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

Form 6-K

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

Filed in the month of November 2020 for the period ended September 30, 2020

Commission File Number 001-37626

Mesoblast Limited
(Exact name of Registrant as specified in its charter)

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

Australia
(Jurisdiction of incorporation or organization)

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

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

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☒

TABLE OF CONTENTS

Currency Presentation and Certain Defined Terms

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

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

Forward-Looking Statements

This Quarterly Report on Form 6-K includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, "believe", "expect", "anticipate", "estimate", "intend", "plan", "targets", "likely", "will", "would", "could", 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;
- 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 they are approved, to be withdrawn from the market due to patient adverse events or deaths;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations;
- our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to obtain additional financing;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our financial performance;
- developments relating to our competitors and our industry;

- the pricing and reimbursement of our product candidates, if approved; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” included elsewhere in this Quarterly Report on Form 6-K.

You should read thoroughly this Quarterly Report on Form 6-K and the documents that we refer to herein with the understanding that our actual future results may be materially different from and/or worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Other sections of this Quarterly Report on Form 6-K include additional factors which could adversely impact our business and financial performance. Moreover, we operate in an evolving environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

Consolidated Income Statement
(unaudited)

(in U.S. dollars, in thousands, except per share amount)	Note	Three Months Ended September 30, 2020	2019
Revenue	3	1,305	17,048
Research & development		(19,278)	(12,389)
Manufacturing commercialization		(11,924)	(2,698)
Management and administration		(7,680)	(5,463)
Fair value remeasurement of contingent consideration	3	15,107	(288)
Other operating income and expenses	3	2,018	(169)
Finance costs	3	(4,822)	(3,457)
Loss before income tax	3	**(25,274)**	**(7,416)**
Income tax benefit	4	730	1,932
Loss attributable to the owners of Mesoblast Limited		**(24,544)**	**(5,484)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**
Basic - losses per share		(4.21)	(1.10)
Diluted - losses per share		(4.21)	(1.10)

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

Consolidated Statement of Comprehensive Income
(unaudited)

(in U.S. dollars, in thousands)	Note	Three Months Ended September 30, 2020	2019
Loss for the period		**(24,544)**	**(5,484)**
Other comprehensive (loss)/income			
Items that may be reclassified to profit and loss			
Financial assets at fair value through other comprehensive income		81	(365)
Exchange differences on translation of foreign operations		408	(332)
Other comprehensive (loss)/income for the period, net of tax		**489**	**(697)**
Total comprehensive losses attributable to the owners of Mesoblast Limited		**(24,055)**	**(6,181)**

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

Consolidated Statement of Changes in Equity
(unaudited)

(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 July 1, 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		—	—	—	—	(5,484)	(5,484)
Other comprehensive income/(loss)		—	—	(365)	(332)	—	(697)
Total comprehensive profit/(loss) for the period		**—**	**—**	**(365)**	**(332)**	**(5,484)**	**(6,181)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		299	—	—	—	—	299
		299	**—**	**—**	**—**	**—**	**299**
Transfer of exercised options		238	(238)	—	—	—	—
Fair value of share-based payments		—	804	—	—	—	804
		238	**566**	**—**	**—**	**—**	**804**
Balance as of September 30, 2019	8	**910,942**	**80,600**	**(348)**	**(39,745)**	**(476,302)**	**475,147**
Balance as of July 1, 2020		**1,051,450**	**85,330**	**(429)**	**(38,267)**	**(548,758)**	**549,326**
Loss for the period		—	—	—	—	(24,544)	(24,544)
Other comprehensive income/(loss)		—	—	81	408	—	489
Total comprehensive profit/(loss) for the period		**—**	**—**	**81**	**408**	**(24,544)**	**(24,055)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		8,354	—	—	—	—	8,354
		8,354	**—**	**—**	**—**	**—**	**8,354**
Transfer of exercised options		3,201	(3,201)	—	—	—	—
Fair value of share-based payments		—	4,881	—	—	—	4,881
		3,201	**1,680**	**—**	**—**	**—**	**4,881**
Balance as of September 30, 2020	8	**1,063,005**	**87,010**	**(348)**	**(37,859)**	**(573,302)**	**538,506**

Consolidated Balance Sheet
(unaudited)

(in U.S. dollars, in thousands)	Note	As of September 30, 2020	As of June 30, 2020
Assets			
Current Assets			
Cash & cash equivalents	5(a)	108,123	129,328
Trade & other receivables	5(b)	2,446	1,574
Prepayments	5(b)	5,168	5,646
Total Current Assets		**115,737**	**136,548**
Non-Current Assets			
Property, plant and equipment		2,294	2,293
Right-of-use assets		8,038	7,978
Financial assets at fair value through other comprehensive income		1,952	1,871
Other non-current assets		3,334	3,311
Intangible assets	6(a)	581,217	581,601
Total Non-Current Assets		**596,835**	**597,054**
Total Assets		**712,572**	**733,602**
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	27,602	24,972
Provisions		22,218	29,197
Borrowings	5(d)	34,893	32,455
Lease liabilities		2,984	3,519
Total Current Liabilities		**87,697**	**90,143**
Non-Current Liabilities			
Deferred tax liability	6(b)	—	730
Provisions		20,723	27,563
Borrowings	5(d)	56,098	57,023
Lease liabilities		7,048	6,317
Deferred consideration		2,500	2,500
Total Non-Current Liabilities		**86,369**	**94,133**
Total Liabilities		**174,066**	**184,276**
Net Assets		**538,506**	**549,326**
Equity			
Issued Capital	8	1,063,005	1,051,450
Reserves		48,803	46,634
(Accumulated losses)/retained earnings		(573,302)	(548,758)
Total Equity		**538,506**	**549,326**

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

Consolidated Statement of Cash Flows
(unaudited)

(in U.S. dollars, in thousands)	Note	Three Months Ended September 30, 2020	2019
Cash flows from operating activities			
Commercialization revenue received		682	1,739
Upfront and milestone payments received		—	—
Government grants and tax incentives received		17	1,499
Payments to suppliers and employees (inclusive of goods and services tax)		(27,484)	(17,539)
Interest received		13	173
Interest and other costs of finance paid		(1,389)	(1,427)
Income taxes (paid)		(6)	(3)
Net cash (outflows) in operating activities	7(b)	**(28,167)**	**(15,558)**
Cash flows from investing activities			
Investment in fixed assets		(81)	(153)
Payments for licenses		—	(100)
Net cash (outflows) in investing activities		**(81)**	**(253)**
Cash flows from financing activities			
Proceeds from issue of shares		8,134	299
Payments for share issue costs		(897)	—
Payments for lease liabilities		(695)	(335)
Net cash inflows by financing activities		**6,542**	**(36)**
Net increase/(decrease) in cash and cash equivalents		(21,706)	(15,847)
Cash and cash equivalents at beginning of period		129,328	50,426
FX gain/(losses) on the translation of foreign bank accounts		501	(43)
Cash and cash equivalents at end of period	7(a)	**108,123**	**34,536**

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

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

1. Basis of preparation

Mesoblast Limited is a for-profit entity for the purpose of preparing the financial statements. The condensed financial statements of Mesoblast Limited and its subsidiaries have been prepared in accordance with International Accounting Standard IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board ("IASB"), and are unaudited. These interim financial statements do not include all of the notes and disclosures required by International Financial Reporting Standards, as issued by the IASB, for annual consolidated financial statements and should therefore be read in conjunction with our annual report on Form 20-F for the year ended June 30, 2020. In our annual report on Form 20-F, remestemcel-L for the treatment of pediatric SR-aGVHD was referred to as its brand name RYONCIL®.

(i) Going concern

For the three months ended September 30, 2020, the Group incurred a total comprehensive loss after income tax of $24.1 million and had net cash outflows from operations of $28.2 million. The Group held total cash and cash equivalents of $108.1 million as of September 30, 2020. On November 20, 2020 the Group entered into a license and collaboration agreement with Novartis Pharma AG ("Novartis"). The Group will receive $50.0 million in proceeds consisting of an upfront payment of $25.0 million and $25.0 million through the placement of new fully-paid Mesoblast ordinary shares on closing of the license agreement. Closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvement Act and certain other conditions.

The Group has an overarching strategy to fund operations predominately through non-dilutive strategic and commercial transactions. The Group intends to fund operations through drawing on up to $170.0 million in additional funds from existing strategic and financing partnerships, subject to certain conditions, or 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. In addition, the Group expects to achieve cash inflows through sales of remestemcel-L, subject to receiving accelerated approval from the United States Food and Drug Administration ("FDA") on its Biologics License Application ("BLA") for remestemcel-L for the treatment of pediatric SR-aGVHD.

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) New and amended standards adopted by the Group

In the opinion of management, the interim financial data includes all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the results for the interim periods. There were no new or amended standards adopted by the Group in the three months ended September 30, 2020. These interim financial statements follow the same accounting policies as compared to the June 30, 2020 consolidated financial statements and related notes as filed with the Australian Securities Exchange and the Securities and Exchange Commission.

(iii) 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 September 30, 2020 reporting period.

(iv) Use of estimates

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. Specifically, for the Group's Phase 3 clinical trial in 566 patients with advanced forms of New York Heart Association Class II or Class III disease, COVID-19 related restrictions resulted in delays in completion of data quality review at the study sites which has in turn delayed the data readout for the trial. For the Group's Phase 3 clinical trial in 404 patients with chronic low back pain, COVID-19 related restrictions resulted in delays in completion of data quality review at the study sites which has in turn delayed the data readout for the trial. In addition, health regulators may rate other treatments as higher priorities due to the crisis.

On the other hand, at the initial onset of the pandemic, the Group was able to offer remestemcel-L to sufferers of COVID-19 after the FDA cleared it for expanded access protocol ("EAP") for compassionate use. Remestemcel-L is being evaluated for its potential to reduce mortality in a Phase 3 randomized controlled trial of up to 300 ventilator-dependent adults with moderate or severe COVID-19 ARDS.

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.

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 three months ended September 30, 2020.

- In August 2020, the Oncologic Drugs Advisory Committee ("ODAC") of the FDA voted in favor that available data from a single-arm Phase 3 trial and evidence from additional studies support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD. Although the FDA considers 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. Remestemcel-L had been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the PDUFA.
- In August 2020, the Group amended the terms of the Hercules loan agreement to defer principal repayments to March 2021. Principal repayments can be further deferred to the loan maturity date of March 2022 if certain milestones are satisfied.
- On September 30, 2020, the FDA issued a Complete Response Letter to Mesoblast's BLA for remestemcel-L for the treatment of pediatric SR-aGVHD. Despite the overwhelming ODAC vote, the FDA recommended that Mesoblast conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD. As discussed in Note 11, in November 2020, a Type A meeting was held with the FDA to discuss the review of the BLA for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until Mesoblast receives the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, Mesoblast will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Three Months Ended September 30, 2020	2019
Revenue			
Commercialization revenue		1,289	1,872
Milestone revenue		—	15,000
Interest revenue		16	176
Total Revenue		**1,305**	**17,048**
Clinical trial and research & development		**(8,627)**	**(6,057)**
Manufacturing production & development		**(11,494)**	**(1,295)**
Employee benefits			
Salaries and employee benefits		(7,181)	(4,731)
Defined contribution superannuation expenses		(84)	(75)
Equity settled share-based payment transactions[1]		(4,881)	(804)
Total Employee benefits		**(12,146)**	**(5,610)**
Depreciation and amortization of non-current assets			
Plant and equipment depreciation		(211)	(104)
Right of use asset depreciation		(409)	(351)
Intellectual property amortization		(385)	(394)
Total Depreciation and amortization of non-current assets		**(1,005)**	**(849)**
Other Management & administration expenses			
Overheads & administration		(1,961)	(1,774)
Consultancy		(1,806)	(1,145)
Legal, patent and other professional fees		(1,274)	(3,226)
Intellectual property expenses (excluding the amount amortized above)		(569)	(594)
Total Other Management & administration expenses		**(5,610)**	**(6,739)**
Fair value remeasurement of contingent consideration			
Remeasurement of contingent consideration	5(e)(iii)	15,107	(288)
Total Fair value remeasurement of contingent consideration		**15,107**	**(288)**
Other operating income and expenses			
Remeasurement of borrowing arrangements		1,919	(401)
Government grant revenue		17	—
Foreign exchange gains/(losses)		82	232
Total Other operating income and expenses		**2,018**	**(169)**
Finance (costs)/gains			
Remeasurement of borrowing arrangements		(896)	120
Interest expense		(3,926)	(3,577)
Total Finance costs		**(4,822)**	**(3,457)**
Total loss before income tax		**(25,274)**	**(7,416)**

(1) Share-based payment transactions

For the three months ended September 30, 2020 and 2019, the share-based payment transactions have been reflected in the Consolidated Income Statement functional expense categories as follows:

	Three Months Ended, September 30,	
(in U.S. dollars)	**2020**	**2019**
Research and development	2,835,722	319,681
Manufacturing and commercialization	194,316	53,579
Management and administration	1,851,199	430,538
Equity settled share-based payment transactions	**4,881,237**	**803,798**

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 has 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 has 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 September 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 is still considered deferred consideration as of September 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.

For the three months ended September 30, 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.

For the three months ended September 30, 2020, no milestone revenue was recognized in relation to this strategic partnership with Grünenthal.

Tasly arrangement

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

The Group received a $20.0 million up-front technology access fee from Tasly upon closing of this strategic alliance in October 2018. The Group 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 in revenue in February 2020 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.

For the three months ended September 30, 2020 and 2019, respectively, no revenue was recognized in relation to this strategic alliance with Tasly.

TiGenix arrangement

In December 2017, the Group entered into a patent license agreement with TiGenix NV ("TiGenix"), now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell ("MSC") product, Alofisel® a registered trademark of TiGenix, previously known as Cx601, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties. 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 the culture-expanded, MSC-based assets, from Osiris Therapeutics, Inc. ("Osiris"). These assets included assumption of a collaboration agreement (the "JCR Agreement") with JCR Pharmaceuticals Co., Ltd. ("JCR"), a pharmaceutical company in Japan. Revenue recognized under this agreement is limited to the amount of cash received or for which the Group 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, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. With respect to the First JCR Field, the Group are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, the Group are entitled to 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® Hs. Inj. ("TEMCELL"), a registered trademark of JCR 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 recognizes royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the three months ended September 30, 2020, the Group recognized $1.2 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $1.9 million for the three months ended

September 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

Inventories

Inventories are included in the financial statements at the lower of cost (including raw materials, direct labor, other direct costs and related production overheads) and net realizable value. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product in accordance with IAS 2 *Inventories*. Before that point, a provision is made against the carrying value to its recoverable amount in accordance with IAS 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 September 30, 2020, there was $14.6 million of pre-launch inventory recognized on the balance sheet that was fully provided for, compared with $8.8 million at June 30, 2020, and $5.8m of pre-launch inventory costs have been recognized within Manufacturing Commercialization expenses for the three months ended September 30, 2020.

4. Income tax benefit/(expense)

	Three Months Ended September 30,	
(in U.S. dollars, in thousands)	**2020**	**2019**
Income tax expense/(benefit)		
Current tax		
Current tax	—	—
Total current tax expense/(benefit)	—	—
Deferred tax		
(Increase)/decrease in deferred tax assets	(818)	(2,029)
(Decrease)/increase in deferred tax liabilities	88	97
Total deferred tax expense/(benefit)	**(730)**	**(1,932)**
Income tax expense/(benefit)	**(730)**	**(1,932)**

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

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

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

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Deferred tax assets not brought to account		
Unused tax losses		
Potential tax benefit at local tax rates	64,594	55,573
Other temporary differences		
Potential tax benefit at local tax rates	7,137	6,782
Other tax credits		
Potential tax benefit at local tax rates	3,220	3,220
	74,951	**65,575**

As of September 30, 2020 and June 30, 2020, the Group has deferred tax assets not brought to account of $75.0 million and $65.6 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 September 30, 2020					
Cash & cash equivalents	5(a)	—	—	108,123	108,123
Trade & other receivables	5(b)	—	—	2,446	2,446
Financial assets at fair value through other comprehensive income		1,952	—	—	1,952
Other non-current assets		—	—	3,334	3,334
		1,952	**—**	**113,903**	**115,855**
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		1,871	—	—	1,871
Other non-current assets		—	—	3,311	3,311
		1,871	**—**	**134,213**	**136,084**

(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 September 30, 2020					
Trade and other payables	5(c)	—	—	27,602	27,602
Borrowings	5(d)	—	—	90,991	90,991
Contingent consideration	5(e)(iii)	—	29,875	—	29,875
		—	**29,875**	**118,593**	**148,468**
As of June 30, 2020					
Trade and other payables	5(c)	—	—	24,972	24,972
Borrowings	5(d)	—	—	89,478	89,478
Contingent consideration	5(e)(iii)	—	45,166	—	45,166
		—	**45,166**	**114,450**	**159,616**

(1) Fair value through other comprehensive income
(2) Fair value through profit or loss

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

a. Cash and cash equivalents

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Cash at bank	107,697	128,916
Deposits at call(1)	426	412
	108,123	**129,328**

(1) As of September 30, 2020 and June 30, 2020, 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 September 30, 2020	As of June 30, 2020
Trade debtors	1,295	678
Foreign withholding tax recoverable	471	471
Security deposit	252	252
Other recoverable taxes (Goods and services tax and value-added tax)	428	173
Trade and other receivables	**2,446**	**1,574**

(ii) Prepayments

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Clinical trial research and development expenditure	3,152	3,304
Prepaid insurance and subscriptions	608	1,337
Other	1,408	1,005
Prepayments	**5,168**	**5,646**

(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 9.

c. Trade and other payables

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Trade payables and other payables	27,602	24,972
Trade and other payables	**27,602**	**24,972**

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

d. Borrowings

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Borrowings		
Secured liabilities:		
Borrowing arrangements	80,000	80,000
Less: transaction costs	(6,738)	(6,738)
Amortization of carrying amount, net of payments made	17,729	16,216
	90,991	**89,478**

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2019
Borrowings		
Current	34,893	32,455
Non-current	56,098	57,023
	90,991	**89,478**

(i) Borrowing arrangements

Hercules Capital, Inc.

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.

Principal repayments are due to commence in March 2021. Principal repayments can be further deferred to 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%. 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, 2019, 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%, and remains at 9.70% at September 30, 2020, in line with the amended terms of the loan agreement. As at September 30, 2020, the Group recognized $3.8 million in interest payable within twelve months as a current liability.

In the three months ended September 30, 2020, the Group recognized a loss of $0.1 million in the Income Statement as remeasurement of borrowing arrangements within finance costs. These remeasurement losses 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.

There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2020.

NovaQuest Capital Management, L.L.C.

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 remestemcel-L for the treatment in pediatric patients with 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 remestemcel-L for pediatric SR-aGVHD are significantly higher than current forecasts.

If there are no net sales of remestemcel-L for pediatric SR-aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of remestemcel-L 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 remestemcel-L for pediatric SR-aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of remestemcel-L for pediatric SR-aGVHD. Any unpaid interest will be added to the principal amounts owing and shall accrue further interest. At maturity date, any unpaid loan balances are repaid.

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

In the three months ended September 30, 2020, the Group recognized a gain of $1.9 million in the Income Statement as remeasurement of borrowing arrangements within other operating income in relation to the changes in our estimated net sales of remestemcel-L for pediatric SR-aGVHD as a net result of changes to the key assumptions in development timelines. In the three months ended September 30, 2019, the Group recognized a $0.4 million loss in the Income Statement as remeasurement of borrowing arrangements within other operating income in relation to changes in our estimated net sales of remestemcel-L for pediatric SR-aGVHD as a net result of changes to the key assumptions in development timelines and market penetration.

In the three months ended September 30, 2020 and 2019, the Group recognized a loss of $0.8 million and a gain of $0.1 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs in relation to the revision in the estimated future cash flows.

These remeasurement gains and losses 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.

As at September 30, 2020, the Group has recognized a current liability of $4.2 million which represents the present value of interest payable of $3.9 million and $0.3 million loan administration fee which is payable annually in June.

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 we 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 three months ended September 30, 2020 and during the year ended June 30, 2020.

(iii) Net Debt Reconciliation

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Cash and cash equivalents	108,123	129,328
Borrowings Repayable within one year	(37,877)	(35,974)
Borrowings Repayable after one year	(63,146)	(63,340)
Net Debt(1)	**7,100**	**30,014**
Cash and cash equivalents	108,123	129,328
Gross debt - fixed interest rates	(50,210)	(49,414)
Gross debt - variable interest rates	(50,813)	(49,900)
Net Debt(1)	**7,100**	**30,014**

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

	Liabilities from financing activities			Other assets	
(in U.S. dollars, in thousands)	Borrowings	Leases	Sub-total	Cash and cash equivalents	Total
Net Debt as at June 30, 2020	(89,478)	(9,836)	(99,314)	129,328	30,014
Cash Flows(1)	—	695	695	(21,706)	(21,011)
Remeasurement of borrowing arrangements	1,023	—	1,023	—	1,023
Other Changes(2)	(2,536)	(374)	(2,910)	—	(2,910)
Acquisition - leases	—	(395)	(395)	—	(395)
Foreign exchange adjustments	—	(122)	(122)	501	379
Net Debt as at September 30, 2020	**(90,991)**	**(10,032)**	**(101,023)**	**108,123**	**7,100**

(1) Cash flows include the payments of lease liabilities which are presented as financing cash flows in the statement of cash flows.
(2) Other changes include accrued interest expenses and interest payments for borrowings and leases, which are 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.

e. 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 September 30, 2020 and June 30, 2020 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		—	—	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(e)(iii)	—	—	45,166	45,166
Total Financial Liabilities		**—**	**—**	**45,166**	**45,166**

As of September 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		—	—	1,952	1,952
Total Financial Assets		**—**	**—**	**1,952**	**1,952**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(e)(iii)	—	—	29,875	29,875
Total Financial Liabilities		**—**	**—**	**29,875**	**29,875**

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

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

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

Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for provisions (contingent consideration) and equity securities (unlisted).

(ii) Valuation techniques used.

The Group used 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 three months ended September 30, 2020 and the year ended June 30, 2020.

(in U.S. dollars, in thousands)	Contingent consideration provision
Opening balance - July 1, 2019	47,534
Amount used during the period	(988)
Charged/(credited) to consolidated income statement:	
Remeasurement(1)	(1,380)
Closing balance - June 30, 2020	**45,166**
Opening balance - July 1, 2020	45,166
Amount used during the period	(184)
Charged/(credited) to consolidated income statement:	
Remeasurement(2)	(15,107)
Closing balance - September 30, 2020	**29,875**

(1) 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.

(2) In the three months ended September 30, 2020 a gain of $15.1 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain was a net result of changing the key assumptions of the contingent consideration valuation primarily as a result of receiving the Complete Response Letter from the FDA on the BLA for remestemcel-L for the treatment of pediatric SR-aGVHD on September 30, 2020. The assumptions of probability of success and development timeline have been updated to reflect current expectations as a result of the Complete Response Letter and the Group's request to the FDA for accelerated approval of the BLA for remestemcel-L for pediatric SR-aGVHD, as discussed in Note 11.

(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 September 30, 2020	Fair value as of June 30, 2020	Valuation technique	Unobservable inputs(1)	Range of inputs (weighted average) Three Months Ended September 30, 2020	Range of inputs (weighted average) Year Ended June 30, 2020	Relationship of unobservable inputs to fair value
Contingent consideration provision	29,875	45,166	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.5%. Year ended June 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.4%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2020: A change in the price assumptions by 10% would increase/decrease the fair value by 2%. Year ended June 30, 2020: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 3%.
				Expected sales volumes	n/a	n/a	Three months ended September 30, 2020: A change in the volume assumptions by 10% would increase/decrease the fair value by 2%. Year ended June 30, 2020: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 3%.
				Probability of success	Various	Various	Three months ended September 30, 2020: A change in the probability of success assumptions by 10% and 20% would increase/decrease the fair value by 8.6% and 17.2%, respectively. Year ended June 30, 2020: A 10% and 20% increase in the probability of success assumptions would increase the fair value by 9% and 12.9%, respectively, and a 10% and 20% decrease in the probability of success assumptions would decrease the fair value by 9% and 18%, respectively.

(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 three months ended September 30, 2020 and the year ended June 30, 2020, 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. For each indication we determine the probability of success based on the current development status within each jurisdiction. Cash flows relevant to each jurisdiction are discounted appropriately based on the probability of success assumed. The remeasurement charged to the consolidated income statement in the three months ended September 30, 2020 was a net result of changing the key assumptions of the contingent consideration valuation primarily as a result of receiving the Complete Response Letter from the FDA on the BLA for remestemcel-L for the treatment of pediatric SR-aGVHD on September 30, 2020. The assumptions of probability of success and development timeline have been updated to reflect current expectations as a result of the Complete Response Letter and the Group’s request to the FDA for accelerated approval of the BLA for remestemcel-L for pediatric SR-aGVHD, as discussed in Note 11. When the outcome of the request for accelerated approval is known, this could change the key assumptions and a further remeasurement of contingent consideration, up or down, could occur.

The fair value of contingent consideration (in U.S. dollars, in thousands)	**As of September 30, 2020**	**As of June 30, 2020**
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	18,636	28,801
Fair value of royalty payments from commercialization of the intellectual property acquired	11,239	16,365
	29,875	**45,166**

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.
Probability of success:	Expected cash flows used to measure contingent consideration are risk adjusted for the probability of successful development of products. This assumption is reviewed as part of the valuation process outlined above.

6. Non-financial assets and liabilities

a. Intangible assets

(in U.S. dollars, in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Current marketed products	Total
Year Ended June 30, 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**
Three Months Ended September 30, 2020					
Opening net book amount	134,453	1,673	427,779	17,696	581,601
Additions	—	—	—	—	—
Exchange differences	—	—	—	1	1
Amortization charge	—	(21)	—	(364)	(385)
Closing net book amount	**134,453**	**1,652**	**427,779**	**17,333**	**581,217**
As of September 30, 2020					
Cost	134,453	2,878	489,698	24,001	651,030
Accumulated amortization	—	(1,226)	—	(6,668)	(7,894)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,652**	**427,779**	**17,333**	**581,217**

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

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Cardiovascular products[1]	254,351	254,351
Intravenous products for metabolic diseases and inflammatory/immunologic conditions[2]	70,730	70,730
MSC products[3]	102,698	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 remestemcel-L 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) Significant estimate: Impairment of goodwill and assets with an indefinite useful life

The Group tests annually or more frequently if events or changes in circumstances indicate that they might be impaired whether goodwill and its assets with indefinite useful lives have suffered any impairment in accordance with its accounting policy stated in Note 22(j) in the Form 20-F for the year ended June 30, 2020. 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.

On September 30, 2020, the FDA issued a Complete Response Letter to Mesoblast's BLA for remestemcel-L for the treatment of pediatric SR-aGVHD and the Group has considered this to be an impairment indicator that could cause the carrying amount of our MSC products intangible asset to exceed its recoverable amount. As a result, the Group has completed an impairment assessment on the MSC products as at September 30, 2020. The impairment assessment on the MSC products has been determined based on fair value less costs to dispose calculations as at September 30, 2020, which require the use of certain assumptions and no impairment of the in-process research and development and goodwill was identified.

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

In-process research and development acquired is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form (see Note 22(p)(iii) in the Form 20-F for the year ended June 30, 2020). 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 and in-process research and development pertaining to MSC products was reassessed as of September 30, 2020 based on the fair value less costs to dispose. Management assess for indicators of impairment as at September 30, 2020 including considering events up to the date of the approval financial statements. No impairment as at September 30, 2020 was identified.

(iv) Key assumptions used for fair value less costs to dispose calculations as it pertains to MSC products

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 the MSC programs valued by the Group's internal valuation team and reviewed by the CFO as at September 30, 2020. 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 market capitalization of the Group on the ASX (ASX:MSB) on the impairment testing date of September 30, 2020; and

Costs of disposal were assumed to be immaterial at September 30, 2020.

Discounted cash-flows used a real post-tax discount rate of 13.8% 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.

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 the MSC products have 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.

(v) Impact of possible changes in key assumptions

The Group has considered and assessed reasonably possible changes in the key assumptions and has not identified any instances that could cause the carrying amount of our MSC products intangible asset at September 30, 2020 to exceed its recoverable amount.

Whilst there is no impairment indicator, the key sensitivities in this assessment remain the continued successful development of the Group's technology platforms. If we are unable to successfully develop our technology platforms, an impairment of the carrying amount of the Group's intangible assets may result.

b. Deferred tax balances

(i) Deferred tax balances

(in U.S. dollars, in thousands)	As of September 30, 2020	As of June 30, 2020
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	72,941	72,899
Other temporary differences	6,972	6,196
Total deferred tax assets	**79,913**	**79,095**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	79,913	79,825
Total deferred tax liabilities	**79,913**	**79,825**
Net deferred tax liabilities	—	**730**
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	79,913	79,095
Deferred tax liabilities expected to be settled within 12 months	141	99
Deferred tax liabilities expected to be settled after 12 months	79,772	79,726

(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, 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**
Charged/(credited) to:				
- profit or loss	(42)	(776)	88	(730)
- directly to equity	—	—	—	—
As of September 30, 2020	**(72,942)**	**(6,971)**	**79,913**	**—**

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

7. Cash flow information

(in U.S. dollars, in thousands) (a) Reconciliation of cash and cash equivalents	As of September 30, 2020	As of June 30, 2020
Cash at bank	107,697	128,916
Deposits at call	426	412
	108,123	**129,328**

(in U.S. dollars, in thousands) (b) Reconciliation of net cash flows used in operations with loss after income tax	Three Months Ended September 30,	
	2020	2019
Loss for the period	(24,544)	(5,484)
Add/(deduct) net loss for non-cash items as follows:		
Depreciation and amortization	1,005	849
Foreign exchange (gains)/losses	(113)	(232)
Finance costs	2,534	2,165
Remeasurement of borrowing arrangements	(1,023)	281
Remeasurement of contingent consideration	(15,107)	288
Equity settled share-based payment	4,881	804
Deferred tax benefit	(730)	(1,932)
Change in operating assets and liabilities:		
Decrease/(increase) in trade and other receivables	(869)	(15,378)
Decrease/(increase) in prepayments	795	(164)
Decrease/(increase) in tax assets	—	1,499
Increase/(decrease) in trade creditors and accruals	3,601	(300)
Increase/(decrease) in provisions	1,403	2,046
Net cash outflows used in operations	**(28,167)**	**(15,558)**

8. Issued capital

Contributed equity

(i) Share capital

	As of September 30,			
	2020	2019	2020	2019
	Shares No.		(U.S. dollars, in thousands)	
Contributed equity				
(i) Share capital				
Ordinary shares	586,586,780	499,179,434	1,063,005	910,942
Less: Treasury Shares(1)	(791,647)	(3,500,000)	—	—
Total Contributed Equity	**585,795,133**	**495,679,434**	**1,063,005**	**910,942**

(1) In July 2020, the Group formed the Mesoblast Employee Share Trust, being a new trust formed to administer the Group's employee share scheme. Prior to forming the new trust, the Group had been using the Mesoblast Limited Employee Share Trust for administering some aspects of the Group's employee share scheme. In July 2020, 3,500,000 shares were transferred from Mesoblast Limited Employee Share Trust to the Mesoblast Employee Share Trust. The treasury shares have reduced during the period ended September 30, 2020 due to share option exercises. These trusts have been consolidated, as the substance of the relationship is that the trusts are controlled by the Group.

(ii) Movements in ordinary share capital

	As of September 30,		As of September 30,	
	2020	2019	2020	2019
	Shares No.		(U.S. dollars, in thousands)	
Opening balance	583,949,612	498,626,208	1,051,450	910,405
Issues of ordinary shares during the period				
Exercise of share options(1)	—	553,226	6,706	299
Transfer to employee share trust(1)	1,450,000	—	—	—
Share based compensation for services rendered	1,187,168	—	1,867	—
Transaction costs arising on share issue	—	—	(219)	—
	2,637,168	553,226	8,354	299
Share options reserve transferred to equity on exercise of options	—	—	3,201	238
Ending balance	**586,586,780**	**499,179,434**	**1,063,005**	**910,942**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Option Plan. The shares issued and share capital received on the exercise of options are recorded above.

9. Financial risk management

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

Risk	Exposure arising from	Measurement	Management
Market risk – currency risk	Future commercial transactions Recognized financial assets and liabilities not denominated in the functional currency of each entity within the Group	Cash flow forecasting Sensitivity analysis	The future cash flows of each currency are forecast and the quantum of cash reserves held for each currency are managed in line with future forecasted requirements. Cross currency swaps are undertaken as required.
Market risk – interest rate risk	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.

(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 is 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 three months ended September 30, 2020.

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

	As of September 30, 2020		As of June 30, 2020	
(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	30,682	34%	27,949	31%
Non-current borrowings				
Variable rate borrowings - Hercules	20,131	22%	21,951	25%
	50,813	**56%**	**49,900**	**56%**

An analysis by maturities is provided in Note 9(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 September 30, 2020 and June 30, 2020. The effect on profit is shown if interest rates change by 5%, in either direction, is as follows:

	As of September 30, 2020			As of June 30, 2020		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Borrowings - USD	9.70%	9.70%	50,813(1)	9.70%	9.70%	49,900(1)
Rate increase by 5%	10.19%	10.19%	243	10.19%	10.19%	243
Rate decrease by 5%	9.22%	9.22%	(243)	9.22%	9.22%	(243)

(1) Effect on profit/loss of interest rate changes is based on the loan principal amount of $50.0 million as of September 30, 2020, and June 30, 2020.

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 September 30, 2020 and June 30, 2020. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

	As of September 30, 2020			As of June 30, 2020		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Funds invested - USD	0.00%(1)	0.00%(1)	73,886	0.03%	0.03%	102,925
Rate increase by 10%	0.03%(1)	0.03%(1)	4	0.03%	0.03%	3
Rate decrease by 10%	0.03%(1)	0.03%(1)	(4)	0.03%	0.03%	(3)

AUD	**Low**	**High**	**AUD**	**Low**	**High**	**AUD**
Funds invested - AUD	0.64%	0.64%	600	0.86%	0.86%	600
Rate increase by 10%	0.70%	0.70%	0	0.95%	0.95%	1
Rate decrease by 10%	0.58%	0.58%	(0)	0.77%	0.77%	(1)

(1) The interest rate reduced to 0% for the period ended September 30, 2020. The sensitivity assumes the interest rate to increase or decrease by 0.03%, which is the opening rate on July 1, 2020.

(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 remestemcel-L for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of remestemcel-L 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.

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

	As of September 30, 2020		As of June 30, 2020	
(in U.S. dollars, in thousands, except percent data)	**Total**	**% of total loans**	**Total**	**% of total loans**
Financial liabilities				
Current borrowings				
Borrowings - NovaQuest	4,211	5%	4,506	5%
Non-current borrowings				
Borrowings - NovaQuest	35,967	39%	35,072	39%
	40,178	**44%**	**39,578**	**44%**

As at September 30, 2020, all other factors held constant, a 20% increase in the forecast net sales of remestemcel-L 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 $5.0 million, whereas a 20% decrease in the net sales of remestemcel-L 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 $1.6 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 September 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 maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets as mentioned in Note 5.

c. Liquidity risk

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

All financial liabilities, excluding contingent consideration, borrowings and lease liabilities, held by the Group as of September 30, 2020 and June 30, 2020, 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 September 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]	(39,097)	(34,496)	(53,051)	(12,011)	(138,655)	(90,991)
Trade payables	(27,602)	—	—	—	(27,602)	(27,602)
Lease liabilities	(3,573)	(3,034)	(4,173)	(614)	(11,394)	(10,032)
	(70,272)	**(37,530)**	**(57,224)**	**(12,625)**	**(177,651)**	**(128,625)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at September 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 remestemcel-L for the treatment of pediatric SR-aGVHD**.**

Purchase commitments

In December 2019, the Group commenced production under its manufacturing service agreement with Lonza for the supply of commercial product for the potential approval and launch of remestemcel-L for the treatment of pediatric SR-aGVHD and/or for the treatment of COVID-19 ARDS in the US market. This agreement contains lease and non-lease components with a non-cancellable term of 4.5 years through June 2024. As of September 30, 2020, the agreement contains a minimum financial commitment of $46.4 million. The Group has accounted for the lease component within the agreement as a lease liability separately from the non-lease components. As of September 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 $41.1 million. At the Group's discretion, the minimum financial commitment under this manufacturing services agreement can be reduced by $24.8 million, with $3.6 million of this reduction relating to the lease component and $21.2 million relating to the non-lease component of the agreement.

The Group did not have any other purchase commitments as of September 30, 2020.

10. (Losses)/earnings per share

	Three Months Ended	
	September 30, 2020	September 30, 2019
(Losses) per share		
(in cents)		
(a) Basic (losses) per share		
From continuing operations attributable to the ordinary equity holders of the company	(4.21)	(1.10)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(4.21)**	**(1.10)**
(b) Diluted (losses) per share		
From continuing operations attributable to the ordinary equity holders of the company	(4.21)	(1.10)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(4.21)**	**(1.10)**
(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	(24,544)	(5,484)
Diluted (losses) per share		
(Losses) from continuing operations attributable to the ordinary equity holders of the company:		
Used in calculating basic (losses) per share	(24,544)	(5,484)
(Losses) attributable to the ordinary equity holders of the company used in calculating diluted losses per share	(24,544)	(5,484)

	Three Months Ended	
	September 30, 2020 (In Shares)	September 30, 2019 (In Shares)
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	582,489,625	499,301,409
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	582,489,625	499,301,409

Options granted to employees are considered to be potential ordinary shares. These securities have been excluded from the determination of basic losses per share in the three months ended September 30, 2020 and 2019. Shares that may be paid as contingent consideration have also been excluded from basic losses per share. They have been excluded from the calculation of diluted losses per share because they are anti-dilutive for the three months ended September 30, 2020 and 2019.

11. Events occurring after the reporting period

On November 17, 2020, a Type A meeting was held with the FDA to discuss the review of the BLA for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until Mesoblast receives the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, Mesoblast will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

On November 20, 2020, the Group entered into a worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of remestemcel-L, with an initial focus on the development of the treatment of acute respiratory distress syndrome ("ARDS"), including that associated with COVID-19. The Group will retain full rights and economics for remestemcel-L for graft versus host disease, and Novartis has an option to, if exercised, become the commercial distributor outside of Japan. The Group will receive $50.0 million in proceeds consisting of an upfront payment of $25.0 million and $25.0 million through the placement of new fully-paid Mesoblast ordinary shares on closing of the license agreement. Closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvement Act and certain other conditions. The Group may receive a total of $505.0 million pending achievement of pre-commercialization milestones for ARDS indications. The Group may receive additional payments post-commercialization of up to $750.0 million based on achieving certain sales milestones and tiered double-digit royalties on product sales. The Group has not yet assessed the accounting impact of this agreement.

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

12. Segment information

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

13. Legal proceedings

In October 2020, in light of the Complete Response Letter released by the FDA and the decline in the market price of our ADS, a purported class action lawsuit was filed in the U.S. Federal District Court for the Southern District of New York on behalf of purchasers or acquirers of our ADSs against the Company, its Chief Executive Officer and its Chief Financial Officer for alleged violations of the U.S. Securities Exchange Act of 1934. The Company cannot provide any assurance as to the possible outcome or cost to us from the lawsuit, particularly as it is at an early stage, nor how long it may take to resolve lawsuit, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

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

For us and our subsidiaries that use a functional currency that is not U.S. dollars, the assets and liabilities have been translated at the closing exchange rate, while the income and expenses have been translated at the exchange rate at the transaction date. The resulting exchange differences are recognized in our consolidated statement of comprehensive income. See note 22(c) in the notes to our consolidated financial statements and the related notes thereto included in our annual report on Form 20-F for the fiscal year ended June 30, 2020 ("Form 20-F"), filed with the Securities and Exchange Commission on September 3, 2020, for more information.

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

Overview

Mesoblast (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic cellular medicines. We have leveraged our 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:

- Remestemcel-L for pediatric SR-aGVHD;
- Remestemcel-L for moderate to severe acute respiratory distress syndrome ("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.

We also have a promising emerging pipeline and next generation technologies.

Mesoblast's goal is for remestemcel-L to be the first commercially available allogeneic MSC product in the United States.

On November 11, 2020, we announced that the Phase 3 randomized controlled trial of remestemcel-L in patients with moderate to severe ARDS due to COVID-19 infection had received a recommendation to continue from the independent Data Safety Monitoring Board ("DSMB") following completion of the trial's second interim analysis. The analysis was performed on the trial's first 135 patients, 45% of the total target of up to 300 randomized patients, with the DSMB recommending continuation after reviewing the trial's primary endpoint. Patients are randomized 1:1 in the double-blinded trial to receive either two intravenous infusions of remestemcel-L within five days, or placebo, on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization. The key secondary endpoint is days alive off mechanical ventilatory support within 60 days of randomization. ARDS is the principal cause of death in COVID-19 infection and is thought to be due to a dysregulated immune response in the lungs to COVID-19. Deaths continue to increase in ventilator-dependent ARDS patients as COVID-19 cases continue to surge globally. The Phase 3 trial aims to confirm findings from a pilot study at New York's Mt Sinai Hospital in March-April this year where nine of 12 ventilator-dependent patients (75%) were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L within five days. Confirmation of the results of the pilot data in the 300 patient Phase 3 trial will not provide a guarantee that remestemcel-L will be deemed to be safe or effective for the treatment of COVID-19 and regulatory approval will be required before remestemcel-L can be commonly prescribed for the treatment of COVID-19. The ongoing Phase 3 trial, which is treating patients across more than 20 hospitals in the United States, uses the same dosing regimen. Mesoblast holds an Investigational New Drug ("IND") submission for remestemcel-L in COVID-19 ARDS, with trial size, protocol design, and endpoints developed with input from the United States Food and Drug Administration ("FDA"). The third and final interim analysis will occur when 60% of the randomized target has completed 30 days of follow-up.

On October 22, 2020, we announced that a randomized, controlled study of remestemcel-L delivered by an endoscope directly to the areas of inflammation and tissue injury in up to 48 patients with medically refractory Crohn's disease and ulcerative colitis had commenced at Cleveland Clinic. According to recent estimates, more than three million people (1.3%) in the United States alone have inflammatory bowel disease, with more than 33,000 new cases of Crohn's disease and 38,000 new cases of ulcerative colitis diagnosed every year. Despite recent advances, approximately 30% of patients are primarily unresponsive to anti-TNFα agents and

even among responders, up to 10% will lose their response to the drug every year. Up to 80% of patients with medically-refractory Crohn's disease eventually require surgical treatment of their disease, which can have a devastating impact on quality of life. Mesoblast's objective is to confirm the potential for remestemcel-L to induce luminal healing and early remission in a wider spectrum of diseases with severe inflammation of the gut, in addition to SR-aGVHD. The investigator-initiated study at Cleveland Clinic is the first in humans using local cell delivery in the gut, and will enable Mesoblast to compare clinical outcomes using this delivery method with results from an ongoing randomized, placebo-controlled trial in patients with biologic-refractory Crohn's disease where remestemcel-L was administered intravenously.

On October 13, 2020, we announced that the randomized controlled Phase 3 trial of remestemcel-L on top of maximal care in ventilator-dependent patients with ARDS due to COVID-19 infection has surpassed 50% enrollment. The trial's primary endpoint is reduction in 30-day mortality relative to maximal care. ARDS continues to be the primary cause of death in COVID-19 patients.

On October 2, 2020, we announced that the FDA had issued a Complete Response Letter to its Biologics License Application ("BLA") for remestemcel-L for the treatment of pediatric SR-aGVHD. Despite the overwhelming Oncologic Drugs Advisory Committee ("ODAC") of the FDA vote in August 2020, the FDA recommended that Mesoblast conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD. Mesoblast believes that remestemcel-L meets the criteria for accelerated approval as there are currently no approved treatments for this life-threatening condition in children under 12. On November 17, 2020, a Type A meeting was held with the FDA to discuss the review of the BLA for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until we receive the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, we will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

On September 15, 2020 we announced that remestemcel-L had been selected as the winner of the Fierce Innovation Awards - Life Sciences Edition 2020 for Biotech Innovation. The Fierce Innovation Awards is a peer-reviewed program from the publisher of FierceBiotech and FiercePharma highlighting innovative solutions, technologies, and services that have the potential to make the greatest impact for biotech and pharma companies. The evaluation criteria are effectiveness, technical innovation, competitive advantage, financial impact, and true innovation. Remestemcel-L is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. It is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions by 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.

On September 4, 2020, we announced that the independent DSMB recommended continuation of the Phase 3 trial of remestemcel-L in patients with ARDS due to COVID-19 infection, following completion of trial's first interim analysis. The analysis was performed on the first 30% of the total target of randomized patients, with the DSMB reviewing the trial's primary endpoint, all-cause mortality within 30 days of randomization and all safety data. Mesoblast Chief Medical Officer Dr Fred Grossman said: "We are very pleased with the recommendation by the DSMB. This important trial seeks to confirm whether remestemcel-L improves survival in ventilated COVID-19 patients with moderate to severe ARDS, where death rates remain high despite best existing treatments." The multi-center study includes three interim analyses for stopping accrual early for efficacy or futility when 30%, 45% and 60% of the total target of randomized patients have reached the primary endpoint. Up to 300 patients are planned to be randomized 1:1 in the double-blinded Phase 3 trial to receive either two intravenous infusions of remestemcel-L within five days, or placebo, on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization. The key secondary endpoint is days alive off mechanical ventilatory support within 60 days of randomization. The trial is expected to complete recruitment during Q4 CY2020.

On September 2, 2020, we announced that we had received ethics approval to include Australian hospitals in the Phase 3 randomized controlled trial of remestemcel-L in ventilator-dependent COVID-19 patients with ARDS. Participating hospitals in Melbourne and Sydney have been granted approval by the Human Research Ethics Committee of Monash Health and will join leading US medical centers already in the Phase 3 trial.

On August 14, 2020, we announced that the ODAC of the FDA voted overwhelmingly in favor that available data support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD.

On July 30, 2020, we announced that the independent DSMB set a date for early September to complete the first interim analysis of the Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate to severe ARDS.

On July 24, 2020, we announced the appointment of Dagmar Rosa-Bjorkeson as Chief Operating Officer. Her responsibilities include managing commercial operations, leading the business units, building out key strategic alliances, and overseeing product launches.

On July 6, 2020, we announced that an Expanded Access Protocol ("EAP") has been initiated in the US 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.

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 three months ended September 30, 2020, we had an accumulated deficit of $573.3 million. Our net loss for the three months ended September 30, 2020 was $24.5 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 three months ended September 30, 2020, we recognized $1.3 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 $1.9 million for the three months ended September 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the three months ended September 30, 2019, 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 three months ended September 30, 2019 for the up-front fee receivable from Grünenthal as the performance obligation in regards 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 three months ended September 30, 2020.

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 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 a net remeasurement gain of $15.1 million and a net remeasurement loss of $0.3 million for the three months ended September 30, 2020 and 2019, respectively.

Other Operating Income and Expenses. Other operating income and expenses primarily comprise remeasurement of borrowing arrangements, tax incentives 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 three months ended September 30, 2020, we recognized a remeasurement gain of $1.9 million as a net result of changes to the key assumptions in development timelines, compared with a remeasurement loss of $0.4 million in the three months ended September 30, 2019 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 foreign exchange gains of $0.1 million in the three months ended September 30, 2020 and $0.2 million in the three months ended September 30, 2019.

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

Remeasurement of borrowing arrangements 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 three months ended September 30, 2020 and 2019, we recognized a remeasurement loss of $0.1 million and $Nil in relation to our existing credit facility with Hercules, respectively. In the three months ended September 30, 2020 and 2019, we recognized a remeasurement loss of $0.8 million and a remeasurement gain of $0.1 million 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 $0.7 million in the three months ended September 30, 2020 and $1.9 million in the three months ended September 30, 2019.

Results of Operations

Comparison of Our Results for the Three Months Ended September 30, 2020 with the Three Months Ended September 30, 2019

The following table summarizes our results of operations for the three months ended September 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)	Three months ended September 30, 2020	2019	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 1,289	$ 1,872	(583)	(31%)
Milestone revenue	—	15,000	(15,000)	(100%)
Interest revenue	16	176	(160)	(91%)
Total revenue	**1,305**	**17,048**	**(15,743)**	**(92%)**
Research & development	(19,278)	(12,389)	(6,889)	56%
Manufacturing commercialization	(11,924)	(2,698)	(9,226)	NM
Management and administration	(7,680)	(5,463)	(2,217)	41%
Fair value remeasurement of contingent consideration	15,107	(288)	15,395	NM
Other operating income and expenses	2,018	(169)	2,187	NM
Finance costs	(4,822)	(3,457)	(1,365)	39%
Loss before income tax	**(25,274)**	**(7,416)**	**(17,858)**	**NM**
Income tax benefit	730	1,932	(1,202)	(62%)
Loss attributable to the owners of Mesoblast Limited	**$ (24,544)**	**$ (5,484)**	**(19,060)**	**NM**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(4.21)	(1.10)	(3.12)	NM
Diluted - losses per share	(4.21)	(1.10)	(3.12)	NM

* NM = not meaningful.

Revenue

Revenues were $1.3 million for the three months ended September 30, 2020, compared with $17.0 million for the three months ended September 30, 2019, a decrease of $15.7 million. The following table shows the movement within revenue for the three months ended September 30, 2020 and 2019, together with the changes in those items.

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Revenue:				
Milestone revenue	—	15,000	(15,000)	(100%)
Commercialization revenue	1,289	1,872	(583)	(31%)
Interest revenue	16	176	(160)	(91%)
Revenue	**$ 1,305**	**$ 17,048**	**(15,743)**	**(92%)**

We recognized $15.0 million in milestone revenue during the three months ended September 30, 2019 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. No milestone revenue was recognized in the three months ended September 30, 2020.

Commercialization revenue from royalty income earned on sales of TEMCELL in Japan by our licensee JCR was $1.2 million in the three months ended September 30, 2020, a decrease of $0.6 million (31%) as compared with $1.9 million in the three months ended September 30, 2019. In the three months ended September 30, 2020 we also earned $0.1 million of royalty income on sales of Alofisel® in Europe by our licensee Takeda, compared to a minimal amount in the three months ended September 30, 2019.

The $0.1 million decrease in interest revenue for the three months ended September 30, 2020, compared with the three months ended September 30, 2019 was primarily driven by lower interest rates on US$ cash deposits in the three months ended September 30, 2020, when compared with the three months ended September 30, 2019.

Research and development

Research and development expenses were $19.3 million for the three months ended September 30, 2020, compared with $12.4 million for the three months ended September 30, 2019, an increase of $6.9 million. The $6.9 million increase in research and development expenses primarily reflects an increase in third party and product support costs for research and development and pre-commercial functions as we prepare for the potential launch of remestemcel-L for the treatment of pediatric SR-aGVHD in the United States.

(in U.S. dollars, in thousands)	Year ended September 30, 2020	2019	$ Change	% Change
Research and development:				
Third party costs	8,737	6,566	2,171	33%
Product support costs	9,522	4,834	4,688	97%
Intellectual property support costs	655	625	30	5%
Amortization of current marketed products	364	364	—	0%
Research and development	**$ 19,278**	**$ 12,389**	**6,889**	**56%**

Third party costs, which consist of all external expenditure on our research and development programs, increased by $2.2 million in the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

This $2.2 million increase in third party costs was primarily associated with clinical enrollment for our Phase 3 clinical trial for the treatment of ARDS in COVID-19 patients as we commenced this trial in April 2020. In the three months ended September 30, 2020, there was a reduction in our third party costs for our Phase 3 clinical trials for MPC-150-IM (CHF), MPC-06-ID (CLBP) and remestemcel-L (for pediatric SR-aGVHD) as activities and costs have reduced as enrollment was completed in January 2019, March 2018 and December 2019, respectively. We continued to incur costs for MPC-150-IM (CHF) and MPC-06-ID (CLBP) during the three months ended September 30, 2020 as patients were monitored during follow up visits and other testing was completed. In the three months ended September 30, 2020, we also incurred costs of $1.7m associated with our pre-commercial activities as we prepare for the potential launch of remestemcel-L for the treatment of pediatric SR-aGVHD 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 $4.7 million, for the three months ended September 30, 2020 compared with the three months ended September 30, 2019. Within this $4.7 million increase, $3.7 million relates to an increase in product support costs for research and development functions and $1.0 million relates to an increase in product support costs for pre-commercial functions.

The $3.7 million increase in product support costs for personnel in research and development functions is primarily due to an increase of $1.0 million across salaries and associated costs as full time equivalents increased by 11.6 (24%) from 48.3 for the three months ended September 30, 2019 to 59.9 for the three months ended September 30, 2020 as we increased our full time equivalents of medical science liaisons by 5.0 in anticipation of the potential US launch of remestemcel-L for the treatment of pediatric SR-aGVHD. There was also an increase of $0.6 million in consulting expenses and $2.5 million in share-based payment expenses for the three months ended September 30, 2020 compared with the three months ended September 30, 2019. These increases were offset by a decrease of $0.2 million in travel expenses and $0.2 million in recruitment expenses in the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

The $1.0 million increase in product support costs for personnel in pre-commercial functions is primarily due to an increase of $0.7 million across salaries and associated costs as full time equivalents increased by 10.8 (1080%) from 1.0 for the three months ended September 30, 2019 to 11.8 for the three months ended September 30, 2020 as we prepare for the potential launch of remestemcel-L for the treatment of pediatric SR-aGVHD in the United States. There was also an increase of $0.1 million and $0.2 million in recruitment and share-based payment expenses, respectively, for the three months ended September 30, 2020 compared with the three months ended September 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 costs of renewing our granted patents. These costs have remained relatively consistent for the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

Manufacturing commercialization

Manufacturing commercialization expenses were $11.9 million for the three months ended September 30, 2020, compared with $2.7 million for the three months ended September 30, 2019, an increase of $9.2 million. This increase primarily reflects an increase in platform technology costs.

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Manufacturing commercialization:				
Platform technology	11,384	2,285	9,099	NM
Manufacturing support costs	540	413	127	31%
Manufacturing commercialization	**$ 11,924**	**$ 2,698**	**9,226**	**NM**

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 $9.1 million for the three months ended September 30, 2020 compared with three months ended September 30, 2019. The increase was primarily due to increased spend for stock build in preparation for the potential launch of remestemcel-L and MSC process development activities.

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 three months ended September 30, 2020 compared with the three months ended September 30, 2019 due to an increase in share-based payment expenses.

Management and administration

Management and administration expenses were $7.7 million for the three months ended September 30, 2020, compared with $5.5 million for the three months ended September 30, 2019, an increase of $2.2 million. This increase was primarily due to an increase in labor and associated expenses.

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Management and administration:				
Labor and associated expenses	4,009	2,111	1,898	90%
Corporate overheads	2,675	1,995	680	34%
Legal and professional fees	996	1,357	(361)	(27%)
Management and administration	**$ 7,680**	**$ 5,463**	**2,217**	**41%**

Labor and associated expenses increased by $1.9 million from $2.1 million for the three months ended September 30, 2019 to $4.0 million for the three months ended September 30, 2020. This $1.9 million increase in the three months ended September 30, 2020 is primarily due to an increase of $1.2 million in share-based payment expenses. There was also an increase of $0.7 million in overall costs of salaries and associated expenses primarily due to a one-off adjustment in short-term incentives in the three months ended September 30, 2019, compared with the three months ended September 30, 2020. These increases were offset by a decrease of $0.1 million in consulting expenses. Labor and associated expenses also experienced unfavorable exchange rate fluctuations of $0.1 million in the three months ended September 30, 2020 compared with the three months ended September 30, 2019, as the A$ strengthened 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 $0.7 million from $2.0 million for the three months ended September 30, 2019 to $2.7 million for the three months ended September 30, 2020 primarily due to an increase in insurance, depreciation and sponsorship expenses.

Legal and professional fees decreased by $0.4 million from $1.4 million for the three months ended September 30, 2020 to $1.0 million for the three months ended September 30, 2019 primarily due to increased legal and professional fees incurred during the three months ended September 30, 2019 associated with establishing 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.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $15.1 million gain for the three months ended September 30, 2020 compared with a $0.3 million loss the three months ended September 30, 2019. The $15.1 million gain for the three months ended September 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 changing the key assumptions of the contingent consideration valuation primarily as a result of receiving the Complete Response Letter from the FDA on the BLA for remestemcel-L for the treatment of pediatric SR-aGVHD on September 30, 2020. The assumptions of probability of success and development timeline have been updated to reflect current expectations as a result of the Complete Response Letter and our request to the FDA for accelerated approval of the BLA for remestemcel-L for pediatric SR-aGVHD.

The $0.3 million loss for the three months ended September 30, 2019 was due to 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 product pricing, development timelines, market penetration 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 income of $2.0 million for the three months ended September 30, 2020, compared with an expense of $0.2 million for the three months ended September 30, 2019, an increase in income of $2.2 million. The following table shows movements within other operating income and expenses for the three months ended September 30, 2020 and 2019, together with the changes in those items:

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Other operating income and expenses:				
Remeasurement of borrowing arrangements	(1,919)	401	(2,320)	NM
Foreign exchange losses/(gains) (net)	(82)	(232)	150	(65%)
Government grant revenue	(17)	—	(17)	NM
Other operating income and expenses	**$ (2,018)**	**$ 169**	**(2,187)**	**NM**

In the three months ended September 30, 2020, we recognized a $1.9 million gain for remeasurement of borrowing arrangements 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 in relation to our existing credit facility with NovaQuest.

In the three months ended September 30, 2019, we recognized a $0.4 million loss for remeasurement of borrowing arrangements 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 three months ended September 30, 2019, we recognized a foreign exchange gain of $0.2 million. In the three months ended September 30, 2020, we recognized a foreign exchange gain of $0.1 million, primarily due to movements in exchange rates on US$ unearned revenue balances held in Mesoblast Limited as the A$ depreciated against the US$ during the period the US$ unearned revenue balances were held.

Finance costs

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Finance costs:				
Remeasurement of borrowing arrangements	896	(120)	1,016	NM
Interest expense	3,926	3,577	349	10%
Finance costs	**$ 4,822**	**$ 3,457**	**1,365**	**39%**

In the three months ended September 30, 2020, we recognized a $0.9 million loss for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facilities with Hercules and NovaQuest, a decrease of $1.0 million as compared with a $0.1 million gain for the three months ended September 30, 2019.

Interest expenses increased by $0.3 million from $3.6 million for the three months ended September 30, 2019 to $3.9 million for the three months ended September 30, 2020.

In the three months ended September 30, 2019 and 2020, we recognized $2.0 million of interest expenses in relation to our loan and security agreement with Hercules. Within this $2.0 million recognized in the three months ended September 30, 2020, $1.2 million was recognized with regard to interest expense payable on the loan balance within the year and a further $0.8 million of interest expense was recognized with regard to the amortization of transaction costs incurred on the outstanding loan principal for the three months ended September 30, 2020 using the effective interest rate method over the period of initial recognition through maturity.

In the three months ended September 30, 2020, we recognized $1.8 million of interest expenses in relation to our loan and security agreement with NovaQuest, an increase of $0.3 million as compared with $1.5 million for the three months ended September 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 remestemcel-L for the treatment of pediatric patients with SR-aGVHD in the United States and other geographies excluding Asia ("pediatric SR-aGVHD").

In the three months ended September 30, 2019 and 2020, in line with IFRS 16 *Leases*, we also recognized interest expenses of $0.1 million in relation to lease charges, respectively.

Loss after income tax

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Loss before income tax	(25,274)	(7,416)	(17,858)	NM
Income tax benefit	730	1,932	(1,202)	(62%)
Loss after income tax	**$ (24,544)**	**$ (5,484)**	**(19,060)**	**NM**

Loss before income tax was $25.3 million for the three months ended September 30, 2020 compared with $7.4 million for the three months ended September 30, 2019, an increase in the loss by $17.9 million. This increase is the net effect of the changes in revenues and expenses which have been fully discussed above.

A non-cash income tax benefit of $0.7 million was recognized in the three months ended September 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 $1.9 million was recognized in the three months ended September 30, 2019 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

Liquidity and Capital Resources

Sources of liquidity

We have incurred losses from operations since our inception in 2004 and as of September 30, 2020, we had an accumulated deficit of $573.3 million. We had cash and cash equivalents of $108.1 million as of September 30, 2020 and incurred net cash outflows from operations of $28.2 million for the three months ended September 30, 2020. On November 20, 2020 we entered into a license and collaboration agreement with Novartis Pharma AG ("Novartis"). We will receive $50.0 million in proceeds consisting of an upfront payment of $25.0 million and $25.0 million through the placement of new fully-paid Mesoblast ordinary shares on closing of the license agreement. Closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvement Act and certain other conditions.

We have an overarching strategy to fund operations predominately through non-dilutive strategic and commercial transactions. We intend to fund operations through drawing on up to $170.0 million in additional funds from existing strategic and financing partnerships, subject to certain conditions, or 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. In addition, we expect to achieve cash inflows through sales of remestemcel-L for the treatment of

pediatric SR-aGVHD, subject to receiving accelerated approval from the United States Food and Drug Administration ("FDA") on its Biologics License Application ("BLA") for remestemcel-L for the treatment of pediatric SR-aGVHD.

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.

Cash flows

(in U.S. dollars, in thousands)	Three months ended September 30, 2020	2019	$ Change	% Change
Cash Flow Data:				
Net cash (outflows) in operating activities	(28,167)	(15,558)	(12,609)	81%
Net cash (outflows) in investing activities	(81)	(253)	172	(68%)
Net cash inflows/(outflows) by financing activities	6,542	(36)	6,578	NM
Net increase in cash and cash equivalents	**(21,706)**	**(15,847)**	**(5,859)**	**37%**

Net cash outflows in operating activities

Net cash outflows for operating activities were $28.2 million for the three months ended September 30, 2020, compared with $15.6 million for the three months ended September 30, 2019, an increase of $12.6 million. The increase of $12.6 million is due to an increase in cash outflows of $9.9 million and a decrease in cash inflows of $2.7 million in the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

The $2.7 million decrease of inflows comprised: receipts for the research and development tax incentive decreased by $1.5 million in the three months ended September 30, 2020 compared with the three months ended September 30, 2019; inflows from royalty income earned on sales of TEMCELL in Japan decreased by $1.0 million during the three months ended September 30, 2020, compared with the three months ended September 30, 2019; and inflows from interest receipts reduced by $0.2 million in the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

Outflows for payments to suppliers and employees and interest and other costs of finance paid increased by $9.9 million from $18.9 million for the three months ended September 30, 2019 to $28.8 million for the three months ended September 30, 2020 primarily due to an increase in payments in relation to product manufacturing and operating costs, manufacturing commercialization and research and development costs.

Net cash outflows in investing activities

Net cash outflows for investing activities decreased by $0.2 million in the three months ended September 30, 2020, compared with the three months ended September 30, 2019 due to a decrease in payments for fixed assets, such as plant and equipment and intellectual property, in the three months ended September 30, 2020 when compared with the three months ended September 30, 2019.

Net cash inflows in financing activities

Net cash inflows for financing activities increased by $6.5 million for the three months ended September 30, 2020, compared with the three months ended September 30, 2019. We received $6.7 million in receipts from employee share option exercises during the three months ended September 30, 2020, compared to $0.3 million for the three months ended September 30, 2019. In the three months ended September 30, 2020, we received receipts of $1.4 million for shares issued through the exercise of incentive rights in connection with our existing Kentgrove Capital equity facility agreement. These receipts were offset by a $0.7 million payment for lease liabilities during the three months ended September 30, 2020, compared to $0.3 million for the three months ended September 30, 2019. Additionally, there were $0.9 million and $Nil of payments for associated capital raising costs in the three months ended September 30, 2020 and 2019, respectively.

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.

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 September 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)	(39,097)	(34,496)	(53,051)	(12,011)	(138,655)
Trade payables	(27,602)	—	—	—	(27,602)
Lease liabilities(3)	(3,573)	(3,034)	(4,173)	(614)	(11,394)
Purchase commitments(3)	(18,359)	(7,213)	(15,562)	—	(41,134)
	(88,631)	**(44,743)**	**(72,786)**	**(12,625)**	**(218,785)**

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

(3) In December 2019, we commenced production under our manufacturing service agreement with Lonza for the supply of commercial product for the potential approval and launch of remestemcel-L for the treatment of pediatric SR-aGVHD and/or for the treatment of COVID-19 ARDS in the US market. This agreement contains lease and non-lease components with a non-cancellable term of 4.5 years through June 2024. As of September 30, 2020, the agreement contains a minimum remaining financial commitment of $46.4 million. We have accounted for the lease component within the agreement as a lease liability separately from the non-lease components. As of September 30, 2020, the minimum financial commitment of the lease and non-lease components are $5.3 million and $41.1 million, respectively, disclosed within the contractual obligations as lease liabilities

and purchase commitments on an undiscounted basis, respectively. At our discretion, the minimum financial commitment under this manufacturing services agreement can be reduced by $24.8 million, with $3.6 million of this reduction relating to the lease component and $21.2 million relating to the non-lease component of the agreement.

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

Lease and sub-lease commitments

We lease various offices under non-cancellable leases expiring within 1 to 6 years. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated. We 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 remestemcel-L for the treatment of pediatric SR-aGVHD and/or the treatment of COVID-19 ARDS in the US market expiring within 5 years.

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 September 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 September 30, 2020.

Off-Balance Sheet Arrangements

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

Certain Differences Between IFRS and GAAP

IFRS differs from GAAP in certain respects. Management has not assessed the materiality of differences between IFRS and GAAP. Our significant accounting policies are described in Note 22 to our consolidated financial statements and the related notes thereto included in our Form 20-F.

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.

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 three months ended September 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.

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.

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 remestemcel-L for the treatment of SR-aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of remestemcel-L 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

Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by IFRS 15 *Revenue from Contracts with Customers*.

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.

Revenues from contracts with customers comprise commercialization and milestone revenue. We also have revenue from 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 September 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 is still considered deferred consideration as of September 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 three months ended September 30, 2020.

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 in revenue in February 2020 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.

No milestone revenue was recognized in relation this strategic alliance with Tasly in the three months ended September 30 2020 and 2019.

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 three months ended September 30, 2020, we recognized $1.2 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $1.9 million for the three months ended September 30, 2019. These amounts were recorded in revenue as there are no further performance obligations required in relation to these items.

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. 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 September 30, 2020 and September 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. There was no impairment charge recognized during the three months ended September 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 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.

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. During the three months ended September 30, 2020, an indicator of impairment was identified for our MSC products intangible asset as a result of the Complete Response Letter received from the FDA on the BLA for remestemcel-L for pediatric SR-aGVHD. An impairment test for our MSC products was carried out as at September 30, 2020. No impairment charges were recorded as the recoverable amount exceeded the carrying value of the asset.

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 the impairment testing on MSC products completed in September 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 labor, other direct costs and related production overheads) and net realizable value. Pre-launch inventory is held as an asset when there is a high probability of regulatory approval for the product in accordance with IAS 2 *Inventories*. Before that point, a provision is made against the carrying value to its recoverable amount in accordance with IAS 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 September 30, 2020 and June 30, 2020, there was $14.6 million and $8.8 million of pre-launch inventory recognized on the balance sheet that was fully provided for, respectively.

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 September 30, 2020 and June 30, 2020, 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 September 30, 2020 and June 30, 2020.

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 September 30, 2020 and June 30, 2020. 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 September 30, 2020	Fair value as of June 30, 2020	Valuation technique	Unobservable inputs(1)	Range of inputs (weighted average) Three Months Ended September 30, 2020	Range of inputs (weighted average) Year Ended June 30, 2020	Relationship of unobservable inputs to fair value
Contingent consideration provision	29,875	45,166	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.5%. Year ended June 30, 2020: A change in the discount rate by 0.5% would increase/decrease the fair value by 0.4%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2020: A change in the price assumptions by 10% would increase/decrease the fair value by 2%. Year ended June 30, 2020: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 3%.
				Expected sales volumes	n/a	n/a	Three months ended September 30, 2020: A change in the volume assumptions by 10% would increase/decrease the fair value by 2%. Year ended June 30, 2020: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 3%.
				Probability of success	Various	Various	Three months ended September 30, 2020: A change in the probability of success assumptions by 10% and 20% would increase/decrease the fair value by 8.6% and 17.2%, respectively. Year ended June 30, 2020: A 10% and 20% increase in the probability of success assumptions would increase the fair value by 9% and 12.9%, respectively, and a 10% and 20% decrease in the probability of success assumptions would decrease the fair value by 9% and 18%, respectively.

(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.

Hercules arrangement

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.

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. 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 September 30, 2020 in line with the amended terms of the loan agreement. As at September 30, 2020, we recognized $3.8 million in interest payable within twelve months as a current liability.

In the three months ended September 30, 2020, we recognized a loss of $0.1 million in the Income Statement as remeasurement of borrowing arrangements within finance costs. This remeasurement loss relates to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility.

There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2019.

NovaQuest arrangement

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 remestemcel-L 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 remestemcel-L for pediatric SR-aGVHD are significantly higher than current forecasts.

If there are no net sales of remestemcel-L for pediatric SR-aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of remestemcel-L 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 remestemcel-L for pediatric SR-aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of remestemcel-L 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.

In the three months ended September 30, 2020, we recognized a gain of $1.9 million in the Income Statement as remeasurement of borrowing arrangements within other operating income in relation to the changes in our estimated net sales of remestemcel-L for pediatric SR-aGVHD as a net result of changes to the key assumptions in development timelines. In the three months ended

September 30, 2019, we recognized a $0.4 million loss in the Income Statement as remeasurement of borrowing arrangements within other operating income in relation to changes in our estimated net sales of remestemcel-L for pediatric SR-aGVHD as a net result of changes to the key assumptions in development timelines and market penetration.

In the three months ended September 30, 2020 and 2019, we recognized a loss of $0.8 million and a gain of $0.1 million, respectively, in the Income Statement as remeasurement of borrowing arrangements within finance costs in relation to the revision in the estimated future cash flows.

These remeasurement gains and losses 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.

As at September 30, 2020, we recognized a current liability of $4.2 million which represents the present value of interest payable of $3.9 million and $0.3 million loan administration fee which is payable annually in June.

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

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.

Events subsequent to balance date

On November 17, 2020, a Type A meeting was held with the FDA to discuss the review of the BLA for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until we receive the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, we will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

On November 20, 2020, we entered into a worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of remestemcel-L, with an initial focus on the development of the treatment of ARDS, including that associated with COVID-19. We will retain full rights and economics for remestemcel-L for graft versus host disease, and Novartis has an option to, if exercised, become the commercial distributor outside of Japan. We will receive $50.0 million in proceeds consisting of an upfront payment of $25.0 million and $25.0 million through the placement of new fully-paid Mesoblast ordinary shares on closing of the license agreement. Closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvement Act and certain other conditions. We may receive a total of $505.0 million pending achievement of pre-commercialization milestones for ARDS indications. We may receive additional payments post-commercialization of up to $750.0 million based on achieving certain sales milestones and tiered double-digit royalties on product sales. We have not yet assessed the accounting impact of this agreement.

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

Rounding of amounts

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

Directors' resolution

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

RISK FACTORS

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

Risks Related to Our Financial Position and Capital Requirements

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

We are a clinical-stage biotechnology company 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 three months ended September 30, 2020 was $24.5 million. As of September 30, 2020, we have an accumulated deficit of $573.3 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 September 30, 2020, our cash and cash equivalents were $108.1 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 non-dilutive strategic and commercial transactions. We intend to fund operations through drawing on additional funds from existing strategic and financing partnerships, subject to certain conditions, or 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. In addition, we expect to achieve cash inflows through sales of remestemcel-L, subject to receiving accelerated approval from the FDA on its Biologics License Application ("BLA") for remestemcel-L for the treatment of pediatric SR-aGVHD.

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 remestemcel-L 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 79% of our cash and cash equivalents as of September 30, 2020 were denominated in U.S. dollars and 21% 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 remestemcel-L, 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 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, remestemcel-L, 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, remestemcel-L 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. On September 30, 2020, the FDA issued a Complete Response Letter to our BLA for remestemcel-L for the treatment of pediatric SR-aGVHD.

We have received Fast Track designation from the FDA for remestemcel-L in pediatrics with SR-aGVHD. 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. 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.

In August 2020, the Oncologic Drugs Advisory Committee (“ODAC”) of the FDA voted in favor that available data from a single-arm Phase 3 trial and evidence from additional studies support the efficacy of remestemcel-L in pediatric patients with SR-aGVHD. Although the FDA considers 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.

Remestemcel-L had been accepted for Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (“PDUFA”). On September 30, 2020, the FDA issued a Complete Response Letter to our BLA for remestemcel-L for the treatment of pediatric SR-aGVHD. Despite the overwhelming ODAC vote, the FDA recommended that we conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for SR-aGVHD.

On November 17, 2020, a Type A meeting was held with the FDA to discuss the review of the BLA for remestemcel-L and a potential pathway for accelerated approval with a post-approval requirement to conduct an additional randomized controlled study in patients 12 years and older. At the current time it appears that the FDA review team will not agree to accelerated approval. However, the definitive outcome of the Type A meeting will not be known until we receive the formal minutes which are expected within 30 days of the meeting. If the current review team does not agree to accelerated approval, we will request a further Type A meeting to initiate the well-established FDA dispute resolution pathway.

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 remestemcel-L for the treatment of pediatric SR-aGVHD, 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.

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 remestemcel-L 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 remestemcel-L

The FDA has accepted for Priority Review our BLA for remestemcel-L for the treatment of pediatric SR-aGVHD. 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 remestemcel-L 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 remestemcel-L's continued safety, purity and potency. In this case, the BLA review process for remestemcel-L could be negatively affected.

The ability of FDA inspectors to visit the site to conduct GMP inspections has been 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 remestemcel-L, 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 remestemcel-L. We currently also manufacture our other product candidates with Lonza Singapore.

Due to the COVID-19 pandemic, countries in which Mesoblast has operations, including Singapore - where our contract manufacturer is located, have implemented some level of quarantine "stay at home" orders, and other restrictions in order to contain spread of the virus. Continued restrictions on the movement of people and products may adversely affect our and our contract manufacturer's ability to operate efficiently. In addition, 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 remestemcel-L 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 September 30, 2020, our cumulative operating losses have a total potential tax benefit of $137.5 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. Such volatility may lead to securities litigation.

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

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

- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our 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. In October 2020, in light of the Complete Response Letter released by the FDA and the decline in the market price of our ADS, a purported class action lawsuit was filed in the U.S. Federal District Court for the Southern District of New York on behalf of purchasers or acquirers of our ADSs against our Company, our Chief Executive Officer and our Chief Financial Officer for alleged violations of the U.S. Securities Exchange Act of 1934. We cannot provide any assurance as to the possible outcome or cost to us from the lawsuit, particularly as it is at an early stage, nor how long it may take to resolve lawsuit.

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 three months ended September 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.

Signatures

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

Mesoblast Limited

Date: November 20, 2020

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