
**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 2019 for the period ended September 30, 2019

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

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**QUARTERLY REPORT ON FORM 6-K
FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2019**

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 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,	
		2019	2018
Revenue	3	17,048	11,637
Research & development		(12,389)	(18,489)
Manufacturing commercialization		(2,698)	(4,317)
Management and administration		(5,463)	(5,614)
Fair value remeasurement of contingent consideration	3	(288)	(622)
Other operating income and expenses	3	(169)	(151)
Finance costs	3	(3,457)	(2,653)
Loss before income tax	3	(7,416)	(20,209)
Income tax benefit	4	1,932	711
Loss attributable to the owners of Mesoblast Limited		(5,484)	(19,498)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:			
		Cents	Cents
Basic - losses per share	10	(1.10)	(4.07)
Diluted - losses per share	10	(1.10)	(4.07)

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,	
		2019	2018
Loss for the period		(5,484)	(19,498)
Other comprehensive (loss)/income			
<i>Items that may be reclassified to profit and loss</i>			
Financial assets at fair value through other comprehensive income		(365)	87
Exchange differences on translation of foreign operations		(332)	(23)
Other comprehensive income/(loss) for the period, net of tax		(697)	64
Total comprehensive losses attributable to the owners of Mesoblast Limited		(6,181)	(19,434)

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	Total
Balance as of July 1, 2018		889,481	75,974	21	(39,276)	(380,192)	546,008
Profit/(loss) for the period		—	—	—	—	(19,498)	(19,498)
Other comprehensive income/(loss)		—	—	87	(23)	—	64
Total comprehensive profit/(loss) for the period		—	—	87	(23)	(19,498)	(19,434)
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		212	—	—	—	—	212
	8	212	—	—	—	—	212
Transfer of exercised options		287	(287)	—	—	—	—
Fair value of share-based payments		—	814	—	—	—	814
Reclassification of modified options to/(from) liability		—	(1)	—	—	—	(1)
		287	526	—	—	—	813
Balance as of September 30, 2018	8	889,980	76,500	108	(39,299)	(399,690)	527,599
Balance as of June 30, 2019		910,405	80,034	17	(39,413)	(469,991)	481,052
Adjustment on adoption of IFRS 16 (net of tax)		—	—	—	—	(827)	(827)
Restated balance as of July 1, 2019		910,405	80,034	17	(39,413)	(470,818)	480,225
Profit/(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
	8	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

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

Consolidated Balance Sheet
(unaudited)

(in U.S. dollars, in thousands)	Note	As of September 30, 2019	As of June 30, 2019
Assets			
Current Assets			
Cash & cash equivalents	5(a)	34,536	50,426
Trade & other receivables	5(b)	17,857	4,060
Prepayments	5(b)	8,200	8,036
Total Current Assets		60,593	62,522
Non-Current Assets			
Property, plant and equipment		978	826
Right-of-use assets		4,233	—
Financial assets at fair value through other comprehensive income		1,952	2,317
Other non-current assets		3,299	3,324
Intangible assets	6(a)	582,731	583,126
Total Non-Current Assets		593,193	589,593
Total Assets		653,786	652,115
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	12,740	13,060
Provisions		26,977	7,264
Borrowings	5(d)	18,851	14,007
Lease liabilities	5(f)	1,524	—
Deferred consideration	6(c)	10,000	10,000
Total Current Liabilities		70,092	44,331
Non-Current Liabilities			
Deferred tax liability	6(b)	9,195	11,124
Provisions		30,555	48,329
Borrowings	5(d)	64,881	67,279
Lease liabilities	5(f)	3,916	—
Total Non-Current Liabilities		108,547	126,732
Total Liabilities		178,639	171,063
Net Assets		475,147	481,052
Equity			
Issued Capital	8	910,942	910,405
Reserves		40,507	40,638
(Accumulated losses)/retained earnings		(476,302)	(469,991)
Total Equity		475,147	481,052

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,	
		2019	2018
Cash flows from operating activities			
Commercialization revenue received		1,739	1,095
Milestone payment received		—	500
Research and development tax incentive received		1,499	1,654
Payments to suppliers and employees (inclusive of goods and services tax)		(17,539)	(22,039)
Interest received		173	136
Interest and other costs of finance paid		(1,427)	(887)
Income taxes (paid)/refunded		(3)	(3)
Net cash (outflows) in operating activities	7(b)	(15,558)	(19,544)
Cash flows from investing activities			
Investment in fixed assets		(153)	(39)
Payments for licenses		(100)	—
Net cash (outflows)/inflows in investing activities		(253)	(39)
Cash flows from financing activities			
Proceeds from borrowings		—	28,950
Payments of transaction costs from borrowings		—	(1,534)
Proceeds from issue of shares		299	10,048
Payments for share issue costs		—	(358)
Payment of lease liabilities		(335)	—
Net cash inflows by financing activities		(36)	37,106
Net increase/(decrease) in cash and cash equivalents		(15,847)	17,523
Cash and cash equivalents at beginning of period		50,426	37,763
FX (losses)/gains on the translation of foreign bank accounts		(43)	(143)
Cash and cash equivalents at end of period	7(a)	34,536	55,143

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, 2019.

(i) Going concern

For the three months ended September 30, 2019, the Group incurred a total comprehensive loss after income tax of \$6.2 million and had net cash outflows from operations of \$15.6 million. As of September 30, 2019, the Group held total cash and cash equivalents of \$34.5 million. As of September 30, 2019, the Group recognized funds receivable from revenues of \$15.0 million pursuant to a strategic partnership with Grünenthal GmbH (“Grünenthal”), on October 1, 2019 the proceeds of which were received and recognized in cash and cash equivalents. On October 3, 2019 the Group raised gross proceeds of A\$75.0 million (US\$50.5 million) through the placement of 37.5 million new fully-paid Mesoblast ordinary shares.

Additionally, over the next 12 months the Group may receive up to an additional \$30.0 million in milestone payments under the strategic partnership with Grünenthal and a further \$35.0 million under the agreements with Hercules Capital, Inc. (“Hercules”) and NovaQuest Capital Management, L.L.C. (“NovaQuest”).

There is uncertainty related to the Group’s ability to access payments from the strategic partnership with Grünenthal or to draw down funds from Hercules and NovaQuest. The ability of the Group to continue as a going concern and meet its debts and commitments as they fall due are dependent upon meeting the milestones under our Grünenthal and NovaQuest agreements, and drawing on remaining funds under our Hercules agreement, or entering into additional strategic partnerships for our product candidates, or equity-based financings.

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 the Group’s ability to continue as a going concern and that it may be unable to realize its assets and 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 standards.

(ii) New and amended standards adopted by the Group

Leases

The Group adopted IFRS 16 *Leases* on July 1, 2019. Our principal accounting policy from July 1, 2019, are that leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. For principal accounting policies relating to the comparative year, refer to our annual report on Form 20-F for the year ended June 30, 2019. In accordance with the transition provisions in IFRS 16 the new rules have been adopted retrospectively with the cumulative effect of initially applying the new standard recognized on July 1, 2019. Comparatives have not been restated as permitted under the specific transition provisions in the standard.

On adoption of IFRS16, the Group recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 *Leases*. These liabilities were measured at the present value of the remaining lease payments, discounted using the incremental borrowing rate as of July 1, 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on July 1, 2019 was 6.52%. A reconciliation between the operating lease commitments disclosed applying IAS 17 at June 30, 2019 and the lease liabilities recognized at July 1, 2019 is described in Note 13.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- Fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payment that are based on an index or a rate
- amounts expected to be payable by the lessee under residual value guarantees
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the interest rate implicit in the lease, if that rate can be determined, or the Group's incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date, less any lease incentives received
- any initial direct costs, and
- restoration costs.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT-equipment and small items of office furniture.

In the opinion of management, the interim financial data includes all adjustments, consisting only of normal recurring adjustments, necessary to a fair statement of the results for the interim periods. Other than the new and amended standards adopted by the Group above these interim financial statements follow the same accounting policies as compared to the June 30, 2019 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, 2019 reporting period.

2. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was affected by the following events during the three months ended September 30, 2019:

- On September 10, 2019, the Group announced that it had entered into a strategic partnership with Grünenthal, to develop and commercialize MPC-06-ID, a Phase 3 allogeneic product candidate for the treatment of chronic low back pain due to degenerative disc disease. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. The Group has recognized revenue and a trade receivable of \$15.0 million in the current reporting period.

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Three Months Ended September 30,	
		2019	2018
Revenue			
Commercialization Revenue		1,872	1,006
Milestone Revenue		15,000	10,500
Interest Revenue		176	131
Total Revenue		17,048	11,637
Clinical trial and research & development			
		(6,057)	(13,374)
Manufacturing production & development			
		(1,295)	(3,650)
Employee benefits			
Salaries and employee benefits		(4,731)	(4,926)
Defined contribution superannuation expenses		(75)	(90)
Equity settled share-based payment transactions ⁽¹⁾		(804)	(818)
Total Employee benefits		(5,610)	(5,834)
Depreciation and amortization of non-current assets			
Plant and equipment depreciation		(455)	(160)
Intellectual property amortization		(394)	(394)
Total Depreciation and amortization of non-current assets		(849)	(554)
Other Management & administration expenses			
Overheads & administration		(1,774)	(1,995)
Consultancy		(1,145)	(849)
Legal, patent and other professional fees		(3,226)	(1,573)
Intellectual property expenses (excluding the amount amortized above)		(594)	(591)
Total Other Management & administration expenses		(6,739)	(5,008)
Fair value remeasurement of contingent consideration			
Remeasurement of contingent consideration	5(e)(iii)	(288)	(622)
Total Fair value remeasurement of contingent consideration		(288)	(622)
Other operating income and expenses			
Remeasurement of borrowing arrangements		(401)	—
Foreign exchange gains/(losses)		232	(151)
Total Other operating income and expenses		(169)	(151)
Finance (costs)/gains			
Remeasurement of borrowing arrangements		120	—
Interest expense		(3,577)	(2,653)
Total Finance costs		(3,457)	(2,653)
Total loss before income tax		(7,416)	(20,209)

(1) Share-based payment transactions

For the three months ended September 30, 2019 and 2018, the share-based payment transactions have been reflected in the Consolidated Income Statement functional expense categories as follows:

(in U.S. dollars)	Three Months Ended September 30,	
	2019	2018
Research and development	319,681	527,855
Manufacturing and commercialization	53,579	64,607
Management and administration	430,538	225,096
Equity settled share-based payment transactions	803,798	817,558

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 is entitled to receive a non-refundable upfront payment of \$15.0 million on signing of the contract with Grünenthal, and this payment was received on October 1, 2019. The Group is eligible to receive up to \$150.0 million in upfront, clinical, manufacturing, regulatory and reimbursement approval related milestone payments 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.

The Group evaluated the constraint over variable consideration and determined only the upfront payment of \$15.0 million can be included in the transaction price as at September 30, 2019. All of the milestone payments were considered constrained as at September 30, 2019. 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.

Upon signing of this strategic partnership on September 9, 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. In future periods, 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 comparative period, being the three months ended September 30, 2018, 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 on September 14, 2018, the Group recognized \$10.0 million in milestone revenue from the \$20.0 million up-front technology access fee received from Tasly in October 2018 as this is the portion of revenue that control has been transferred to Tasly. The Group recognized the remaining \$10.0 million from the \$20.0 million up-front payment as deferred consideration on the consolidated balance sheet. The deferred consideration amount will be recognized in revenue when and if control transfers 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, 2019, no milestone 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, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the license agreement, the Group received \$5.9 million (€5.0 million) as a non-refundable up-front payment and recognized this amount in revenue in December 2017 upon receipt. In December 2018, the Group received a milestone payment of €5.0 million, the Group recognized revenue of €5.0 million (\$5.9 million) pertaining to this milestone in December 2017 as all performance obligations had been satisfied at that time. 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®.

No milestone revenue was recognized in relation to the patent license agreement with Takeda in the three months ended September 30, 2019 and 2018.

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. In October 2018, the Group expanded its partnership with JCR in Japan for wound healing in patients with Epidermolysis Bullosa (“EB”). The Group will receive royalties on TEMCELL® Hs. Inj. (“TEMCELL”), a registered trademark of JCR product sales for EB. The Group applies the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognizes royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the three months ended September 30, 2019, the Group recognized \$1.9 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with \$1.0 million for the three months ended September 30, 2018. 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 and 2018, the Group recognized \$Nil and \$0.5 million respectively, in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan. This amount was recorded in revenue as there are no further performance obligations required in regards to these items.

4. Income tax benefit/(expense)

(in U.S. dollars, in thousands)	Three Months Ended September 30,	
	2019	2018
(a) Income tax expense		
Current tax		
Current tax	—	—
Total current tax expense	<u>—</u>	<u>—</u>
Deferred tax		
(Increase)/decrease in deferred tax assets	(2,029)	(686)
(Decrease)/increase in deferred tax liabilities	97	(25)
Total deferred tax expense/(benefit)	<u>(1,932)</u>	<u>(711)</u>
Income tax expense/(benefit)	<u>(1,932)</u>	<u>(711)</u>

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, 2019	As of June 30, 2019
(b) Deferred tax assets not brought to account		
Unused tax losses		
Potential tax benefit at local tax rates	47,545	51,807
Other temporary differences		
Potential tax benefit at local tax rates	3,510	3,130
Other tax credits		
Potential tax benefit at local tax rates	3,220	3,220
	<u>54,275</u>	<u>58,157</u>

As of September 30, 2019 and June 30, 2019, the Group has deferred tax assets not brought to account of \$54.3 million and \$58.2 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, 2019					
Cash & cash equivalents	5(a)	—	—	34,536	34,536
Trade & other receivables	5(b)	—	—	17,857	17,857
Financial assets at fair value through other comprehensive income	5(e)	1,952	—	—	1,952
Other non-current assets		—	—	3,299	3,299
		<u>1,952</u>	<u>—</u>	<u>55,692</u>	<u>57,644</u>
As of June 30, 2019					
Cash & cash equivalents	5(a)	—	—	50,426	50,426
Trade & other receivables	5(b)	—	—	4,060	4,060
Financial assets at fair value through other comprehensive income	5(e)	2,317	—	—	2,317
Other non-current assets		—	—	3,324	3,324
		<u>2,317</u>	<u>—</u>	<u>57,810</u>	<u>60,127</u>

(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, 2019					
Trade and other payables	5(c)	—	—	12,740	12,740
Borrowings	5(d)	—	—	83,732	83,732
Lease liabilities	5(f)	—	—	5,440	5,440
Contingent considerations	5(e)(iii)	—	47,528	—	47,528
		<u>—</u>	<u>47,528</u>	<u>101,912</u>	<u>149,440</u>
As of June 30, 2019					
Trade and other payables	5(c)	—	—	13,060	13,060
Borrowings	5(d)	—	—	81,286	81,286
Contingent considerations	5(e)(iii)	—	47,534	—	47,534
		<u>—</u>	<u>47,534</u>	<u>94,346</u>	<u>141,880</u>

(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.

a. Cash and cash equivalents

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Cash at bank	34,131	50,005
Deposits at call ⁽¹⁾	405	421
	<u>34,536</u>	<u>50,426</u>

(1) As of September 30, 2019 and June 30, 2019, interest-bearing deposits at call include amounts of \$0.4 million and \$0.4 million, respectively, held as security and restricted for use.

(i) Classification as cash equivalents

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

b. Trade and other receivables and prepayments

(i) Trade receivables

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Trade debtors	1,872	1,739
Funds receivable from Development and Commercialization Agreement ⁽¹⁾	15,000	—
Income tax and tax incentives recoverable ⁽²⁾	—	1,511
Foreign withholding tax recoverable	471	471
Security deposit	250	250
Sundry debtors	45	2
Other recoverable taxes (Goods and services tax and value-added tax)	215	86
Interest receivables	4	1
Trade and other receivables	<u>17,857</u>	<u>4,060</u>

- (1) On September 9, 2019, the Group entered into a strategic partnership with Grünenthal, to develop and commercialize its allogeneic product candidate MPC-06-ID for the treatment of chronic low back pain due to degenerative disc disease. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. The contractual terms of the agreement pertaining to the receipt of funds that became payable on signing, were binding and therefore the Group recognized a receivable of \$15.0 million at September 30, 2019. On October 1, 2019 the net proceeds of \$15.0 million were received and recognized in cash and cash equivalents.
- (2) The Group's research and development activities are not eligible for the refundable tax offset, under an Australian Government tax incentive as a result of the Group earning revenues in excess of A\$20.0 million. For the three months ended September 30, 2019, the Group has recognized \$Nil income. The \$1.5 million recognized as a receivable at June 30, 2019, related to the July 1, 2017 to June 30, 2018 financial period, and was received in July 2019.

(ii) *Prepayments*

<i>(in U.S. dollars, in thousands)</i>	As of September 30, 2019	As of June 30, 2019
Clinical trial research and development expenditure	6,516	6,042
Prepaid insurance and subscriptions	432	1,095
Other	1,252	899
Prepayments	8,200	8,036

(iii) *Classification as trade and other receivables*

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 30 to 60 days and therefore are all classified as current. Trade receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. The group holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method. Interest receivables are amounts due at maturity of term deposits. Income tax and tax incentives recoverable relates to the Group's claim for the Australian Government tax incentive.

(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.

c. Trade and other payables

<i>(in U.S. dollars, in thousands)</i>	As of September 30, 2019	As of June 30, 2019
Trade payables and other payables	12,740	13,060
Trade and other payables	12,740	13,060

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

d. Borrowings

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Current		
Secured liabilities:		
Borrowing arrangements	18,851	14,007
	<u>18,851</u>	<u>14,007</u>
Non-current		
Secured liabilities:		
Borrowing arrangements	61,549	65,601
Less: transaction costs	(6,738)	(6,738)
Amortization of carrying amount, net of payments made	10,070	8,416
	<u>64,881</u>	<u>67,279</u>

(i) Borrowing arrangements

Hercules Capital, Inc.

On March 6, 2018, the Group drew the first tranche of \$35.0 million of the principal amount from the \$75.0 million floating rate loan with Hercules. An additional tranche of \$15.0 million was drawn by the Group on January 14, 2019.

An additional \$25.0 million may be drawn by the Group as certain milestones are met. The loan matures in March 2022 with principal repayments due to commence in October 2019, as the milestone to defer principal repayments was not met before September 30, 2019. As a result, we have recognized \$18.4 million of the borrowings as a current liability. Subsequent to September 30, 2019, as disclosed in Note 11, the Group satisfied the milestones to defer principal repayments to April 2020. Principal repayments can be deferred to October 2020 if further 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, 2019 and September 19, 2019, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20% and 9.95%, respectively.

The carrying amount of the loan is secured by a first charge over the assets of the Group, excluding \$0.7 million of bank guarantees and \$1.2 million of letters of credit included in other non-current assets (refer to Note 5(d) in "Item 18 Financial Statements" included in our Form 20-F), \$0.4 million of interest-bearing deposits at call included in cash and cash equivalents (refer to Note 5(a)) and \$0.3 million of cash held as security included in trade and other receivables (refer to Note 5(b)). These items have been used to secure liabilities other than the non-current loan.

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. A \$0.4 million loan administration fee is payable annually in June and is recognized as a current liability. 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 our allogeneic product candidate MSC-100-IV in pediatric patients with steroid refractory aGVHD, in the United States and other geographies excluding Asia (“pediatric aGVHD”). We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing (“the payment cap”), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and 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. In the three months ended September 30, 2019, \$0.4 million loss has been recognized by the Group in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses.

In the three months ended September 30, 2019, the Group recognized a \$0.1 million gain in the Income Statement as remeasurement of borrowing arrangements within finance gains. This 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 with NovaQuest.

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

(ii) Compliance with loan covenants

Our loan facilities with Hercules and NovaQuest contain a number of covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. In addition, under our loan and security agreement with Hercules 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, 2019 and during the year ended June 30, 2019.

(iii) Net debt reconciliation

<i>(in U.S. dollars, in thousands)</i>	<i>As of September 30, 2019</i>	<i>As of June 30, 2019</i>
Cash and cash equivalents	34,536	50,426
Borrowings Repayable within one year	(20,375)	(14,007)
Borrowings Repayable after one year	(68,797)	(67,279)
Net Debt(1)	(54,636)	(30,860)
Cash and cash equivalents	34,536	50,426
Gross debt - fixed interest rates	(40,249)	(33,060)
Gross debt - variable interest rates	(48,923)	(48,226)
Net Debt(1)	(54,636)	(30,860)

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

(in U.S. dollars, in thousands)	Notes	Liabilities from financing activities			Other assets	Total
		Borrowings	Leases	Sub-total	Cash and cash equivalents	
Net Debt as at 30 June 2019		(81,286)	—	(81,286)	50,426	(30,860)
Recognized on adoption of IFRS 16	13	—	(5,775)	(5,775)	—	(5,775)
		<u>(81,286)</u>	<u>(5,775)</u>	<u>(87,061)</u>	<u>50,426</u>	<u>(36,635)</u>
Cash Flows		—	335	335	(15,847)	(15,512)
Remeasurement of borrowing arrangements		(281)	—	(281)	—	(281)
Other Changes ⁽¹⁾		(2,165)	—	(2,165)	—	(2,165)
Foreign exchange adjustments		—	—	—	(43)	(43)
Net Debt		<u>(83,732)</u>	<u>(5,440)</u>	<u>(89,172)</u>	<u>34,536</u>	<u>(54,636)</u>

(1) Other changes include non-cash movements including accrued interest expense which will be presented as operating cash flows in the statement of cash flows when paid.

(iv) Fair values of borrowing arrangements

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

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, 2019 and June 30, 2019 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of June 30, 2019 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector		—	—	2,317	2,317
Total Financial Assets		<u>—</u>	<u>—</u>	<u>2,317</u>	<u>2,317</u>

Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(e)(iii)	—	—	47,534	47,534
Total Financial Liabilities		<u>—</u>	<u>—</u>	<u>47,534</u>	<u>47,534</u>

As of September 30, 2019 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector		—	—	1,952	1,952
Total Financial Assets		<u>—</u>	<u>—</u>	<u>1,952</u>	<u>1,952</u>

Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(e)(iii)	—	—	47,528	47,528
Total Financial Liabilities		<u>—</u>	<u>—</u>	<u>47,528</u>	<u>47,528</u>

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, 2019 and the year ended June 30, 2019:

(in U.S. dollars, in thousands)	Contingent consideration provision
Opening balance - July 1, 2018	42,070
Amount used during the year	(800)
Charged/(credited) to consolidated income statement:	
Remeasurement ⁽¹⁾	6,264
Closing balance - June 30, 2019	47,534
Opening balance - July 1, 2019	47,534
Amount used during the period	(294)
Charged/(credited) to consolidated income statement:	
Remeasurement ⁽²⁾	288
Closing balance - September 30, 2019	47,528

(1) In the year ended June 30, 2019 a loss of \$6.3 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, developmental timelines, product pricing and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

(2) In the three months ended September 30, 2019 a loss of \$0.3 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a net result of changes to the key assumptions of the contingent consideration valuation such as 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.

(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, 2019	Fair value as of June 30, 2019	Valuation technique	Unobservable inputs(1)	Range of inputs (weighted average)		Relationship of unobservable inputs to fair value
					Three Months Ended September 30, 2019	Year Ended June 30, 2019	
Contingent consideration provision	47,528	47,534	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Three months ended September 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

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

(v) Valuation processes

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

For the three months ended September 30, 2019 and the year ended June 30, 2019, the Group has adopted a process to value contingent consideration internally. This valuation has been completed by the Group’s internal valuation team and reviewed by the Chief Financial Officer (the “CFO”). The valuation team is responsible for the valuation model. The valuation team also manages a process to continually refine the key assumptions within the model. This is done with input from the relevant business units. The key assumptions in the model have been clearly defined and the responsibility for refining those assumptions has been assigned to the most relevant business units. The remeasurement charged to the consolidated income statement was a net result of changes to key assumptions such as developmental timelines, product pricing, market population, market penetration, probability of success and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

The fair value of contingent consideration (in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	28,247	28,005
Fair value of royalty payments from commercialization of the intellectual property acquired	19,281	19,529
	<u>47,528</u>	<u>47,534</u>

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.

f. Lease liabilities

(in U.S. dollars, in thousands)	As of September 30, 2019
Current	1,524
Non-current	3,916
Lease liabilities included in the statement of financial position	<u>5,440</u>

The lease liability is measured at the present value of the fixed and variable lease payments net of cash lease incentives that are not paid at the balance date. Lease payments are apportioned between the finance charges and reduction of the lease liability using the incremental borrowing rate to achieve a constant rate of interest on the remaining balance of the liability. Lease payments for buildings exclude service fees for cleaning and other costs.

6. Non-financial assets and liabilities

a. Intangible assets

(in U.S. dollars, in thousands)	<u>Goodwill</u>	<u>Acquired licenses to patents</u>	<u>In-process research and development acquired</u>	<u>Current marketed products</u>	<u>Total</u>
Year Ended June 30, 2019					
Opening net book amount	134,453	1,770	427,779	20,604	584,606
Additions	—	100	—	—	100
Exchange differences	—	(4)	—	1	(3)
Amortization charge	—	(122)	—	(1,455)	(1,577)
Closing net book amount	134,453	1,744	427,779	19,150	583,126
As of June 30, 2019					
Cost	134,453	2,822	489,698	23,999	650,972
Accumulated amortization	—	(1,078)	—	(4,849)	(5,927)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	134,453	1,744	427,779	19,150	583,126
Three Months Ended September 30, 2019					
Opening net book amount	134,453	1,744	427,779	19,150	583,126
Exchange differences	—	(1)	—	—	(1)
Amortization charge	—	(31)	—	(363)	(394)
Closing net book amount	134,453	1,712	427,779	18,787	582,731
As of September 30, 2019					
Cost	134,453	2,803	489,698	23,999	650,953
Accumulated amortization	—	(1,091)	—	(5,212)	(6,303)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	134,453	1,712	427,779	18,787	582,731

b. Deferred tax balances

(i) *Deferred tax balances*

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	63,162	61,742
Other temporary differences	4,292	3,687
Total deferred tax assets	67,454	65,429
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	76,649	76,553
Total deferred tax liabilities	76,649	76,553
Net deferred tax liabilities	9,195	11,124
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	67,454	65,429
Deferred tax liabilities expected to be settled within 12 months	99	99
Deferred tax liabilities expected to be settled after 12 months	76,550	76,454

(ii) *Movements*

(in U.S. dollars, in thousands)	Tax losses ⁽¹⁾ (DTA)	Other temporary differences ⁽¹⁾ (DTA)	Intangible assets (DTL)	Total (DTL)
As of June 30, 2018	(55,904)	(669)	76,652	20,079
Charged/(credited) to:				
- profit or loss	(5,838)	(3,018)	(99)	(8,955)
As of June 30, 2019	(61,742)	(3,687)	76,553	11,124
Charged/(credited) to:				
- profit or loss	(1,420)	(605)	96	(1,929)
As of September 30, 2019	(63,162)	(4,292)	76,649	9,195

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

c. Deferred consideration

(in U.S. dollars, in thousands)	As of September 30, 2019	As of June 30, 2019
Opening balance	10,000	—
Up-front milestone receivable recognized during the period	—	20,000
Amount recognized as revenue in the period	—	(10,000)
Balance as of the end of the period	10,000	10,000

Deferred consideration represents the portion of the up-front technology access fee receivable from Tasly that has not been recognized as revenue. In accordance with the Group's accounting policy, revenue related to the licensing of intellectual property is only recognized to the extent that control has been transferred to the customer. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on the Group's decision regarding the exercise of the Group's rights in the terms and conditions of the agreement.

7. Cash flow information

(in U.S. dollars, in thousands)

	As of September 30, 2019	As of June 30, 2019
(a) Reconciliation of cash and cash equivalents		
Cash at bank	34,131	50,005
Deposits at call	405	421
	34,536	50,426

(in U.S. dollars, in thousands)

	Three months ended September 30, 2019	Three months ended September 30, 2018
(b) Reconciliation of net cash flows used in operations with loss after income tax		
Loss for the period	(5,484)	(19,498)
Add/(deduct) net loss for non-cash items as follows:		
Depreciation and amortization	849	554
Foreign exchange (gains)/losses	(232)	10
Finance costs	2,165	1,762
Remeasurement of borrowing arrangements	281	—
Remeasurement of contingent consideration	288	622
Equity settled share-based payment	804	818
Deferred tax benefit	(1,932)	(711)
Change in operating assets and liabilities:		
(Increase)/decrease in trade and other receivables	(15,378)	(19,616)
(Increase)/decrease in prepayments	(164)	(251)
Decrease/(increase) in tax assets	1,499	1,654
Increase/(decrease) in trade creditors and accruals	(300)	2,186
Increase/(decrease) in provisions	2,046	2,926
Increase/(decrease) in deferred consideration	—	10,000
Net cash outflows used in operations	(15,558)	(19,544)

8. Issued capital

	As of September 30, 2019		As of September 30, 2018	
	Shares No.		(U.S. dollars, in thousands)	
Opening balance	498,626,208	482,639,654	910,405	889,481
Issues of ordinary shares during the period				
Exercise of share options ⁽¹⁾	553,226	262,000	299	231
Transaction costs arising on share issue	—	—	—	(19)
	<u>553,226</u>	<u>262,000</u>	<u>299</u>	<u>212</u>
Share options reserve transferred to equity on exercise of options	—	—	238	287
Ending balance	<u>499,179,434</u>	<u>482,901,654</u>	<u>910,942</u>	<u>889,980</u>

- (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 Term deposits at fixed rates	Sensitivity analysis 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. 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, 2019.

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

(in U.S. dollars, in thousands, except percent data)	As of September 30, 2019		As of June 30, 2019	
	Total	% of total loans	Total	% of total loans
Financial liabilities				
Current borrowings				
Variable rate borrowings - Hercules	18,451	22%	13,607	17%
Non-current borrowings				
Variable rate borrowings - Hercules	30,472	36%	34,619	43%
	<u>48,923</u>	<u>58%</u>	<u>48,226</u>	<u>60%</u>

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, 2019 and June 30, 2019. The effect on profit is shown if interest rates change by 5%, in either direction, is as follows:

(in U.S. dollars, in thousands, except percent data)	As of September 30, 2019			As of June 30, 2019		
	Low	High	USD	Low	High	USD
Borrowings - USD	9.95%	9.95%	48,923(1)	10.45%	10.45%	48,226(1)
Rate increase by 5%	10.45%	10.45%	249	10.97%	10.97%	261
Rate decrease by 5%	9.45%	9.45%	(249)	9.93%	9.93%	(261)

(1) Effect on profit/loss of interest rate changes is based on the loan principal amount of \$50.0 million as of September 30, 2019, and loan principal amount of \$50.0 million as of June 30, 2019.

The Group is also exposed to interest rate movements which impacts interest income earned on its deposits and at call accounts. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by periodically reviewing interest rates available for suitable interest bearing accounts to ensure we earn interest at market rates. The Group ensures that sufficient funds are available, in at call accounts, to meet the working capital requirements of the Group.

The deposits held which derive interest revenue are described in the table below, together with the maximum and minimum interest rates being earned as of September 30, 2019 and June 30, 2019. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

(in U.S. dollars, in thousands, except percent data)	As of September 30, 2019			As of June 30, 2019		
	Low	High	USD	Low	High	USD
Funds invested - USD	1.67%	1.67%	27,935	1.76%	1.76%	45,051
Rate increase by 10%	1.84%	1.84%	47	1.94%	1.94%	81
Rate decrease by 10%	1.50%	1.50%	(47)	1.58%	1.58%	(81)

AUD	Low	High	AUD	Low	High	AUD
Funds invested - AUD	2.23%	2.23%	600	2.23%	2.23%	600
Rate increase by 10%	2.45%	2.45%	1	2.45%	2.45%	1
Rate decrease by 10%	2.01%	2.01%	(1)	2.01%	2.01%	(1)

(iii) Price risk

Price risk is the risk that future cash flows derived from financial instruments will be altered as a result of a market price movement, which is defined as movements other than foreign currency rates and interest rates. The Group is exposed to price risk which arises from long-term borrowings under its facility with NovaQuest, where the timing and amounts of principal and interest payments is dependent on net sales of product candidate MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of MSC-100-IV for the treatment of 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:

(in U.S. dollars, in thousands, except percent data)	As of September 30, 2019		As of June 30, 2019	
	Total	% of total loans	Total	% of total loans
Financial liabilities				
Current borrowings				
Borrowings - NovaQuest	400	0%	400	0%
Non-current borrowings				
Borrowings - NovaQuest	34,409	42%	32,660	40%
	<u>34,809</u>	<u>42%</u>	<u>33,060</u>	<u>40%</u>

As at September 30, 2019, all other factors held constant, a 20% increase in the forecast net sales of MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia would increase non-current borrowing and decrease profit by \$4.6 million, whereas a 20% decrease in the net sales of MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia would decrease non-current borrowings and increase profit by \$2.8 million.

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 and borrowings, held by the Group as of September 30, 2019 and June 30, 2019 are non-interest bearing and mature within 6 months. The total contractual cash flows associated with these liabilities equate to the carrying amount disclosed within the financial statements.

As of September 30, 2019 the maturity profile of the anticipated future contractual cash flows including interest in relation to the Group's borrowings, 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)	(23,073)	(29,761)	(59,066)	(32,821)	(144,721)	(83,732)
Trade payables	(12,740)	—	—	—	(12,740)	(12,740)
Lease liabilities	(1,875)	(1,540)	(2,121)	(1,039)	(6,575)	(5,440)
	<u>(37,688)</u>	<u>(31,301)</u>	<u>(61,187)</u>	<u>(33,860)</u>	<u>(164,036)</u>	<u>(101,912)</u>

11. Events occurring after the reporting period

On October 3, 2019, the Group announced completion of a A\$75.0 million (US\$50.5 million) capital raise through the placement of 37.5 million new fully-paid ordinary shares at a price of A\$2.00 per share to existing and new institutional investors.

On October 4, 2019, the Group satisfied the milestones required to defer the commencement of principal repayments of the Hercules borrowings to April 2020. Principal repayments can be further deferred to October 2020 if further milestones are met. Given the milestones were satisfied after the reporting period, the principal repayments that were to be due in October 2019 to March 2020 are classified as current as at the reporting date.

On October 17, 2019, the Group announced that it had entered into manufacturing service agreement with Lonza Bioscience Singapore Pte. Ltd. for the supply of commercial product for the potential approval and launch of remestemcel-L for the treatment of pediatric acute graft versus host disease in the US market. The agreement contains a minimum financial commitment of \$15.1 million.

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. Change in accounting policies

(in U.S. dollars, in thousands)	2019
Operating lease commitments disclosed as at June 30, 2019	7,460
Discounted using the group's average incremental borrowing rate of 6.52%	6,146
(Less): Short term leases recognized on a straight line basis as expense	(371)
Lease liability recognized as at July 1, 2019	5,775

The associated right-of-use assets for property leases were measured on a retrospective basis as if the new rules had always been applied. Property, plant and equipment increased by \$4.7 million and lease liabilities increased by \$5.6 million on July 1, 2019. The net impact on retained earnings on July 1, 2019 was \$0.9m.

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics
- the accounting for operating leases with a remaining lease term of less than 12 months as at July 1, 2019 as short term leases
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Group has also elected not to reassess whether a contract is, or contains a lease at the date of initial application. Instead, for contracts entered into before the transition date the group relied on its assessment made applying IAS 17 and Interpretation 4 *Determining whether an Arrangement contains a Lease*.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our 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, 2019 ("Form 20-F"), filed with the Securities and Exchange Commission on August 31, 2019, 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's leadership in the development and commercialization of allogeneic cellular medicines is based on its innovative technology platform, proprietary manufacturing processes and multiple Phase 3 assets.

Our off-the-shelf product candidates target advanced stages of inflammatory diseases with high, unmet medical needs.

Three product candidates are being evaluated in Phase 3 clinical trials for approval by the United States Food and Drug Administration ("FDA"):

- remestemcel-L (MSC-100-IV) for steroid refractory acute graft versus host disease ("aGVHD");
- Revascor (MPC-150-IM) for advanced heart failure; and
- MPC-06-ID for chronic low back pain due to degenerative disc disease.

We also have a promising emerging pipeline of products for follow-on indications.

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

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

On October 17, 2019, we announced that we had entered into an agreement for commercial manufacture of our lead allogeneic cell therapy product candidate, remestemcel-L for pediatric aGVHD. This agreement will facilitate inventory build ahead of the planned US market launch of remestemcel-L and commercial supply to meet Mesoblast's long-term market projections. The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

On October 3, 2019, we announced that we successfully completed an A\$75.0 million capital raising via a private placement of ordinary shares to existing and new Australian and global institutional investors outside the United States. The net proceeds will principally be used to build product inventory and a targeted US sales force in preparation for the potential US commercial launch of remestemcel-L in the treatment of pediatric aGVHD. Proceeds will also be used to complete Phase 3 trials for chronic low back pain and advanced heart failure, and for working capital and general corporate purposes.

On September 10, 2019, we announced that we entered into a strategic partnership with Grünenthal GmbH (“Grünenthal”) to develop and commercialize MPC-06-ID, Mesoblast’s Phase 3 allogeneic cell therapy candidate for the treatment of chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America. Mesoblast will receive up to \$150.0 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. These payments include commitments up to \$45.0 million within the first year comprising \$15.0 million on signing, \$20.0 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and \$10.0 million on certain clinical and manufacturing outcomes. Cumulative milestone payments could exceed \$1.0 billion depending on the final outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales. There can not be any assurance as to the total amount of future milestone and royalty payments that Mesoblast will receive nor when they will be received. Grünenthal and Mesoblast have agreed on an overall development plan for MPC-06-ID to meet European regulatory requirements. As part of this plan, the companies will collaborate on the study design for a confirmatory Phase III trial in Europe. The results of the two Phase III trials are expected to support both FDA and European Medicines Agency (“EMA”) regulatory approvals for MPC-06-ID in chronic low back pain due to degenerative disc disease.

On August 27, 2019, we announced positive outcomes from our meeting with the FDA on the pathway for marketing authorization of its allogeneic cell therapy product candidate Revascor in end-stage heart failure patients implanted with a left ventricular assist device (“LVAD”). Key outcomes were that the FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, was an important clinical outcome in patients implanted with an LVAD; it confirmed that data from the recently completed 159-patient placebo-controlled trial showing that Revascor reduced major mucosal bleeding events could support product marketing authorization through a Biologics License Application (“BLA”), with confirmatory clinical data, and agreed on a confirmatory Phase 3 trial of Revascor in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

On August 13, 2019, we announced that we intend to provide remestemcel-L for evaluation under an investigator-initiated Investigational New Drug (IND) submission as a potential treatment in children with steroid-refractory chronic GVHD. In both acute and chronic forms of GVHD, the donated bone marrow stem cells view the recipient’s body as foreign, and attack the body causing significant morbidity and mortality. Acute GVHD usually manifests within 100 days following a transplant while chronic GVHD generally manifests later (>100 days), and the two may occur separately or within the same patient.

On August 12, 2019, we announced the appointment of Dr. Fred Grossman as Chief Medical Officer, who has a wealth of commercial experience gained from numerous leadership roles at global pharmaceutical companies. The appointment aligns closely with the Company’s commercial objectives for its lead products.

On July 25, 2019, we announced that the American Heart Association journal Circulation Research published a Special Article highlighting the important potential clinical benefits of Revascor as an immunotherapy in patients with advanced chronic heart failure (“CHF”), stating that there is a biologic rationale for the use of Revascor in targeting cardiac inflammation in order to improve heart failure outcomes. The ongoing, placebo-controlled double-blind Phase 3 trial of Mesoblast’s heart failure cellular medicine Revascor is evaluating the immunotherapy for reduction of heart failure-related hospitalizations and terminal cardiac events in patients with advanced heart failure.

Mergers and Acquisitions

We had no mergers or acquisitions during the three month period ended September 30, 2019.

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, 2019, we had an accumulated deficit of \$476.3 million. Our net loss for the three months ended September 30, 2019 was \$5.5 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 research and development expenditure to decrease over the next 12 to 24 months as we complete our Phase 3 trials or if we are able to successfully partner one or more of our products candidates. We expect management and administration expenses to remain relatively consistent. 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 revenue or 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, 2019, we recognized \$1.9 million in commercialization revenue relating to royalty income earned on sales of, in Japan by our licensee, JCR, compared with \$1.0 million for the three months ended September 30, 2018. 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 regard to this milestone had been satisfied as the right of use license of IP had been transferred to Grünenthal upon signing of the contract. There was no milestone revenue recognized in relation to this strategic partnership with Grünenthal in the three months ended September 30, 2018.

In the three months ended September 30, 2018, we recognized \$10.0 million in milestone revenue from the \$20.0 million up-front payment received in October 2018 in relation to our strategic alliance with Tasly Pharmaceutical Group (“Tasly”) for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. Tasly has received exclusive rights to, and will fund all development, manufacturing and commercialization activities in China for MPC-150-IM and MPC-25-IC. Upon completion of this strategic alliance on September 14, 2018, we recognized revenue of \$10.0 million for the up-front technology access fee receivable from Tasly as this is the portion of revenue that control has been transferred to Tasly. There was no milestone revenue recognized in relation to this strategic alliance with Tasly in the three months ended September 30, 2019.

In the three months ended September 30, 2018, we also recognized \$0.5 million in milestone revenue upon our licensee JCR Pharmaceuticals Co. Ltd. (“JCR”) achieving a sales milestone on cumulative net sales of TEMCELL® Hs. Inj., a registered trademark of JCR (“TEMCELL”) in Japan. This amount was recorded in revenue as there were no further performance obligations required in regard to this milestone. There was no milestone revenue recognized in the three months ended September 30, 2019 in relation to the JCR partnership.

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

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

Our research and development expenses consist primarily of:

- third party costs comprising all external expenditure on our research and development programs such as fees paid to Contract Research Organizations (“CROs”), and 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 functions (for example wages, salaries and associated on costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires);
- intellectual property support costs comprising payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents; and
- amortization of currently marketed products on a straight-line basis over the life of the asset.

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

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

- salaries and related overhead expenses including share-based incentives for personnel in manufacturing functions;
- fees paid to our contract manufacturing organizations, which perform process development on our behalf and under our direction; and
- costs related to laboratory supplies used in our manufacturing development efforts.

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 loss of \$0.3 million and a net remeasurement loss of \$0.6 million for the three months ended September 30, 2019 and 2018, 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. We recognized 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 such as development timelines and market penetration. There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2018.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our foreign currency amounts in our Australian based entity, whose functional currency is the A\$, and foreign currency amounts in our Switzerland and Singapore based entities, whose functional currencies are the US\$, plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates. We recognized a foreign exchange gain of \$0.2 million in the three months ended September 30, 2019 and a foreign exchange loss of \$0.2 million in the three months ended September 30, 2018.

Finance Costs. Finance costs consists of remeasurement of borrowing arrangements, 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 agreement 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. We recognized a remeasurement gain of \$0.1 million in the three months ended September 30, 2019 in relation to our existing credit facility with NovaQuest. There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2018.

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 \$1.9 million in the three months ended September 30, 2019 and \$0.7 million in the three months ended September 30, 2018.

Results of Operations

Comparison of Our Results for the Three Months Ended September 30, 2019 with the Three Months Ended September 30, 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018, 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,		\$ Change	% Change
	2019	2018		
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	\$ 1,872	\$ 1,006	866	85%
Milestone revenue	15,000	10,500	4,500	43%
Interest revenue	176	131	45	34%
Total revenue	17,048	11,637	5,411	46%
Research & development	(12,389)	(18,489)	6,100	(33%)
Manufacturing commercialization	(2,698)	(4,317)	1,619	(38%)
Management and administration	(5,463)	(5,614)	151	(3%)
Fair value remeasurement of contingent consideration	(288)	(622)	334	(54%)
Other operating income and expenses	(169)	(151)	(18)	12%
Finance costs	(3,457)	(2,653)	(804)	30%
Loss before income tax	(7,416)	(20,209)	12,793	(63%)
Income tax benefit	1,932	711	1,221	172%
Loss attributable to the owners of Mesoblast Limited	\$ (5,484)	\$ (19,498)	14,014	(72%)
Losses per share from continuing operations attributable to the ordinary equity holders:				
	Cents	Cents	Cents	% Change
Basic - losses per share	(1.10)	(4.07)	2.97	(73%)
Diluted - losses per share	(1.10)	(4.07)	2.97	(73%)

* NM = not meaningful.

Revenue

Revenues were \$17.0 million for the three months ended September 30, 2019, compared with \$11.6 million for the three months ended September 30, 2018, an increase of \$5.4 million. The following table shows the movement within revenue for the three months ended September 30, 2019 and 2018, together with the changes in those items.

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Revenue:				
Milestone revenue	15,000	10,500	4,500	43%
Commercialization revenue	1,872	1,006	866	85%
Interest revenue	176	131	45	34%
Revenue	\$ 17,048	\$ 11,637	5,411	46%

Milestone revenue was \$15.0 million in the three months ended September 30, 2019, an increase of \$4.5 million as compared with \$10.5 million in the three months ended September 30, 2018. This \$4.5 million increase in the three months ended September 30, 2019 is due to the recognition of \$15.0 million in milestone revenue for the up-front fee received in October 2019 upon completion of the strategic partnership with Grünenthal for the development and commercialization in Europe and Latin America of our Phase 3 allogeneic MPC product, MPC-06-ID on September 9, 2019. There was no milestone revenue recognized in relation to the strategic partnership with Grünenthal in the three months ended September 30, 2018. This \$15.0 million increase in milestone revenue from Grünenthal was offset by a decrease of \$10.0 million in milestone revenue recognized in the three months ended September 30, 2018 due to the recognition of \$10.0 million in milestone revenue upon completion of the strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC in September 2018. There was no milestone revenue recognized in relation to the strategic alliance with Tasly in the three months ended September 30, 2019. We also recognized \$0.5 million in milestone revenue during the three months ended September 30, 2018, upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan whereas no milestone revenue was recognized in the three months ended September 30, 2019.

Commercialization revenue from royalty income earned on sales of TEMCELL in Japan by our licensee JCR was \$1.9 million in the three months ended September 30, 2019, an increase of \$0.9 million (85%) as compared with \$1.0 million in the three months ended September 30, 2018.

Interest revenue remained relatively consistent for the three months ended September 30, 2019, compared with the three months ended September 30, 2018.

Research and development

Research and development expenses were \$12.4 million for the three months ended September 30, 2019, compared with \$18.5 million for the three months ended September 30, 2018, a decrease of \$6.1 million. The \$6.1 million decrease in research and development expenses primarily reflects a decrease in third party costs.

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Research and development:				
Third party costs	6,566	13,471	(6,905)	(51%)
Product support costs	4,834	4,033	801	20%
Intellectual property support costs	625	622	3	0%
Amortization of current marketed products	364	363	1	0%
Research and development	\$ 12,389	\$ 18,489	(6,100)	(33%)

Third party costs, which consist of all external expenditure on our research and development programs, decreased by \$6.9 million in the three months ended September 30, 2019 compared with the three months ended September 30, 2018.

This \$6.9 million decrease was due to 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 as activities and costs were higher in the prior year given the trials were enrolling patients, whereas in the year ended June 30, 2019, activities and costs have reduced as enrollment was completed for MPC-150-IM (CHF), MPC-06-ID (CLBP) and remestemcel-L in January 2019, March 2018 and December 2017 respectively. We continued to incur costs for these programs, as well as other pre-Phase 3 programs, during the three months ended September 30, 2019 as patients were monitored during follow up visits and other testing was completed.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have increased by \$0.8 million for the three months ended September 30, 2019 compared with the three months ended September 30, 2018. This \$0.8 million increase in the three months ended September 30, 2019 is primarily due to an increase of \$0.4 million across salaries and associated costs as full time equivalents increased by 3.7 (8%) from 45.6 for the three months ended September 30, 2018 to 49.3 for the three months ended September 30, 2019. There was also an increase of \$0.3 million in recruitment expenses and \$0.3 million across consulting and travel expenses for the three months ended September 30, 2019 compared with the three months ended September 30, 2018. These increases were offset by a decrease of \$0.2 million in share-based payment expenses in the three months ended September 30, 2019 compared with the three months ended September 30, 2018.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents. These costs have remained consistent for the three months ended September 30, 2019 compared with the three months ended September 30, 2018.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC and MSC based products, decreased by \$1.6 million for the three months ended September 30, 2019 compared with three months ended September 30, 2018. The decrease was primarily due to process validation activities required ahead of the BLA filing of MSC-100-IV and winding down as they reach completion in the three months ended September 30, 2019.

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Manufacturing commercialization:				
MSC platform technology	2,123	3,466	(1,343)	(39%)
MPC platform technology	162	362	(200)	(55%)
Manufacturing support costs	413	489	(76)	(16%)
Manufacturing commercialization	\$ 2,698	\$ 4,317	(1,619)	(38%)

The MSC-based manufacturing commercialization expenses decreased by \$1.3 million in the three months ended September 30, 2019 compared with the three months ended September 30, 2018 primarily due to process validation activities required ahead of the BLA filing of MSC-100-IV winding down as they reach completion in the three months ended September 30, 2019.

The MPC-based manufacturing commercialization expenses decreased by \$0.2 million in the three months ended September 30, 2019 compared with the three months ended September 30, 2018 primarily due to a decrease in activity for cell storage and shipping.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, decreased by \$0.1 million from \$0.5 million for the three months ended September 30, 2018 to \$0.4 million for the three months ended September 30, 2019 due to a decrease of \$0.1 million across salaries and associated costs as full time equivalents decreased by 1.0 (17%) from 6.0 for the three months ended September 30, 2018 to 5.0 for the three months ended September 30, 2019.

Management and administration

Management and administration expenses were \$5.5 million for the three months ended September 30, 2019, compared with \$5.6 million for the three months ended September 30, 2018, a decrease of \$0.1 million. This decrease was primarily due to a decrease in labor and associated expenses.

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Management and administration:				
Labor and associated expenses	2,111	2,470	(359)	(15%)
Corporate overheads	1,995	1,903	92	5%
Legal and professional fees	1,357	1,241	116	9%
Management and administration	\$ 5,463	\$ 5,614	(151)	(3%)

Labor and associated expenses decreased by \$0.3 million from \$2.4 million for the three months ended September 30, 2018 to \$2.1 million for the three months ended September 30, 2019. This \$0.3 million decrease in the three months ended September 30, 2019 is primarily due to a decrease of \$0.5 million 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, 2018. This decrease was offset by an increase of \$0.2 million in share-based payment expenses and \$0.1 million in consulting expenses for the three months ended September 30, 2019 compared with the three months ended September 30, 2018. Labor and associated expenses also experienced favorable exchange rate fluctuations of \$0.1 million in the three months ended September 30, 2019 compared with the three months ended September 30, 2018, as the A\$ weakened against the US\$ given the majority of management and administration expenses are incurred in A\$ by our headquarter office located in Australia.

Corporate overhead expenses increased by \$0.1 million from \$1.9 million for the three months ended September 30, 2018 to \$2.0 million for the three months ended September 30, 2019 due to an increase in insurance.

Legal and professional fees increased by \$0.1 million from \$1.2 million for the three months ended September 30, 2018 to \$1.3 million for the three months ended September 30, 2019 primarily due to increased legal and professional fees 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 \$0.3 million loss for the three months ended September 30, 2019 compared with a \$0.6 million loss for the three months ended September 30, 2018, a decrease of \$0.3 million. 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 was 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.

The \$0.6 million loss for the three months ended September 30, 2018 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a result of 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

Other operating income and expenses remained consistent for the three months ended September 30, 2019, compared with the three months ended September 30, 2018. The following table shows movements within other operating income and expenses for the three months ended September 30, 2019 and 2018, together with the changes in those items:

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Other operating income and expenses:				
Remeasurement of borrowing arrangements	(401)	—	(401)	NM
Foreign exchange gains/(losses) (net)	232	(151)	383	NM
Other operating income and expenses	\$ (169)	\$ (151)	(18)	12%

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 flow 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. There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2018.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors. In the three months ended September 30, 2018 we recognized a foreign exchange loss of \$0.2 million. In the three months ended September 30, 2019, we recognized a foreign exchange gain of \$0.2 million, primarily due to movements in exchange rates on US\$ receivable held in Mesoblast Limited as the A\$ depreciated against the US\$ during the period the US\$ receivable was held.

Finance costs

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Finance costs:				
Remeasurement of borrowing arrangements	(120)	—	(120)	NM
Interest expense	3,577	2,653	924	35%
Finance costs	\$ 3,457	\$ 2,653	804	30%

In the three months ended September 30, 2019, we recognized a \$0.1 million gain for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows from our existing credit facility with NovaQuest. There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2018.

Interest expenses increased by \$0.9 million from \$2.6 million for the three months ended September 30, 2018 to \$3.5 million for the three months ended September 30, 2019.

In the three months ended September 30, 2019, we recognized \$2.0 million of interest expenses in relation to our loan and security agreement entered into with Hercules on March 6, 2018, an increase of \$0.6 million as compared with \$1.4 million for the three months ended September 30, 2018. Within this \$2.0 million, \$1.3 million was recognized with regard to interest expense payable on the loan balance within the year and a further \$0.7 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, 2019 using the effective interest rate method over the period of initial recognition through maturity.

In the three months ended September 30, 2019, we recognized \$1.5 million of interest expenses in relation to our loan and security agreement entered into with NovaQuest on June 29, 2018, an increase of \$0.3 million as compared with \$1.2 million for the three months ended September 30, 2018. This \$1.5 million is recognized with regard to interest expense accrued on the loan principal balance. All interest payments will be deferred until after the first commercial sale of our allogeneic product candidate remestemcel-L in pediatric aGVHD.

Loss after income tax

(in U.S. dollars, in thousands)	Three months ended September 30,		\$ Change	% Change
	2019	2018		
Loss before income tax	(7,416)	(20,209)	12,793	(63%)
Income tax benefit	1,932	711	1,221	172%
Loss after income tax	\$ (5,484)	\$ (19,498)	14,014	(72%)

Loss before income tax was \$7.4 million for the three months ended September 30, 2019 compared with \$20.2 million for the three months ended September 30, 2018, a decrease in the loss by \$12.8 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

A non-cash income tax benefit of \$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.

A non-cash income tax benefit of \$0.7 million was recognized in the three months ended September 30, 2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period. 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.

Liquidity and Capital Resources

Sources of liquidity

We have incurred losses from operations since our inception in 2004 and as of September 30, 2019, we had an accumulated deficit of \$476.3 million. We had cash and cash equivalents of \$34.5 million as of September 30, 2019 and incurred net cash outflows from operations of \$15.6 million for the three months ended September 30, 2019. As of September 30, 2019, we recognized funds receivable from revenues of \$15.0 million pursuant to a strategic partnership with Grünenthal, on October 1, 2019 the net proceeds of which were received and recognized in cash and cash equivalents. On October 3, 2019, we raised gross proceeds of A\$75.0 million (US\$50.5 million) through the placement of 37.5 million new fully-paid Mesoblast ordinary shares.

Additionally, over the next 12 months, we may receive up to an additional \$30.0 million in milestone payments under the strategic partnership with Grünenthal and a further \$35.0 million under the agreements with Hercules and NovaQuest.

There is uncertainty related to our ability to access payments from the strategic partnership with Grünenthal or to draw down funds from Hercules and NovaQuest. The ability of us to continue as a going concern and meet our debts and commitments as they fall due are dependent upon meeting the milestones under our Grünenthal and NovaQuest agreements, and drawing on remaining funds under our Hercules agreement, or entering into additional strategic partnerships for our product candidates, or equity-based financing.

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 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,		\$ Change	% Change
	2019	2018		
Cash Flow Data:				
Net cash (outflows) in operating activities	(15,558)	(19,544)	3,986	(20%)
Net cash (outflows) in investing activities	(253)	(39)	(214)	NM
Net cash (outflow)/inflows by financing activities	(36)	37,106	(37,142)	(100%)
Net (decrease)/increase in cash and cash equivalents	(15,847)	17,523	(33,370)	(190%)

Net cash outflows in operating activities

Net cash outflows for operating activities were \$15.6 million for the three months ended September 30, 2019, compared with \$19.5 million for the three months ended September 30, 2018, a decrease of \$4.0 million. Outflows for payments to suppliers and employees and interest and other costs of finance paid decreased by \$4.0 million from \$22.9 million for the three months ended September 31, 2018 to \$18.9 million for the three months ended September 30, 2019 primarily due to a decrease in payments in relation to research and development costs.

Net cash outflows in investing activities

Net cash outflows for investing activities increased by \$0.2 million in the three months ended September 30, 2019, compared with the three months ended September 30, 2018 due to an increase in payments for fixed assets, such as plant and equipment and intellectual property, in the three months ended September 30, 2019 when compared with the three months ended September 30, 2018.

Net cash inflows in financing activities

Net cash outflows for financing activities were minimal for the three months ended September 30, 2019, compared with net cash inflows of \$37.1 million for the three months ended September 30, 2018, a decrease in inflows of \$37.1 million. We received \$0.3 million in receipts from employee share option exercises during the three months ended September 30, 2019, compared to \$Nil for the three months ended September 30, 2018. This receipt was offset by a \$0.3 million payment for lease liabilities during the three months ended September 30, 2019, compared to \$Nil for the three months ended September 30, 2018. The net cash inflows in the three months ended September 30, 2018 include a \$28.9 million receipt of net proceeds drawn pursuant to a non-dilutive, eight-year credit facility with NovaQuest and a \$10.0 million receipt of gross proceeds from a share placement with NovaQuest in July 2018. Additionally, there was \$0.3 million of payments for associated capital raising costs and \$1.5 million of payments for other associated borrowings cost in the three months ended September 30, 2018, compared with \$Nil in the three months ended September 30, 2019, a net decrease in outflows for capital raising and borrowing costs of \$1.6 million.

Operating Capital Requirements

To date, revenues have not been significant. 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 expect to incur additional costs associated with operating as a U.S. public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our research and development expenses will decrease in the short term (12 to 24 months) as we complete our Phase 3 trials or if we are able to successfully partner one or more of our product candidates. We expect management and administration expenses to remain relatively consistent. 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

Borrowing commitments

The maturity profile of the anticipated future contractual cash flows including interest in relation to our borrowings, 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⁾	(23,073)	(29,761)	(59,066)	(32,821)	(144,721)	(83,732)
Trade payables	(12,740)	—	—	—	(12,740)	(12,740)
Lease liabilities	(1,875)	(1,540)	(2,121)	(1,039)	(6,575)	(5,440)
	<u>(37,688)</u>	<u>(31,301)</u>	<u>(61,187)</u>	<u>(33,860)</u>	<u>(164,036)</u>	<u>(101,912)</u>

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at September 30, 2019 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 pediatric aGVHD.

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. Excess office space is sub-let to a third party also under a non-cancellable lease. We adopted IFRS 16 Leases on July 1, 2019. Our principal accounting policy from July 1, 2019, are that leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use. For principal accounting policies relating to the comparative year, refer to our annual report on Form 20-F for the year ended June 30, 2019. Comparatives have not been restated as permitted under the specific transition provisions in the standard. A reconciliation between the operating lease commitments disclosed applying IAS 17 at June 30, 2019 and the lease liabilities recognized at July 1, 2019 is described in Note 13 to our consolidated financial statements.

Contingent liabilities

We acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with our use of the Medvet IP, on completion of certain milestones we will be obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to \$2.2 million and single-digit royalties on net sales of products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) single-digit royalties on net sales of the specified products for applications outside the specified fields.

We have entered into a number of agreements with other third parties pertaining to intellectual property. Contingent liabilities may arise in the future if certain events or developments occur in relation to these agreements and as of September 30, 2019 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, 2019.

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 operating leases as mentioned above, as defined under SEC rules.

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, 2019.

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\$. We also have foreign currency amounts owing in various other non-US\$ currencies in A\$ and US\$ functional currency entities, 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 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 product candidate remestemcel-L for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of remestemcel-L for the treatment of 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 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 our Form 20-F, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

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

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

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

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

Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products. Payment is generally due on standard terms of 30 to 60 days.

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

Milestone revenue

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

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

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

Licenses of intellectual property

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

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

Sales-based or usage-based royalties

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

Grünenthal arrangement

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

We are entitled to receive a non-refundable upfront payment of \$15.0 million on signing of the contract with Grünenthal, and this payment was received on October 1, 2019. We are eligible to receive up to \$150.0 million in upfront, clinical, manufacturing, regulatory and reimbursement approval related milestone payments 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.

We evaluated the constraint over variable consideration and determined only the upfront payment of \$15.0 million can be included in the transaction price as at September 30, 2019. All of the milestone payments were considered constrained as at September 30, 2019. 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.

Upon signing of this strategic partnership on September 9, 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. In future periods, 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, 2018.

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 on September 14, 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 is the portion of revenue that control has been transferred to Tasly. We recognized the remaining \$10.0 million from the \$20.0 million up-front payment as deferred consideration on our consolidated balance sheet. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on our decision regarding the exercise of our rights in the terms and conditions of the agreement.

There was no milestone revenue recognized in relation to this strategic alliance with Tasly in the three months ended September 30, 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®.

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. In the past 12 months, we have 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, 2019, we recognized \$1.9 million, in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with \$1.0 million for the three months ended September 30, 2018. 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, 2018, we recognized \$0.5 million in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan. This amount was recorded in revenue as there are were no further performance obligations required in regard to this items. There was no milestone revenue recognized in three months ended September 30, 2019.

Government grant income

Revenue from government grants is recognized in the consolidated income statement on a systematic basis over the periods in which the entity recognizes as expense the related costs for which the grants are intended to compensate in accordance with IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance*.

The Australian government allows a refundable tax offset to eligible companies with an annual aggregate turnover of less than A\$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending at the rate of 43.5% for periods from July 1, 2016. All other eligible entities may obtain a non-refundable tax offset equal to 38.5% of their eligible research and development expenditure. We have assessed our research and development activities and expenditure to determine which of these expenses are likely to be eligible under the incentive scheme. At each period end, we estimate and recognize the refundable tax offset available to us based on available information at the time.

The receivable for reimbursable amounts that have not been collected is reflected in trade and other receivables on our consolidated balance sheets.

We anticipate that the combined worldwide turnover of the Mesoblast Group will be in excess of A\$20.0 million for the three months ended September 30, 2019 and 2018, making us ineligible for the refundable tax offset for the research and development tax incentive. Consequently, no income was recognized from the Research and Development Tax Incentive program for the three months ended September 30, 2019 and 2018.

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. 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, 2019 and September 30, 2018 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, 2019 and 2018.

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 June 30, 2017 with the recoverable amount of each asset exceeding its carrying amount.

The recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts in the annual impairment testing completed in March 2019 and, therefore, no impairment charges were recorded.

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

Fair Value Measurements

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

- Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, trading and financial assets at fair value through other comprehensive income securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by us is the current bid price. These instruments are included in level 1.
- Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.
- Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for provisions (contingent consideration) and equity securities (unlisted).

Our level 3 asset consists of an investment in unlisted equity securities in the biotechnology sector. Level 3 assets were 100% of total assets measured at fair value as at September 30, 2019 and June 30, 2019.

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

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

(in U.S. dollars, in thousands, except percent data) Description	Fair value as of September 30, 2019	Fair value as of June 30, 2019	Valuation technique	Unobservable inputs ⁽¹⁾	Range of inputs (weighted average)		Relationship of unobservable inputs to fair value
					Three Months Ended September 30, 2019	Year Ended June 30, 2019	
Contingent consideration provision	47,528	47,534	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Three months ended September 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

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

Borrowings

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

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or 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

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 on closing and a further tranche of \$15.0 million was drawn in January 2019. In the three months ended September 30, 2019, we recognized a \$2.3 million and \$0.6 million gain in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses and finance costs, respectively. There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2018.

An additional \$25.0 million may be drawn as certain milestones are met. The loan matures in March 2022 with principal repayments due to commence in October 2019. Subsequent to September 30, 2019, we satisfied the milestones to defer principal repayments to April 2020. Principal repayments can be deferred to October 2020 if further 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, 2019 and September 19, 2019, in line with the decreases in the U.S. prime rate, the interest rate on the loan decreased to 10.20% and 9.95%, respectively.

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. A \$0.4 million loan administration fee is payable annually in June and is recognized as a current liability. 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 our allogeneic product candidate remestemcel-L in pediatric aGVHD. We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and 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 in the period the revision is made.

There was no remeasurement of borrowing arrangements recognized in the three months ended September 30, 2019 and 2018.

Net deferred tax assets

We record deferred tax assets if, based upon the available evidence, it is more likely than not that we will recognize some or all of the deferred tax assets. Deferred tax assets were 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) following our conclusion in the year ended June 30, 2016 to retain existing intellectual property assets in their relative jurisdictions as we are no longer planning to consolidate intellectual property assets. There have been no significant developments on this conclusion during the three months ended September 30, 2019.

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 October 3, 2019, we announced completion of a A\$75.0 million (US\$51.0 million) capital raise through a private placement of 37.5 million new fully-paid ordinary shares at a price of A\$2.00 per share to existing and new institutional investors in Australia and elsewhere outside the United States.

On October 4, 2019, we satisfied the milestones required to defer the commencement of principal repayments of the Hercules borrowings to April 2020. Principal repayments can be further deferred to October 2020 if further milestones are met. Given the milestones were satisfied after the reporting period, the principal repayments that were to be due in October 2019 to March 2020 are classified as current as at the reporting date.

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 for the treatment of pediatric aGVHD in the US market. The agreement contains a minimum financial commitment of \$15.1 million.

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, 2019 was \$5.5 million. As of September 30, 2019, we have an accumulated deficit of \$476.3 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, 2019, our cash and cash equivalents were \$34.5 million. We expect to continue to incur significant expenses and increasing 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”)), MSC-100-IV (“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, our continuing viability and our ability to continue as a going concern and meet our debts and commitments as they fall due are dependent upon meeting the milestones under our Grünenthal GmbH and NovaQuest Capital Management, L.L.C. (“NovaQuest”) agreements, and drawing on remaining funds under our Hercules Capital, Inc. (“Hercules”) agreement, or entering into additional strategic partnerships for our product candidates, or equity-based financings.

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 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 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 97% of our cash and cash equivalents as of September 30, 2019 were denominated in U.S. dollars and 3% 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.

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.

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; and
- 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.

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. 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 new law is designed to advance medical innovation, and includes a number of provisions that may impact our product development programs. For example, the Cures Act establishes a new "regenerative medicine advanced therapy" designation ("RMAT"), and creates a pathway for increased interaction with FDA for the development of products which obtain designations. Although the FDA has issued guidance documents in 2018, it remains unclear how and when the FDA will fully implement all deliverables under the Cures Act.

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

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

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

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

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

On December 21, 2017, the FDA granted RMAT designation for our novel MPC therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices. While the Cures Act offers several potential benefits to drugs designated as RMATs, including eligibility for increased agency support and advice during development, priority review on filing, a potential pathway for accelerated approval based on surrogate or intermediate endpoints, and the potential to use patient registry data and other sources of real world evidence for post approval confirmatory studies, there is no assurance that any of these potential benefits will either apply to any or all of our drug candidates or, if applicable, accelerate marketing approval. RMAT designation does not change the evidentiary standards of safety and effectiveness needed for marketing approval.

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

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

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

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

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

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

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

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

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

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

Orphan drug designation may not ensure that we will enjoy 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 our CHF product candidate, rexlemestrocet-L has received orphan drug designation 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 ongoing BLA submission for paediatric 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 children 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. The outcome of this BLA application is uncertain, and there is a risk that it may not be approved by the FDA.

We have received Fast Track designation from the FDA for remestemcel-L in children with SR aGVHD. A biologic product that receives Fast Track designation can be eligible for regulatory benefits, including rolling BLA review. Rolling review of a BLA enables individual modules of the application to be submitted to and reviewed by the FDA on an ongoing basis, rather than waiting for all sections of a BLA to be completed before submission. If FDA accepts a portion of the BLA application for rolling review, this does not necessarily mean that FDA review will commence or proceed before the complete application is submitted. We reported that FDA has agreed we can submit on a rolling basis our BLA for remestemcel-L for children with SR-aGVHD and that we have filed the first component of this rolling submission. 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 FDA if the product no longer meets the qualifying criteria.

The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. During the course of review of our BLA, the FDA may request or require additional preclinical, clinical, chemistry and manufacturing, controls (or CMC), or other data and information. The development and provision of these data and information may be time consuming and expensive. Our failure to comply, or the failure of our contract manufacturers to satisfy, applicable FDA CMC requirements could result in a delay or failure to obtain approval of our BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in our submission and may request additional testing or information. The testing and approval process requires substantial time, effort and financial resources, and may take several years to complete. In addition, the FDA or other regulatory agencies may find the data from our clinical studies insufficient to support marketing approval. For example, our Phase 3 study for remestemcel-L, 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 intend to provide 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 likely that we will have to participate in FDA Advisory Committee proceedings in connection with the FDA's review of the BLA for our aGVHD product candidate as well as potentially other of our product candidates. FDA Advisory Committees are convened to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to FDA. New product candidates may be referred for review by Advisory Committees whether 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 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.

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 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 do not have any direct experience in manufacturing commercial quantities of any of our product candidates. 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 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.

We rely on Lonza as our sole supplier and manufacturer of 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 as our sole source 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 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 Lonza. 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 and the product candidates themselves. We rely exclusively on Lonza to supply certain of our product candidates. In addition, we rely on additional third parties to provide 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;
- 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. Further, we may be required to conduct additional clinical trials using 3D manufacturing processes before we receive regulatory approval.

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, Lonza for compliance with the regulatory requirements. If Lonza 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 Lonza 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 and patients 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. The United Kingdom's vote to leave the European Union creates 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 USPTO 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. We do not maintain “key person” insurance for any of our executives or other employees.

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 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, 2019, our cumulative operating losses have a total potential tax benefit of \$110.7 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 are 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.

There can be no assurances that we will continue to benefit from these incentives or that such tax incentive credit programs will not be revoked or modified in any way in the future. 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, such as us, 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.

For the year ended June 30, 2019, our combined worldwide turnover is in excess of A\$20.0 million making us ineligible for the refundable cash tax offset for the research and development tax incentive. As a result, we recognized income of \$Nil and \$1.4 million, respectively, from the Research and Development Tax Incentive program for the years ended June 30, 2019 and 2018.

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.

Risks Related to Our Trading Markets

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

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

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

- results of clinical trials of our product candidates;
- results of clinical trials of our competitors’ products;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated fluctuations in our quarterly operating results or those of our competitors;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- additions to or departures of our key management personnel;
- issuances by us of debt or equity securities;
- litigation or investigations involving our company, including: shareholder litigation; investigations or audits by regulators into the operations of our company; or proceedings initiated by our competitors or clients;

- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- changes in trading volume of ADSs on the Nasdaq and of our ordinary shares on the ASX;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, senior management or our shareholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical companies; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

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

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

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

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

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

Risks Related to Ownership of Our ADSs

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

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

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

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.

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

Further, as a foreign private issuer, we are exempt from certain rules under the “Exchange Act”, that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC’s Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, the information may not be disseminated in as timely a manner, or there may be less information publicly available concerning us generally than there is for a company that files as a domestic issuer.

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

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

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

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

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depository 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 depository 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 depository 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 depository as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depository, 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 depository 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, 2019, 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 depository 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 depository 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 depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 26, 2019

By: /s/ Silviu Itescu

Name: Silviu Itescu

Title: Chief Executive Officer