues, expenses and assets are recognized net of the amount of GST except where the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognized as part of the cost of acquisition of the asset or as part of the expense.

Receivables and payables are stated with the amount of GST included. The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the Balance Sheet.

Cash flows are included in the statement of cash flow on a gross basis. The GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority, are classified as operating cash flows.

y. 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 report. 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.

Australian Disclosure Requirements

Directors' Declaration

In the directors' opinion:

(a) the financial statements and Notes set out on pages 154 to 216 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 June 30, 2020 and of its performance for the fiscal year 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.

Note 1 'Basis of preparation' confirms that the financial statements also comply with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The directors have been given the declarations by the chief executive officer and chief financial officer required by section 295A of the *Corporations Act 2001*.

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

/s/ Joseph Swedish	/s/ Silviu Itescu
Joseph Swedish	Silviu Itescu
Chairman	Chief Executive Officer

Melbourne, August 27, 2020

Independent auditor's report

To the members of Mesoblast Limited

Report on the audit of the financial report

Our opinion

In our opinion:

The accompanying financial report of Mesoblast Limited (the Company) and its controlled entities (together the Group) is in accordance with the *Corporations Act 2001*, including:

(a) giving a true and fair view of the Group's financial position as at 30 June 2020 and of its financial performance for the year then ended

(b) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

What we have audited

The Group financial report comprises:

- the consolidated balance sheet as at 30 June 2020
- the consolidated income statement for the year then ended
- the consolidated statement of comprehensive income for the year then ended
- the consolidated statement of changes in equity for the year then ended
- the consolidated statement of cash flows for the year then ended
- the notes to the consolidated financial statements, which include a summary of significant accounting policies
- the directors' declaration.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial report* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

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 and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Material uncertainty related to going concern

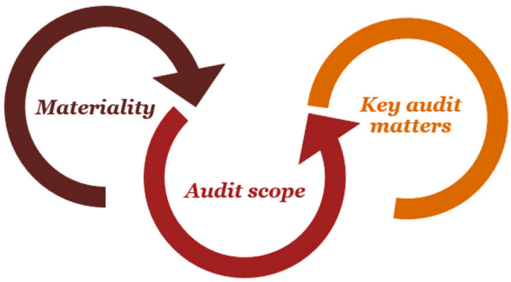
We draw attention to Note 1(i) in the financial report, which indicates that the Group had net cash outflows from operations of $56.4 million for the year ended 30 June 2020 and further cash inflows will be required to meet forecast expenditure over the next 12 months. The ability of the Group to continue as a going concern and meet its debts and commitments as and when they fall due are dependent on product sales and entering into non-dilutive strategic and commercial transactions, meeting milestones from existing strategic and financing partnerships, or equity-based financing. These conditions, along with other matters set forth in Note 1(i), indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Our audit approach

An audit is designed to provide reasonable assurance about whether the financial report is free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial report.

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial report as a whole, taking into account the geographic and management structure of the Group, its accounting processes and controls and the industry in which it operates.

The Group is a biopharmaceutical entity headquartered in Melbourne, Australia, and is in the process of developing and commercialising innovative cell-based regenerative medicine products. The Group has operations in Australia, the United States, and Singapore, with key management functions, including finance, performed in Melbourne, Australia and New York, United States.



Materiality	***Audit scope***
• For the purpose of our audit we used overall Group materiality of $5.5 million, which represents approximately 5% of the Group's adjusted loss before income tax. • We applied this threshold, together with qualitative considerations, to determine the scope of our audit and the nature, timing and extent of	• Our audit focused on where the Group made subjective judgements; for example, significant accounting estimates involving assumptions and inherently uncertain future events. • Audit procedures were performed over Australian, United States, and Singaporean operations to enable us to give an opinion over the financial report as a whole. Under instruction and supervision by PwC Australia, local

our audit procedures and to evaluate the effect of misstatements on the financial report as a whole.

- We chose Group loss before income tax because, in our view, it is the benchmark against which the performance of the Group is most commonly measured. We adjusted for the fair value remeasurement of contingent consideration as it is a volatile item. We also adjusted for the impact of milestone revenue generated from the licensing of certain intellectual property as it is an infrequently occurring item.
- We utilised a 5% threshold based on our professional judgement, noting it is within the range of commonly acceptable thresholds.

component auditors in the United States assisted with the procedures.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report for the current period. The key audit matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. Further, any commentary on the outcomes of a particular audit procedure is made in that context. We communicated the key audit matters to the Audit and Risk Committee.

In addition to the matter described in the *Material uncertainty related to going concern* section, we have determined the matters described below to be the key audit matters to be communicated in our report.

Key audit matter	***How our audit addressed the key audit matter***
Impairment assessment of in-process research and development intangible assets and goodwill	
As described in Note 6(c) to the consolidated financial statements, the Group's consolidated in-process research and development ("IPRD") intangible asset balance and consolidated goodwill balance were $427.8 million and $134.5 million at 30 June 2020, respectively. The Group tests the IPRD intangible asset and goodwill balances for impairment on an annual basis. The recoverable amounts of the goodwill and IPRD intangible assets are estimated by the Group using future cash flow projections and assumptions related to the outcome of research and development activities. These significant judgements and assumptions made by the Group are specific to the nature of the Group's activities including the	Our audit procedures included, among others, testing how the Group made the fair value estimate which included: • evaluating the appropriateness of the discounted cash flow model used to estimate recoverable amount in light of the requirements of the Australian Accounting Standards; • testing the completeness, accuracy and relevance of significant underlying data used in the model; and • evaluating the reasonableness of significant assumptions used by the Group including,

Key audit matter	*How our audit addressed the key audit matter*
probability of success, product pricing, market populations and the discount rates. The principal considerations for our determination that performing procedures relating to the impairment assessment of IPRD intangible assets and goodwill was a key audit matter are there were significant judgements made by the Group in estimating the recoverable amount of the Group's IPRD and goodwill, including the use by the Group of an external valuation expert. This in turn led to a high degree of auditor judgement, subjectivity, and effort in performing procedures to evaluate the Group's cash flow projections, key data inputs and significant assumptions, including the probability of success, product pricing, market populations and the discount rates. In addition, the audit effort involved the use of professionals with specialised skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained.	the probability of success, product pricing, market populations and the discount rates. Evaluating the significant assumptions relating to the estimates of the recoverable amount of goodwill and IPRD assets involved obtaining evidence to support the reasonableness of the assumptions, including by considering: • consistency with selected external market and industry data; • the outcome of clinical trials; • the findings of the Group's external valuation expert; • other comparable estimates of the Group's valuation released by securities analysts; and • subsequent events occurring prior to the date of the independent auditor's report. Professionals with specialised skill and knowledge were used to assist in the evaluation of the Group's discount rate assumption.
Fair value measurement of the provision for contingent consideration As described in Note 5(g) to the consolidated financial statements, the Group had a balance of $45.2 million as at 30 June 2020 for the provision for contingent consideration. The provision for contingent consideration arose from the acquisition of the stem cell business from Osiris Therapeutics Inc, which occurred in the fiscal year 2014. The fair value of the provision for contingent consideration is determined using an internal valuation by the Group, comprising a discounted cash flow model which required the use of inputs classified as level 3 in the fair value hierarchy. The significant assumptions used by the Group to value the provision for contingent consideration included expected unit revenues, expected sales volumes and the discount rate. The principal considerations for our determination that performing procedures relating to the fair value measurement of contingent consideration was a key audit matter were there are significant judgements	Our audit procedures included, among others, testing how the Group estimated the fair value of the provision for contingent consideration which included: • evaluating the appropriateness of the valuation methodology in light of the requirements of the Australian Accounting Standards; • testing the completeness, accuracy and relevance of significant underlying data used by the Group in the discounted cash flow model; and • evaluating the reasonableness of significant assumptions used by the Group, including expected unit revenues, expected sales volumes and discount rate. Evaluating the significant assumptions relating to the fair value measurement of the provision for

Key audit matter	*How our audit addressed the key audit matter*
made by the Group in estimating the fair value of the provision for contingent consideration due to the use of an internally-developed model, which included the use of level 3 inputs to determine the discounted cash flows and significant assumptions related to expected unit revenues, expected sales volumes and discount rates. This in turn led to high degree of auditor judgement, subjectivity, and effort in performing procedures to evaluate the audit evidence obtained related to the valuation, and the audit effort involved the use of professionals with specialised skill and knowledge.	contingent consideration involved obtaining evidence to support the reasonableness of the assumptions, including by considering: • consistency with selected external market and industry data; • the outcome of clinical trials; • subsequent events occurring prior to the date of the independent auditor's report; and • whether these assumptions were consistent with evidence obtained from our audit procedures over IPRD and goodwill. Professionals with specialised skill and knowledge were used to assist in the evaluation of the Group's discount rate assumption.
Recognition of revenue from the development and commercialisation agreement with Grünenthal GmbH As described in Note 3 to the consolidated financial statements, the Group recognised revenue of $15.0 million for the year ended 30 June 2020, and deferred consideration of $2.5 million as at 30 June 2020 in relation to the development and commercialisation agreement with Grünenthal GmbH. The Group identified three performance obligations in the contract. The standalone selling price of each performance obligation was not directly observable, so the Group estimated the standalone selling price primarily using an expected cost plus a margin approach. Significant judgement was applied by the Group in determining the standalone selling price and the variable consideration that was then allocated to each performance obligation. The principal considerations for our determination that performing procedures relating to the recognition of revenue from the development and commercialisation agreement with Grünenthal GmbH was a key audit matter are there was significant judgement applied by the Group in determining the standalone selling price of each performance obligation and the allocation of variable consideration to each performance obligation. These in turn led to a	Our procedures included, among others: • evaluating and testing how the Group identified the performance obligations in the contract; • evaluating the reasonableness of the Group's cost and margin estimates used in determining the standalone selling price of each performance obligation; and • testing the Group's process for the allocation of each component of variable consideration to specific performance obligations.

Key audit matter	*How our audit addressed the key audit matter*
high degree of auditor judgement, subjectivity, and effort in performing procedures to evaluate the standalone selling prices of the performance obligations, including the estimated costs of the performance obligations, and the allocation of variable consideration to each performance obligation.	

Other information

The directors are responsible for the other information. The other information comprises the information included in the annual report for the year ended 30 June 2020, but does not include the financial report and our auditor's report thereon. Prior to the date of this auditor's report, the other information we obtained included the Part I and Part II of the Form 20-F. We expect the remaining other information to be made available to us after the date of this auditor's report.

Our opinion on the financial report does not cover the other information and we do not and will not express an opinion or any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information that we obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

When we read the other information not yet received, if we conclude that there is a material misstatement therein, we are required to communicate the matter to the directors and use our professional judgement to determine the appropriate action to take.

Responsibilities of the directors for the financial report

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

In preparing the financial report, the directors are responsible for assessing the ability of the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: https://www.auasb.gov.au/admin/file/content102/c3/ar1_2020.pdf. This description forms part of our auditor's report.

Report on the remuneration report

Our opinion on the remuneration report

We have audited the remuneration report included in Item 6 (Directors, Senior Management and Employees) identified by the title 'Start of the Remuneration Report for Australian Disclosure Requirements' to 'End of Remuneration Report' of the directors' report for the year ended 30 June 2020.

In our opinion, the remuneration report of Mesoblast Limited for the year ended 30 June 2020 complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The directors of the Company are responsible for the preparation and presentation of the remuneration report in accordance with section 300A of *the Corporations Act 2001*. Our responsibility is to express an opinion on the remuneration report, based on our audit conducted in accordance with Australian Auditing Standards.

PricewaterhouseCoopers

Sam Lobley
Partner

Melbourne
27 August 2020

Item 19. Exhibits

Item

1.1	Constitution of Mesoblast Limited adopted on November 22, 2018 (incorporated by reference to Exhibit 1.1 to the Company's Annual Report on Form 20-F filed with the SEC on September 9, 2019).
1.2	Certificate of Registration of Mesoblast Limited (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.1	Form of Deposit Agreement between Mesoblast Limited and JPMorgan Chase Bank, N.A., as depositary, and Holders of the American Depositary Receipts (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.2	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.1).
4.3†	Manufacturing Services Agreement by and between Mesoblast Limited and Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., dated September 20, 2011 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.4	Purchase Agreement by and between Mesoblast International Sàrl and Osiris Therapeutics, Inc., dated October 10, 2013 (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.5	Amendment #1 to Purchase Agreement by and between Mesoblast International Sàrl and Osiris Therapeutics, Inc., dated December 17, 2014 (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.6†	License Agreement by and between Osiris Acquisition II, Inc. and JCR Pharmaceuticals Co., Ltd., dated August 26, 2003 (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.7†	Amendment 1 to License Agreement by and between Osiris Acquisition II, Inc. and JCR Pharmaceuticals Co., Ltd., dated June 27, 2005 (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.8	Intellectual Property Assignment Deed by and between Mesoblast Limited and Medvet Science Pty Ltd, dated October 4, 2004 (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.9#	Employment Agreement, dated August 8, 2014, by and between Mesoblast Limited and Silviu Itescu (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.10	Sublease, by and between Mesoblast Limited and CIT Group Inc., dated September 27, 2011 (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.11	Sublease, by and between Mesoblast Limited and Collins Place Pty Ltd, AMP Capital Investors Limited, and Australia and New Zealand Banking Group Limited, dated April 21, 2014 (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.12	Form of 2012 Deed of Indemnity, Insurance and Access (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.13	Form of 2014 Deed of Indemnity, Insurance and Access (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.14†	Patent License and Settlement Agreement with TiGenix S.A.U., dated December 14, 2017 (incorporated by reference to Exhibit 4.21 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.15†	Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated March 6, 2018 (incorporated by reference to Exhibit 4.22 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.16†	Loan and Security Agreement by and between Mesoblast Limited, Mesoblast UK Limited, Mesoblast, Inc., Mesoblast International (UK) Limited, Mesoblast International Sàrl and NQP SPV II, L.P., dated June 29, 2018 (incorporated by reference to Exhibit 4.23 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.17†	Development and Commercialization Agreement by and between Mesoblast Inc., Mesoblast International Sàrl and Tasly Pharmaceutical Group Co., Ltd. dated July 17, 2018 (incorporated by reference to Exhibit 4.24 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.18✓	Supplementary Agreement for Additional License by and between Mesoblast International Sarl and JCR Pharmaceuticals Co., Ltd., dated October 12, 2018 (incorporated by reference to Exhibit 4.25 to the Company's Annual Report on Form 20-F filed with the SEC on September 9, 2019).
4.19✓	First Amendment to Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated January 11, 2019 (incorporated by reference to Exhibit 4.26 to the Company's Annual Report on Form 20-F filed with the SEC on September 9, 2019).

4.20✓	Second Supplementary Agreement for Additional License by and between Mesoblast International Sarl and JCR Pharmaceuticals Co., Ltd., dated June 5, 2019 (incorporated by reference to Exhibit 4.27 to the Company's Annual Report on Form 20-F filed with the SEC on September 9, 2019).
4.21	Employee Share Option Plan (incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 filed with the SEC on July 27, 2020).
4.22✓	Development and Commercialization Agreement by and between Mesoblast Limited and Mesoblast International Sàrl and Grünenthal GmbH, dated September 9, 2019.
4.23✓	Manufacturing Services Agreement by and between Lonza Biosciences Singapore Pte. Ltd. and Mesoblast International Sàrl, dated October 9, 2019.
4.24✓	Second Amendment to Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated December 17, 2019.
4.25✓	Third Amendment to Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated February 25, 2020.
4.26✓	Fourth Amendment to Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated August 15, 2020.
8.1*	List of Significant Subsidiaries of Mesoblast Limited.
10	Consent of independent registered public accounting firm.
12.1*	Certification of the Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
12.2*	Certification of the Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
13.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
99.1*	Appendix 4E preliminary final report for the twelve months to June 30, 2020.
99.2*	Auditor's independence declaration, dated August 27, 2020.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

#	Indicates management contract or compensatory plan.
*	Filed herewith.
†	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and have been filed separately with the Securities and Exchange Commission.
✓	Certain confidential portions of this exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions are not material and would be competitively harmful if publicly disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Mesoblast Limited

By:	/s/ Joseph R Swedish
Name:	Joseph R Swedish
Title:	Chairman

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

Dated: August 27, 2020

SHAREHOLDER INFORMATION

A. Substantial Shareholders

Holders of substantial holdings of ordinary shares in the Company and the numbers of shares in which they and their associates have a relevant interest as of 2 October 2020:

Shareholder	Number of ordinary shares held
Professor Silviu Itescu	68,958,928
M&G Investment Group	51,752,865
Thorney Holdings	30,477,834

B. Distribution of Equity Securities and Voting Rights

Distribution of holders of equity securities as of 2 October 2020:

Range	Ordinary shares (i)	Options (ii)[1]	Incentive Rights (iii)[2]
1 – 1,000	18,318	0	
1,001 – 5,000	12,261	0	
5,001 – 10,000	3,250	1	
10,001 – 100,000	3,342	57	
100,001 and over	305	51	1
Total number of holders of equity securities	**37,476**	**109**	**1**

Number of holders of less than a marketable parcel of 157 shares ($3.19 per share)	**3,138**

(1) There are 34,168,138 options on issue as of 2 October 2020.
(2) 1,500,000 incentive rights are on issue, issued to Kentgrove Capital Pty Ltd.

The voting rights attaching to each class of equity securities are:

i. Ordinary shares

On a show of hands, every member present at a meeting, in person or by proxy, shall have one vote and upon a poll each share shall have one vote.

ii. Options

No voting rights.

iii. Incentive rights

No voting rights.

C. Twenty Largest Holders of Quoted Securities

The names of the 20 largest shareholders of each class of quoted equity security as of 2 October 2020 are listed below.

Rank	Name	No. of shares held	% of total shares
1	J P Morgan Nominees Australia Pty Limited	107,438,069	18.32
2	HSBC Custody Nominees (Australia) Limited	103,290,771	17.61
3	Professor Silviu Itescu	67,751,838	11.55
4	Citicorp Nominees Pty Limited	13,318,990	2.27
5	UBS Nominees Pty Ltd	11,101,280	1.89
6	National Nominees Limited	10,653,027	1.82
7	Independent Asset Management Pty Limited	7,870,558	1.34
8	BNP Paribas Nominees Pty Ltd	6,203,700	1.06
9	Merrill Lynch (Australia) Nominees Pty Limited	6,084,737	1.04
10	BNP Paribas Nominees Pty Ltd	4,986,283	0.85
11	Dalit Pty Ltd	4,828,839	0.82
12	Mr Gregory John Matthews & Mrs Janine Marie Matthews	3,956,219	0.67
13	CA Third Nominees Pty Limited	3,832,425	0.65
14	Dalit Pty Ltd	2,195,000	0.37
15	Citicorp Nominees Pty Limited	2,077,360	0.35
16	Kentgrove Capital Pty Ltd	2,000,100	0.34
17	BNP Paribas Noms Pty Ltd	1,908,014	0.33
18	HSBC Custody Nominees (Australia) Limited-GSCO-ECA	1,784,018	0.30
19	LALP Pty Ltd	1,647,144	0.28
20	BNP Paribas Nominees Pty Ltd	1,645,043	0.28
		364,573,415	**62.15**

D. Securities under escrow

As of 2 October 2020, there are 212,244 ordinary shares in the Company subject to escrow, in relation to which the escrow period will expire on 6 August 2021.

E. On-Market Buy-Back

There is no current on-market buy-back of the Company's ordinary shares.

F. Stock Exchanges

The Company's ordinary shares are listed on the Australian Securities Exchange and are traded under the symbol 'MSB'. The Company's American Depositary Shares, each representing five ordinary shares, are listed on the NASDAQ Global Select Market and are traded under the symbol 'MESO'.

CORPORATE DIRECTORY

Directors

Joseph Swedish (Chairman)
Silviu Itescu
William Burns
Donal O'Dwyer
Eric Rose
Michael Spooner
Shawn Cline Tomasello

Company Secretaries

Charles Harrison
Niva Sivakumar

Registered Office

Level 38
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Melbourne VIC 3000
Australia
Telephone +61 3 9639 6036
Facsimile +61 3 9639 6030

Country of Incorporation

Australia

Listing

Australian Securities Exchange
(ASX Code: MSB)

NASDAQ Global Select Market
(NASDAQ Code: MESO)

Website

www.mesoblast.com

Share Registry

Link Market Services Limited
Tower 4
727 Collins Street
Melbourne
Victoria 3008
Australia
Telephone +61 1300 554 474
Facsimile +61 2 9287 0303
www.linkmarketservices.com.au

Auditors

PricewaterhouseCoopers
Level 19, 2 Riverside Quay
Southbank
Victoria 3006
Australia
Telephone +61 3 8603 1000
Facsimile +61 3 8603 1999


mesoblast