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 2016 for the period ended September 30, 2016

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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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$" or "dollars" or "U.S. dollars" are to the legal currency of the United States and references to "A$" 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 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 6K 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. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 6-K are 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 thousands, except per share amount)	Note	Three Months Ended September 30, 2016	2015
Revenue	3	395	7,513
Research & development		(14,004)	(11,089)
Manufacturing commercialization		(3,295)	(6,203)
Management and administration		(5,459)	(5,535)
Fair value remeasurement of contingent consideration		24	3,729
Other operating income and expenses		473	849
Finance costs		(1,037)	(2,424)
Loss before income tax	3	**(22,903)**	**(13,160)**
Income tax benefit/(expense)	4	3,105	—
Loss attributable to the owners of Mesoblast Limited		**(19,798)**	**(13,160)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**
Basic - losses per share		(5.24)	(3.94)
Diluted - losses per share		(5.24)	(3.94)

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

Consolidated Statement of Comprehensive Income
(unaudited)

(in thousands)	Note	Three Months Ended September 30, 2016	2015
(Loss)/profit for the year		**(19,798)**	**(13,160)**
Other comprehensive income			
Items that may be reclassified to profit and loss			
Changes in the fair value of available-for-sale financial assets		31	—
Exchange differences on translation of foreign operations		703	(3,593)
Other comprehensive (loss)/income for the period, net of tax		**734**	**(3,593)**
Total comprehensive (loss)/income is attributable to the owners of Mesoblast Limited		**(19,064)**	**(16,753)**

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

Consolidated Statement of Changes in Equity
(unaudited)

(in thousands)	Note	Issued Capital	Share Option Reserve	Investment Revaluation Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total
Balance as of July 1, 2015		**709,191**	**60,740**	**—**	**(37,984)**	**(263,960)**	**467,987**
Loss for the period		—	—	—	—	(13,160)	(13,160)
Other comprehensive income		—	—	—	(3,593)	—	(3,593)
Total comprehensive profit/(loss) for the period		**—**	**—**	**—**	**(3,593)**	**(13,160)**	**(16,753)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		268	—	—	—	—	268
	8	**268**	**—**	**—**	**—**	**—**	**268**
Transfer exercised options		134	(134)	—	—	—	—
Fair value of share-based payments		—	1,001	—	—	—	1,001
Reclassification of modified options to liability		—	323	—	—	—	323
		134	**1,190**	**—**	**—**	**—**	**1,324**
Balance as of September 30, 2015		**709,593**	**61,930**	**—**	**(41,577)**	**(277,120)**	**452,826**
Balance as of July 1, 2016		**770,272**	**64,999**	**(334)**	**(38,689)**	**(268,087)**	**528,161**
Loss for the period		—	—	—	—	(19,798)	(19,798)
Other comprehensive income		—	—	31	703	—	734
Total comprehensive profit/(loss) for the period		**—**	**—**	**31**	**703**	**(19,798)**	**(19,064)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		17	—	—	—	—	17
	8	**17**	**—**	**—**	**—**	**—**	**17**
Transfer exercised options		—	—	—	—	—	—
Fair value of share-based payments		—	847	—	—	—	847
Reclassification of modified options to liability		—	(89)	—	—	—	(89)
		—	**758**	**—**	**—**	**—**	**758**
Balance as of September 30, 2016		**770,289**	**65,757**	**(303)**	**(37,986)**	**(287,885)**	**509,872**

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

Consolidated Balance Sheet
(unaudited)

(in thousands)	Note	As of September 30, 2016	As of June 30, 2016
Assets			
Current Assets			
Cash & cash equivalents	5(a)	60,355	80,937
Trade & other receivables	5(b)	4,583	4,054
Prepayments	5(b)	5,759	3,832
Total Current Assets		**70,697**	**88,823**
Non-Current Assets			
Property, plant and equipment		2,925	3,063
Available-for-sale financial assets	5(d)	1,997	1,966
Other non-current assets		2,362	2,343
Intangible assets	6(a)	587,463	587,823
Total Non-Current Assets		**594,747**	**595,195**
Total Assets		**665,444**	**684,018**
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	28,119	27,155
Provisions		3,202	2,260
Total Current Liabilities		**31,321**	**29,415**
Non-Current Liabilities			
Deferred tax liability	6(b)	59,588	62,693
Provisions		64,663	63,749
Total Non-Current Liabilities		**124,251**	**126,442**
Total Liabilities		**155,572**	**155,857**
Net Assets		**509,872**	**528,161**
Equity			
Issued Capital	8	770,289	770,272
Reserves		27,468	25,976
(Accumulated losses)/retained earnings		(287,885)	(268,087)
Total Equity		**509,872**	**528,161**

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

Consolidated Statement of Cash Flows
(unaudited)

(in thousands)	Note	Three months ended September 30, 2016	2015
Cash flows from operating activities			
Commercialization revenue received		361	—
Payments to suppliers and employees (inclusive of goods and services tax)		(21,369)	(28,355)
Interest received		181	288
Net cash (outflows) in operating activities	7(b)	**(20,827)**	**(28,067)**
Cash flows from investing activities			
Payments for investments		—	(805)
Payments for licenses		—	(200)
Investment in fixed assets		(290)	(502)
Net cash (outflows) in investing activities		**(290)**	**(1,507)**
		—	
Cash flows from financing activities			
Proceeds from issue of shares		—	169
Payments for share issue costs		(55)	—
Net cash (outflows) / inflows by financing activities		**(55)**	**169**
Net (decrease)/increase in cash and cash equivalents		(21,172)	(29,405)
Cash and cash equivalents at beginning of period		80,937	110,701
FX (losses)/gains on the translation of foreign bank accounts		590	(3,535)
Cash and cash equivalents at end of period	7(a)	**60,355**	**77,761**

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. On November 18, 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 thousands of U.S. dollars ("$" or "USD"), unless otherwise noted, including certain amounts that are presented in thousands of Australian dollars ("AUD").

1. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was not particularly affected by any significant changes in the three months ended September 30, 2016.

(ii) Going concern

For the three months ended September 30, 2016 and 2015, the Group has incurred a total comprehensive loss after income tax of $19,064 and $16,753, respectively, and net cash outflows from operations of $20,827 and $28,067, respectively. As of September 30, 2016, the Group held total cash and cash equivalents of $60,355.

For the year ended June 30, 2017, the Group has committed to partnering one or more of its four key Tier 1 programs resulting in non-dilutive funding for operations. The Group is also continuing to work on various cost containment and deferment strategies, including the reprioritization of projects and operational streamlining. A fully discretionary equity facility has been established for up to A$120 million / US $90 million over 36 months to provide additional funds as required. The Group may consider issuing new capital to fund future operational requirements.

There is uncertainty related to the Group's ability to partner programs and raise capital at terms meeting the Group's timing and pricing requirements. Additionally, there is uncertainty related to the Group's ability to sustainably implement planned cost reductions and defer programs on a timely basis while achieving expected outcomes.

The continuing viability of the Group and its ability to continue as a going concern and meet its debts and commitments as they fall due are dependent upon either entering into an arrangement with a third party partner on one or more of its four key Tier 1 programs that would result in non-dilutive funding, or otherwise raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects and operational streamlining.

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 ("PCAOB") standards.

2. 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.

3. Loss before income tax

(in thousands)	Note	Three Months Ended September 30, 2016	2015
Revenue			
Commercialization revenue		218	3,751
Milestone Revenue		—	3,500
Interest Revenue		177	262
Total Revenue		**395**	**7,513**
Clinical trial research & development		**(9,325)**	**(4,963)**
Manufacturing production & development		**(1,626)**	**(4,549)**
Employee benefits			
Salaries and employee benefits		(5,915)	(7,189)
Defined contribution superannuation expenses		(90)	(84)
Equity settled share-based payment transactions[(1)]		(847)	(1,001)
Total Employee benefits		**(6,852)**	**(8,274)**
Depreciation and amortization of non-current assets			
Plant and equipment depreciation		(410)	(407)
Intellectual property amortization		(366)	(31)
Total Depreciation and amortization of non-current assets		**(776)**	**(438)**
Other Management & administration expenses			
Overheads & administration		(2,066)	(2,149)
Consultancy		(627)	(1,183)
Legals, patent and other professional fees		(789)	(767)
Intellectual property expenses (excluding the amount amortized above)		(697)	(504)
Total Other Management & administration expenses		**(4,179)**	**(4,603)**
Fair value remeasurement of contingent consideration			
Remeasurement of contingent consideration	5(d)(iii)	24	3,729
Total Fair value remeasurement of contingent consideration		**24**	**3,729**
Other operating income and expenses			
Research & development tax incentive[(2)]		482	1,106
Foreign exchange gains/(losses)		(9)	(257)
Total Other operating income and expenses		**473**	**849**
Finance costs			
Provisions: unwinding of discount	5(d)(iii)	(1,037)	(2,424)
Total Finance costs		**(1,037)**	**(2,424)**
Total loss before income tax		**(22,903)**	**(13,160)**

(1) Share-based payment transactions

For the three months ended September 30, 2016 and 2015, share-based payment transactions have been reflected in the consolidated Income Statement functional expense categories as follows: research and development $523 and $653, respectively, manufacturing commercialization $(9) and $146, respectively, and management and administration $333 and $202, respectively.

(2) Research and development tax incentive

The Group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditures from July 1, 2011. Management has assessed these activities and expenditures to determine which are likely to be eligible under the incentive scheme. At each period end management estimates the refundable tax offset available to the Group based on available information at the time. The Group employs independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim this tax incentive in Australia. For the three months ended September 30, 2016 and 2015, the Group has recognized income of $482 and $1,106, respectively.

Of the $482 research and development tax incentive recorded in other income for the three months ended September 30, 2016, $Nil relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2016.

Of the $1,106 research and development tax incentive recorded in other income for the three months ended September 30, 2015, $Nil relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2015.

4. Income tax benefit/(expense)

(in thousands)	Three Months Ended September 30, 2016	2015
(a) Income tax benefit/(expense)		
Current tax		
Current tax	—	—
Total current tax expense/(benefit)	**—**	**—**
Deferred tax		
Decrease/(increase) in deferred tax assets	(3,105)	—
(Decrease)/increase in deferred tax liabilities	—	—
Total deferred tax expense/(benefit)	**(3,105)**	**—**
Income tax expense/(benefit)	**(3,105)**	**—**

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

Following the Group's strategic review in June 2016 and the resulting operational streamlining, the Group recognized deferred tax assets for operating tax losses and deductible temporary differences in the jurisdictions where there are offsetting taxable temporary differences (deferred tax liabilities). Prior to this strategic review, the Group was in the process of consolidating certain intellectual property assets and consequently taxable temporary differences were not available to offset deferred tax assets in the same jurisdiction.

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.

	As of September 30, 2016	As of June 30, 2016
(b) Deferred tax assets not brought to account		
Unused tax losses		
Potential tax benefit at local tax rates	29,025	27,060
Other temporary differences		
Potential tax benefit at local tax rates	3,513	3,432
	32,538	**30,492**

As of September 30, 2016 and June 30, 2016, the Group has deferred tax assets not brought to account of $32,538 and $30,492, 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 thousands)	Notes	Assets at FVOCI[1]	Assets at FVTPL[2]	Assets at amortized cost	Total
As of September 30, 2016					
Cash & cash equivalents	5(a)	—	—	60,355	60,355
Trade & other receivables	5(b)	—	—	4,583	4,583
Available-for-sale financial asset		1,997	—	—	1,997
Other non-current assets		—	—	2,362	2,362
		1,997	**—**	**67,300**	**69,297**
As of June 30, 2016					
Cash & cash equivalents	5(a)	—	—	80,937	80,937
Trade & other receivables	5(b)	—	—	4,054	4,054
Available-for-sale financial asset		1,966	—	—	1,966
Other non-current assets		—	—	2,343	2,343
		1,966	**—**	**87,334**	**89,300**

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

Financial liabilities (in thousands)	Notes	Liabilities at FVOCI[1]	Liabilities at FVTPL[2]	Liabilities at amortized cost	Total
As of September 30, 2016					
Trade and other payables	5(c)	—	—	28,119	28,119
Provisions	5(d)	—	64,691	—	64,691
		—	**64,691**	**28,119**	**92,810**
As of June 30, 2016					
Trade and other payables	5(c)	—	—	27,155	27,155
Provisions	5(d)	—	63,716	—	63,716
		—	**63,716**	**27,155**	**90,871**

(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 this Note. The maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets mentioned above.

a. Cash and cash equivalents

(in thousands)	As of September 30, 2016	As of June 30, 2016
Cash at bank	16,036	21,860
Deposits at call[(1)]	44,319	59,077
	60,355	**80,937**

(1) As of September 30, 2016 and June 30, 2016, interest-bearing deposits at call include amounts of $4,724 and $4,598, respectively, held as security against future foreign exchange deals and are 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.

(ii) Market risk – interest rate risk

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, 2016 and June 30, 2016.

	As of September 30, 2016			As of June 30, 2016		
(in thousands, except percent data)	Low	High		Low	High	
Funds invested - USD	0.55%	0.55%	34,254	0.55%	0.90%	47,796
Funds invested - AUD	2.54%	2.54%	13,191	3.00%	3.04%	15,191

(iii) Market risk – currency risk

The Group has foreign currency amounts owing primarily in USD in Mesoblast Limited (AUD functional currency) relating to clinical, regulatory and overhead activities. The Group also has foreign currency amounts owing in various other non-USD currencies in USD 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.

(iv) Liquidity risk

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

All financial liabilities, excluding contingent consideration, held by the Group as of September 30, 2016 and June 30, 2016 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.

b. Trade and other receivables and prepayments

(in thousands)	As of September 30, 2016	As of June 30, 2016
Trade debtors	218	460
Income tax and tax incentives recoverable	3,378	2,818
Foreign withholding tax recoverable	471	471
Sundry debtors	142	242
Interest receivables	22	26
Other recoverable taxes (Goods and services tax and value-added tax)	96	24
Other receivables	256	13
Trade and other receivables	**4,583**	**4,054**

(in thousands)	As of September 30, 2016	As of June 30, 2016
Clinical trial research and development expenditure	4,724	2,684
Prepaid insurance and subscriptions	315	638
Other	720	510
Prepayments	**5,759**	**3,832**

(i) Classification as trade and other receivables

Interest receivables are amounts due at maturity of term deposits. All trade and other receivable balances are within their due dates and none are considered to be impaired as of September 30, 2016 and June 30, 2016.

(ii) Other receivables

These amounts generally arise from transactions outside the usual operating activities of the Group.

(iii) 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

(in thousands)	As of September 30, 2016	As of June 30, 2016
Trade payables and other payables	28,119	27,155
Trade and other payables	**28,119**	**27,155**

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. 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, 2016 and June 30, 2016 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of September 30, 2016 (in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Available-for-sale financial assets					
Equity securities - biotech sector		—	—	1,997	1,997
Total Financial Assets		—	—	**1,997**	**1,997**
Financial Liabilities					
Financial liabilities at fair value through profit or loss					
Contingent consideration	5(d)(iii)	—	—	64,691	64,691
Total Financial Liabilities		—	—	**64,691**	**64,691**

As of June 30, 2016 (in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Available-for-sale financial assets					
Equity securities - biotech sector		—	—	1,966	1,966
Total Financial Assets		—	—	**1,966**	**1,966**
Financial Liabilities					
Financial liabilities at fair value through profit or loss					
Contingent consideration	5(d)(iii)	—	—	63,716	63,716
Total Financial Liabilities		—	—	**63,716**	**63,716**

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

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

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and trading and available-for-sale 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, 2016 and the year ended June 30, 2016:

(in thousands)	Contingent consideration provision
Opening balance - July 1, 2015	91,890
Amount used during the year	(62)
Charged/(credited) to consolidated income statement:	
Unwinding of discount[1]	9,311
Remeasurement[2]	(37,423)
Closing balance - June 30, 2016	**63,716**
Opening balance - July 1, 2016	63,716
Amount used during the year	(38)
Charged/(credited) to consolidated income statement:	
Unwinding of discount[1]	1,037
Remeasurement	(24)
Closing balance September 30, 2016	**64,691**

(1) The unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement date of the contingent consideration.

(2) The remeasurement of $37,423 recognized in the year ended June 30, 2016 includes a gain of $34,548 relating to a reduction in contingent consideration expected to be paid to Osiris Therapeutics, Inc. ("Osiris") on the MSC-assets due to a greater certainty over the commencement of the earn out period. This change in assumption results in a reduction in the valuation of contingent consideration as an earlier earn out period results in royalties being applicable to sales in years that are prior to peak year sales. The remaining gain of $2,875 was recognized during the year ended June 30, 2016 as a result of changes to the key assumptions of contingent consideration valuation such as developmental timelines, market population, market penetration and product pricing.

(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 thousands, except percent data) Description	Fair value as of September 30, 2016	Fair value as of June 30, 2016	Valuation technique	Unobservable Inputs[1]	Range of inputs (weighted average) for Three Months Ended September 30, 2016	Range of inputs (weighted average) for Year Ended June 30, 2016	Relationship of unobservable inputs to fair value
Contingent consideration provision	64,691	63,716	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%. Year ended June 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2016: A 10% increase in the price assumptions adopted would increase the fair value by 6%. Year ended June 30, 2016: A 10% increase in the price assumptions adopted would increase the fair value by 6%.

(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, 2016 and the year ended June 30, 2016, 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 result of changes to key assumptions such as periods applicable to royalty payments, developmental timelines, market population, market penetration and product pricing.

The fair value of contingent consideration (in thousands)	As of September 30, 2016	As of June 30, 2016
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	30,366	30,327
Fair value of royalty payments from commercialization of the intellectual property acquired	34,325	33,389
	64,691	**63,716**

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.

6. Non-financial assets and liabilities

a. Intangible assets

(in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Current marketed products	Total
Year Ended June 30, 2016					
Opening net book value	134,453	2,091	513,697	—	650,241
Additions	—	75	—	—	75
Reclassifications[1]	—	—	(23,999)	23,999	—
Exchange differences	—	(7)	—	—	(7)
Amortization charge	—	(123)	—	(444)	(567)
Impairment charge[2]	—	—	(61,919)	—	(61,919)
Closing net book value	**134,453**	**2,036**	**427,779**	**23,555**	**587,823**
As of June 30, 2016					
Cost	134,453	2,769	489,698	23,555	650,475
Accumulated amortization	—	(733)	—	—	(733)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**2,036**	**427,779**	**23,555**	**587,823**
Three Months Ended September 30, 2016					
Opening net book value	134,453	2,036	427,779	23,555	587,823
Additions	—	—	—	—	—
Exchange differences	—	4	—	—	4
Amortization charge	—	(31)	—	(333)	(364)
Impairment charge	—	—	—	—	—
Closing net book value	**134,453**	**2,009**	**427,779**	**23,222**	**587,463**
As of September 30, 2016					
Cost	134,453	2,784	489,698	23,999	650,934
Accumulated amortization	—	(775)	(61,919)	(777)	(63,471)
Net book amount	**134,453**	**2,009**	**427,779**	**23,222**	**587,463**

(1) The Group reclassified $23,999 from in-process research and development ("IPRD") acquired to current marketed products upon TEMCELL® HS Inj. becoming available for use in Japan.

IPRD that was acquired as part of a business acquisition is not amortized as it is considered to be incomplete and cannot be used in its current form and therefore has an indefinite life. IPRD is tested for impairment annually, or when events or circumstances present an indication of impairment. IPRD will continue to be tested for impairment until the related research and development efforts are either completed or abandoned. Upon completion of the related research and development efforts, when the asset

becomes available for use, management determines the remaining useful life of the intangible assets and amortizes them accordingly. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and various other relevant factors.

In the case of abandonment, the related research and development efforts are considered impaired and the asset is fully expensed.

(2) The Group recognized $61,919 non-cash impairment charge during the year ended June 30, 2016 relating to the 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 of June 30, 2016 the Group had completed the Phase IIa MPC-MICRO-IO clinical trial and MPC-CBE was in a Phase III clinical trial. In June 2016, further patient enrolment of both programs was suspended as the Group prioritized the funding of the Tier 1 product candidates. Existing and future cash resources will be deployed on delivery of Tier 1 product candidates for the foreseeable future and therefore the Group is unable to ascertain when MPC-MICRO-IO and MPC-CBE patient enrolment will be restarted. Accordingly impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in line with the Group's accounting policy. These product candidates will remain technically viable and available to consider for future resource allocation and on this basis we have not abandoned the programs. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future. See Note 21(j) and Note 2 of the Group's consolidated financial statements for the year ended June 30, 2016 as filed with the Securities and Exchange Commission for accounting policy on impairment of intangible assets and segment information, respectively.

b. Deferred tax balances

(i) Deferred tax balances

(in thousands)	As of September 30, 2016	June 30, 2016
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	58,534	57,650
Other temporary differences	9,593	7,372
Total deferred tax assets	**68,127**	**65,022**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	127,715	127,715
Total deferred tax liabilities	**127,715**	**127,715**
Net deferred tax liabilities	**59,588**	**62,693**
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	68,127	65,022
Deferred tax liabilities expected to be settled within 12 months	—	—
Deferred tax liabilities expected to be settled after 12 months	127,715	127,715

(ii) Movements

(in thousands)	Tax losses[1] (DTA)	Other temporary differences[1] (DTA)	Intangible assets (DTL)	Total (DTL)
As of July 1, 2015	**—**	**—**	**149,387**	**149,387**
Charged/(credited) to:				
- profit or loss	(57,650)	(7,372)	(21,672)	(86,694)
As of June 30, 2016	**(57,650)**	**(7,372)**	**127,715**	**62,693**
Charged/(credited) to:				
- profit or loss	(884)	(2,221)	—	(3,105)
As of September 30, 2016	**(58,534)**	**(9,593)**	**127,715**	**59,588**

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

7. Cash flow information

(in thousands) (a) Reconciliation of cash and cash equivalents	As of September 30, 2016	As of September 30, 2015
Cash at bank	16,036	11,065
Deposits at call	44,319	66,696
	60,355	**77,761**

(b) Reconciliation of net cash flows used in operations with loss after income tax	Three months ended September 30, 2016	Three months ended September 30, 2015
Loss for the period	(19,798)	(13,160)
Add/(deduct) net loss for non-cash items as follows:		
Commercialization revenue	—	(3,751)
Depreciation and amortization	774	439
Foreign exchange (gains)/losses	10	181
Finance costs	1,037	2,424
Remeasurement of contingent consideration	(24)	(3,729)
Equity settled share-based payment	847	1,001
Deferred tax benefit	(3,105)	—
Change in operating assets and liabilities:		
(Increase)/decrease in trade and other receivables	63	(3,485)
Decrease/(increase) in prepayments	(1,870)	(227)
(Increase)/decrease in tax assets	(482)	(1,106)
(Decrease)/increase in trade creditors and accruals	922	(3,259)
(Decrease)/increase in provisions	799	(3,395)
Net cash outflows used in operations	**(20,827)**	**(28,067)**[1]

(1) Within operating cash flows are share issue costs of $315 associated with the November 2015 NASDAQ IPO equity raising incurred during the three months ended September 30, 2015.

8. Issued capital

	As of September 30,		As of September 30,	
	2016	2015	2016	2015
	Shares No.		(in thousands)	
Opening balance	381,373,137	336,997,729	770,272	709,191
Issues of ordinary shares during the period				
Exercise of share options[1]	—	422,903	—	268
Purchase consideration	280,911	—	240	
Transaction costs arising on share issue			(223)	—
	280,911	422,903	17	268
Share options reserve transferred to equity on exercise of options			—	134
Ending balance	**381,654,048**	**337,420,632**	**770,289**	**709,593**

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

9. Events occurring after the reporting period

There are no events that have occurred after September 30, 2016 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

10. 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. 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. These interim financial statements follow the same accounting policies as compared to the June 30, 2016 consolidated financial statements and related notes as filed with the Australian Securities Exchange and the Securities and Exchange Commission.

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 21(d) in the notes to our consolidated financial statements and the related notes thereto included in our annual report on Form 20-F for the fiscal year ended June 30, 2016 ("Form 20-F"), filed with the Securities and Exchange Commission on August 25, 2016, 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

We are a global leader in developing innovative cell-based medicines. We have leveraged our proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (MLCs), to establish a broad portfolio of late-stage product candidates. Our product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular diseases, immunologic and inflammatory conditions, orthopedic disorders, and oncology and hematology conditions. Each MLC-derived product candidate has distinct technical characteristics, target indications, individual reimbursement strategy, separate commercialization potential, and unique partnering opportunities.

On November 14, 2016, we announced that the Phase 3 trial in intravenous product candidate MSC-100-IV used as front-line therapy in children with steroid-resistant acute graft versus host disease (aGVHD) was successful in a pre-specified interim futility analysis conducted by the independent Data Safety Monitoring Board. The interim analysis showed that the predefined Bayesian futility rule used to determine the probability of the trial's success using the trial's primary endpoint of Day 28 overall response had been passed.

On October 6, 2016, we announced that results from our randomized, placebo-controlled Phase 2 trial of our proprietary allogeneic Mesenchymal Precursor Cell (MPC) product candidate, MPC-300-IV, in patients with diabetic kidney disease have been published the peer-reviewed journal *EBioMedicine*.

Key trial results were:

- the safety profile for MPC-300-IV diabetic kidney disease treatment was similar to placebo, with no treatment-related adverse events;
- efficacy testing showed that patients receiving a single MPC infusion at either dose (150 million MPCs or 300 million MPCs) had improved renal function relative to placebo, as defined by preservation or improvement in glomerular filtration rate (GFR) at 12 weeks;
- the rate of decline in estimated GFR at 12 weeks was significantly reduced in the group receiving a single dose of 150 million MPCs relative to the placebo group ($p=0.05$); and
- there was a trend toward more pronounced treatment effects relative to placebo in the pre-specified subgroup of patients with GFR>30ml/min/1.73m^2 at baseline ($p=0.07$).

The Phase 2 trial in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released on August 9, 2016.

An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks. A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit.

Mesoblast's Phase 2 trial recruited a total of 48 patients with active RA who were on a stable regimen of methotrexate and had an inadequate prior clinical response to at least one anti-Tumor Necrosis Factor (TNF) agent. Of the 48 patients, 30 (63%) had previously received 1-2 biologic agents. Patients were randomized to a single intravenous infusion of 1 million MPCs/kg (1M/kg,

n=16), 2 million MPCs/kg (2M/kg, n=16) or placebo (n=16). The study was comprised of a 12 week primary study period with a 40 week follow-up for a study total duration of 52 weeks.

The primary objective of the study was to evaluate safety and tolerability of a single intravenous MPC infusion in biologic refractory RA patients through a 12 week primary endpoint. Additional objectives were to evaluate pre-specified clinical efficacy endpoints at the primary 12 week timepoint, as well as to assess the onset and time course of effect within the first 12 weeks and subsequent durability of effects and safety profile through the full 52 week study. The American College of Rheumatology (ACR) response, a validated measure of clinical symptoms and signs, and DAS28, a validated measure of disease activity, were assessed at baseline and weeks 1, 4, 8 and 12. The health assessment questionnaire disability index (HAQ-DI), a validated measure of function, was assessed at baseline and weeks 4 and 12. Analyses were performed for the whole study population and for the pre-specified exploratory subgroup based on whether the subjects had previously received 1-2 or more than 2 biologic agents. All analyses and test methods for the trial's efficacy endpoints were pre-specified in the trial's Statistical Analysis Plan. No post hoc analyses were conducted.

Key results at week 12 were:

- cell infusions were well tolerated with no infusion-related adverse events. There were no serious adverse events, and the safety profile over 12 weeks was comparable among placebo and MPC treatment groups;
- there was a dose-related improvement in many of the individual components of the ACR composite following MPC treatment; the 2M/kg group who had previously received 1-2 biologics showed significant improvement over placebo in each of the following categories: swollen joint counts, investigator global assessment, patient global assessment, and patient pain scores;
- ACR70 responses overall showed a dose-related effect after a single MPC infusion, with the greatest effect seen in the 2M/kg group who had previously received 1-2 biologics (36% vs 0% placebo);
- ACR50 responses overall showed a dose-related effect after a single MPC infusion, with the greatest effect seen in the 2M/kg group who had previously received 1-2 biologics (55% vs 11% placebo);
- ACR20 responses were greater in both the 2M/kg and 1M/kg group who had previously received 1-2 biologics than placebo (55% and 60%, respectively, vs 33% placebo);
- a single MPC infusion resulted in a dose-related improvement in function, based on reduction in mean HAQ-DI levels as early as week 4 and sustained reduction in mean HAQ-DI through 12 weeks; maximal effect was seen in the 2M/kg group who had previously received 1-2 biologics (-0.7 vs -0.1 placebo);
- at 12 weeks, MPC treatment resulted in a dose-related increase in the number of patients achieving a minimum clinically important improvement in physical function, defined as a reduction of at least -0.22 in the HAQ-DI; the greatest effect was seen in the 2M/kg group who had previously received 1-2 biologics (91% vs 33% placebo);
- a single MPC infusion resulted in a dose-related reduction in the mean DAS28 activity score relative to placebo, and in an increase in the number of patients achieving the biologically-meaningful target of low disease activity state, defined as DAS28-CRP <3.2.

On August 1, 2016, we announced that the 24-month results from our 100-patient, four-arm, randomized, placebo-controlled Phase 2 trial of our chronic low back pain product candidate, MPC-06-ID, were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award at the meeting.

Key trial results were:

- the procedure and treatment were well tolerated, without any significant differences in safety between cell-treated patients and controls;
- the 6 million MPC dose, currently used in the ongoing Phase 3 trial, resulted in the greatest proportion of patients meeting the Phase 3 primary endpoint of Overall Treatment Success (the composite of both pain and functional responder status) through 24 months;
- a significantly greater proportion of subjects who received 6 million MPCs achieved the pain responder criteria at both 12 and 24 months (50% pain reduction from baseline, as measured using a visual analog scale, with no intervention) than saline-treated controls (50.0% vs 12.5%, p=0.020); pain responder criteria were met by 36.0% of patients who received 18 million MPCs and by 23% who received hyaluronic acid;
- a significantly greater proportion of subjects who received 6 million MPCs achieved the functional responder criteria at both 12 and 24 months (15 point functional improvement from baseline, as measured by the Oswestry disability index, with

no intervention) than saline-treated controls (46.2% vs 12.5%, p=0.042); functional responder criteria were met by 53.9% of patients who received 18 million MPCs (p=0.01 vs saline) and by 29.4% who received hyaluronic acid;

- overall Treatment Success at 12 months was achieved by 50% of patients in the 6 million MPC group compared with 18.8% in the saline group (p=0.056); 77% of MPC-treated patients who achieved Overall Treatment Success at 12 months maintained this at 24 months (p=0.09 vs saline);
- overall Treatment Success at both 12 and 24 months was achieved by 38.5% of the 6 million MPC group, 34.6% of the 18 million MPC group, 17.7% of the hyaluronic acid group, and 12.5% of the saline group.

Mergers and Acquisitions

We had no mergers or acquisitions during the three months ended September 30, 2016.

Financial Overview

We have incurred significant losses since our inception. 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 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 that our research and development as well as management and administration expenses will decrease in the short term. Subject to us achieving successful regulatory approval, we expect an increase in our total expenses driven by an increase in our 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. As described in Note 1(ii) to our accompanying audited financial statements, a fully discretionary equity facility has been established for up to A$120 million / US $90 million over 36 months to provide additional funds as required. 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.

Commercialization and Milestone Revenue. Commercialization and milestone revenue relates to upfront, royalty and milestone payments recognized under development and commercialization agreements.

In the year ended June 30, 2011, we received upfront payments of $130.0 million under a development and commercialization agreement (“DCA”), with Cephalon, Inc., now a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd (collectively “Teva”), which allowed for Teva to obtain world-wide rights to commercialize our mesenchymal precursor cell (MPC) technology platform for specific products in our cardiovascular portfolio. In the month of June 2016, Teva exercised a contractual right under the

DCA to end the joint development of the lead asset in our cardiovascular portfolio, product candidate MPC-150-IM, and we regained full world-wide rights on this product candidate.

Revenues from such non-refundable, up-front payments are initially reported as deferred revenues on the consolidated balance sheet and are recognized in revenue as earned over the estimated development period. As the joint development of product candidate MPC-150-IM was ended in the month of June 2016, we recognized in revenue the remaining full amount of deferred revenues during the month of June 2016. There are no further performance obligations required of us in relation to this DCA. Prior to June 2016, management could not readily estimate the costs required to complete the development program pursuant to the DCA and concluded that the revenue was earned over the estimated development period of MPC-150-IM. Therefore, during the period from the initial recognition date until June 2016, revenues from the up-front payments received were recognized on a straight line basis over the estimated development period of this product candidate.

In the three months ended September 30, 2016, we recognized $Nil in milestone revenue. In the three months ended September 30, 2015, we recognized $3.5 million in milestone revenue from JCR Pharmaceuticals Co. Ltd. ("JCR") for the receipt of full regulatory approval of TEMCELL® HS Inj. in Japan, which is a substantive milestone under our agreement with JCR. This amount was recorded in revenue as there are no further performance obligations required in regards to these items.

We commenced earning royalty income on sales of TEMCELL® HS Inj. by our licensee JCR after the product's launch in Japan on February 24, 2016.

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;
- 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); and
- intellectual property support costs comprising payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents.

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

Management and Administration. Management and administration expenses consist primarily of salaries and related costs 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 result of changes to the key assumptions of the contingent consideration valuation such as periods applicable to royalty payments, developmental timelines, market population, market penetration and product pricing. As the net result of changes to the key assumptions in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones, we recognized a remeasurement gain of $0.024 million and a loss of $3.7 million for the three months ended September 30, 2016 and 2015.

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

Tax incentives comprise payments from the Australian government's Innovation Australia Research and Development Tax Incentive Plan for research and development activities conducted in Australia in relation to our qualifying research that meets the regulatory criteria. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A$20.0 million. The commercialization revenue is not subject to inclusion in the determination of the annual aggregate turnover measure. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For the three months ended September 30, 2016 and 2015, the rate of the refundable tax offset is 43.5% and 45%, respectively. We recognized income of $0.5 million and $1.1 million, respectively, from research and development tax incentives in the three months ended September 30, 2016 and 2015.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our U.S. dollar deposits plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates. We recognized $Nil million foreign exchange losses in the three months ended September 30, 2016 and a foreign exchange loss of $0.3 million in the three months ended September 30, 2015.

Finance Costs. Finance costs relate to the unwinding of contingent consideration items pertaining to the Mesenchymal Stem Cells ("MSC") assets of Osiris. We did not have any borrowings outstanding as of September 30, 2016 and 2015.

Results of Operations:

Comparison of Our Results for the Three Months Ended September 30, 2016 with the Three Months Ended September 30, 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015, together with the changes in those items in dollars and as a percentage.

(in thousands except per share information)	Three months ended September 30, 2016	2015	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 218	$ 3,751	(3,533)	(94%)
Milestone revenue	—	3,500	(3,500)	(100%)
Interest revenue	177	262	(85)	(32%)
Total revenue	**395**	**7,513**	**(7,118)**	**(95%)**
Research & development	(14,004)	(11,089)	(2,915)	26%
Manufacturing commercialization	(3,295)	(6,203)	2,908	(47%)
Management and administration	(5,459)	(5,535)	76	(1%)
Fair value remeasurement of contingent consideration	24	3,729	(3,705)	(99%)
Other operating income and expenses	473	849	(376)	(44%)
Finance costs	(1,037)	(2,424)	1,387	(57%)
Loss before income tax	**(22,903)**	**(13,160)**	**(9,743)**	**74%**
Income tax benefit/(expense)	3,105	—	3,105	NM
Loss attributable to the owners of Mesoblast Limited	**$ (19,798)**	**$ (13,160)**	**(6,638)**	**50%**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	**Cents**	**Cents**	**Cents change**	**% Change**
Basic - losses per share	(5.24)	(3.94)	(1.29)	33%
Diluted - losses per share	(5.24)	(3.94)	(1.29)	33%

* NM = not meaningful.

Revenue

Revenues were $7.5 million for the three months ended September 30, 2015, compared with $0.4 million for the three months ended September 30, 2016, a decrease of $7.1 million. The following table shows the movement within revenues for the three months ended September 30, 2016 and 2015, together with the changes in those items.

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Revenue:				
Commercialization revenue	$ 218	$ 3,751	(3,533)	(94%)
Milestone revenue	—	3,500	(3,500)	(100%)
Interest revenue	177	262	(85)	(32%)
Revenue	**$ 395**	**$ 7,513**	**(7,118)**	**(95%)**

Commercialization revenue was $0.2 million in the three months ended September 30, 2016, a decrease of $3.5 million compared with $3.8 million in the three months ended September 30, 2015. The $3.5 million decrease in commercialization revenue is primarily due to the recognition of $3.8 million of revenue for the three months ended September 30, 2015, being the amortization of the initial up-front payments of $130.0 million received under the DCA with Teva over our initial estimated development program term, compared to $Nil in the three months ended September 30, 2016 as we had fully recognized the remaining deferred revenue amounts relating to the $130.0 million upfront payment in June 2016. This decrease of commercialization revenue in the three months ended September 30, 2016 was offset by an increase of $0.2 million relating to royalty income earned on sales of TEMCELL® HS Inj. in Japan since the launch of the product on February 24, 2016 by our licensee JCR, compared to $Nil for the three months ended September 30, 2015.

We recognized $3.5 million in milestone revenue in the three months ended September 30, 2015 upon our licensee, JCR, receiving full regulatory approval of MSC product TEMCELL® HS Inj. in Japan, which is a substantive milestone under our agreement with JCR. There was no milestone revenue recognized in the three months ended September 30, 2016.

The $0.1 million decrease in interest revenue in the three months ended September 30, 2016 compared with the three months ended September 30, 2015 was primarily driven by us retaining a higher proportion of cash reserves in US$ instead of with A$ in the three months ended September 30, 2016, when compared with the three months ended September 30, 2015. This change in cash reserve holdings decreased revenue as yields on US$ cash deposits are lower than yields on A$ cash deposits. We increased the proportion of cash reserves held in US$ to reduce currency risk. Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

Research and development

Research and development expenses were $14.0 million in the three months ended September 30, 2016, compared with $11.1 million in the three months ended September 30, 2015, an increase of $2.9 million. The $2.9 million net increase in research and development expenses primarily reflects an increase in expenditures on our Tier 1 products which were offset by a reduction in product support costs as management reduced costs in line with our corporate strategy.

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Research and development:				
Third party costs	$ 8,745	$ 4,160	4,585	110%
Product support costs	4,532	6,403	(1,871)	(29%)
Intellectual property support costs	727	526	201	38%
Research and development	**$ 14,004**	**$ 11,089**	**2,915**	**26%**

Third party costs, which consist of all external expenditure on our research and development programs, increased by $4.6 million in the three months ended September 30, 2016 compared with the three months ended September 30, 2015.

Within this $4.6 million increase, there was a $3.8 million increase in third party costs for the advancement of our Tier 1 products due to clinical advancement during the period for the three months ended September 30, 2016 compared with the three months ended September 30, 2015, primarily due to the increased costs on our clinical program for MPC-150-IM (Class II-IV Congestive Heart Falure) as we regained full world-wide rights from Teva on this product candidate in the month of June 2016 and consequentially we were responsible for all research and development expenditure incurred on this product candidate in the three months ended September 30, 2016 whereas Teva was responsible for research and development expenses in the three months ended September 30, 2015. In the three months ended September 30, 2016, we also incurred costs on our MPC-06-ID (Chronic Low Back Pain), MSC-100-IV (acute Graft versus Host Disease), and MPC-300-IV (inflammatory conditions) Tier 1 products. In addition to the increase in Tier 1 third party costs, there was also a $0.8 million increase in Tier 2 third party costs for our Tier 2 and pipeline products for the three months ended September 30, 2016, compared with the three months ended September 30, 2015.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have decreased by $1.9 million for the three months ended September 30, 2016 compared with the three months ended September 30, 2015. In the three months ended September 30, 2016, operational streamlining initiatives took place resulting in full time equivalents reducing by 21.9 from 77.3 for the three months ended September 30, 2015 to 55.4 for the three months ended September 30, 2016. This lead to a cost savings of $1.2 million in salaries, $0.1 million in share based payments, $0.3 million in consultancy expenses and $0.3 million in travel and recruitment expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

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 increased by $0.2 million in the three months ended September 30, 2016 compared with the three months ended September 30, 2015 due to increased activities across our entire patent portfolio.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in the manufacturing commercialization of our MPC and MSC based products, decreased by $2.9 million in the three months ended September 30, 2016 compared to the three months ended September 30, 2015 primarily due to a decrease in the number of production runs completed in the three months ended September 30, 2016 compared to the three months ended September 30, 2015 due to the clinical supply demands of our Tier 1 products for MSC based products being met and a credit for MSC based product expenditure incurred in prior years.

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Manufacturing commercialization:				
MSC platform technology	$ (715)	$ 4,542	(5,257)	(116%)
MPC platform technology	3,455	794	2,661	NM
Manufacturing support costs	555	867	(312)	(36%)
Manufacturing commercialization	**$ 3,295**	**$ 6,203**	**(2,908)**	**(47%)**

* NM = not meaningful.

The MSC-based manufacturing commercialization expenses decreased by $5.3 million in the three months ended September 30, 2016 compared to the three months ended September 30, 2015. $4.1 million of this decrease was a result of no MSC-based production being undertaken in the three months ended September 30, 2016 whereas 100% of production runs in the three months ended September 30, 2015 were for MSC-based clinical supply. The remaining decrease of $1.2 million relates to a credit received in the three months ended September 30, 2016 for MSC-based product expenditure incurred in prior years.

The MPC-based manufacturing commercialization expenses increased by $2.7 million in the three months ended September 30, 2016 compared to the three months ended September 30, 2015 as 100% of the production runs were for MPC-based clinical supply in the three months ended September 30, 2016 whereas no MPC-based production was undertaken in the three months ended September 30, 2015. The balance of expenditure incurred in both the three month periods ended September 30, 2016 and 2015 was for process development activities.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, decreased by $0.3 million from $0.9 million for the three months ended September 30, 2015 to $0.6 million for the three months ended September 30, 2016. Full time equivalents remained relatively consistent for the three months ended September 30, 2016 compared to the three months ended September 30, 2015, decreasing by 0.2 from 10.2 for the three months ended September 30, 2015 to 10.0 for the three months ended September 30, 2016. There was a decrease in manufacturing support expenses, primarily due to a cost savings of $0.2 million that was realized in share based payments resulting from the attrition of staff. Manufacturing support costs also benefited by a decrease of $0.1 million in consulting and travel expenditure due to management's cost reduction efforts.

Management and administration

Management and administration expenses remained relatively consistent with $5.4 million recognized for the three months ended September 30, 2016, compared with $5.5 million for the three months ended September 30, 2015, remaining relatively consistent with a decrease of $0.1 million. This decrease was primarily due to a reduction in labor and associated expenses, and legal and professional fees offset by corporate overhead increases for insurance costs and unfavorable exchange rate fluctuations as the A$ strengthened against the US$ given that the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 2,576	$ 2,736	(160)	(6%)
Corporate overheads	2,352	2,160	192	9%
Legal and professional fees	531	639	(108)	(17%)
Management and administration	**$ 5,459**	**$ 5,535**	**(76)**	**(1%)**

Labor and associated expenses decreased by $0.2 million from $2.7 million for the three months ended September 30, 2015 to $2.5 million for the three months ended September 30, 2016. Within this $0.2 million decrease is a reduction of $0.2 million in consultancy expenses due to management's cost reduction efforts and other associated expenses decreased by $0.1 million. This decrease was offset by an increase of $0.1 million due to an increase of the valuation of share based payments resulting from changes in the key assumptions such as share price and risk free rate. Labor and associated expenses also experienced unfavorable exchange rate fluctuations of $0.1 million as described above. The full time equivalents remained consistent for the three months ended September 30, 2016 with no change from 22.7 for the three months ended September 2015.

Corporate overhead expenses increased by $0.2 million from $2.2 million for the three months ended September 30, 2015 to $2.4 million due to increased insurance costs.

Legal and professional fees decreased by $0.1 million from $0.6 million for the three months ended September 30, 2015 to $0.5 million for the three months ended September 30, 2016 due to reductions on intellectual property management and associated legal, taxation and accounting compliance advice.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was $0.024 million for the three months ended September 30, 2016 compared with a $3.7 million gain for the three months ended September 30, 2015, a decrease of $3.7 million. The $0.024 million of remeasurement in the three months ended September 30, 2016 is due to a revaluation of the estimated royalties, compared to $Nil for the three months ended September 30, 2015. The $3.7 million gain recognized in the three months ended September 30, 2015 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is as a result of changes to the key assumptions of the contingent consideration valuation such as product pricing, market population and developmental timelines. The net result of changes to the key assumptions was a decrease in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones.

Other operating income and expenses

Other operating income and expenses were $0.5 million for the three months ended September 30, 2016, compared with $0.8 million for the three months ended September 30, 2015, a decrease of $0.3 million. The following table shows movements within other operating income and expenses for the three months ended September 30, 2016 and 2015, together with the changes in those items:

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Other operating income and expenses:				
Research and development tax incentive income	$ 482	$ 1,106	(624)	(56%)
Foreign exchange (losses)/gains (net)	(9)	(257)	248	(96%)
Other operating income and expenses	**$ 473**	**$ 849**	**(376)**	**(44%)**

Research and development tax incentive income decreased by $0.6 million from $1.1 million for the three months ended September 30, 2015 to $0.5 million for the three months ended September 30, 2016. We have recognized incentive income pertaining to the eligible expenditure undertaken in each of these periods. At each period end, management estimates the refundable tax incentive available to us based on available information at the time. We employ independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim the research and development tax incentive in Australia.

Of the $0.5 million and $1.1 million research and development tax incentive recorded in other income for the three months ended September 30, 2016 and 2015, respectively, there was no change in the original estimate of the research and development tax incentive income we estimated we would receive from the Australian government for the years ended June 30, 2016 and 2015, respectively.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors and these balances are minimal and therefore in the three months ended September 30, 2016 and 2015, only minor foreign exchange losses have been recognized.

Finance costs

Finance costs decreased by $1.4 million from $2.4 million for the three months ended September 30, 2015 to $1.0 million for the three months ended September 30, 2016. The finance costs for both the three months ended September 30, 2016 and 2015 represent the unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement dates of contingent consideration of the acquired MSC assets of Osiris. 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 the profits generated. The decrease of $1.4 million is driven by a reduction in the valuation of contingent consideration at September 30, 2016 compared to September 30, 2015.

Loss after income tax

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Loss before income tax	$ (22,903)	$ (13,160)	(9,743)	74%
Income tax benefit/(expense)	3,105	—	3,105	NM
Loss after income tax	**$ (19,798)**	**$ (13,160)**	**(6,638)**	**50%**

* NM = not meaningful.

Loss before income tax was $22.9 million for the three months ended September 30, 2016 compared with $13.2 million for the three months ended September 30, 2015, a decrease of $9.7 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 $3.1 million was recognized in the three months ended September 30, 2016, compared with $Nil for the three months ended September 30, 2015.

Following our strategic review in June 2016 and the resulting operational streamlining, we recognized deferred tax assets for operating tax losses and deductible temporary differences in the jurisdictions where there are offsetting taxable temporary differences (deferred tax liabilities). Prior to this strategic review, we were in the process of consolidating certain intellectual property assets and consequently taxable temporary differences were not available to offset deferred tax assets in the same jurisdiction.

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.

As of September 30, 2016 and June 30, 2016, our cumulative operating losses have a total potential tax benefit of $87.6 million and $84.7 million at local tax rates (excluding other temporary differences), respectively, which may be available for us once we are in a taxable profit position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdiction. Further, 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.

Liquidity and Capital Resources

Sources of liquidity

We have incurred losses from operations since our inception in 2004 and as of September 30, 2016, we had an accumulated deficit of $287.9 million. We had cash and cash equivalents of $60.4 million as of September 30, 2016 and incurred net cash outflows from operations of $20.8 million for the three months then ended.

For the year ended June 30, 2017, we have committed to partnering one or more of our four key Tier 1 programs resulting in non-dilutive funding for operations. We are also continuing to work on various cost containment and deferment strategies, including the reprioritization of projects and operational streamlining. A fully discretionary equity facility has been established for up to A$120.0 million / US$90.0 million over 36 months to provide additional funds as required. We may consider issuing new capital to fund future operational requirements.

There is uncertainty related to our ability to partner programs and raise capital at terms meeting our timing and pricing requirements. Additionally, there is uncertainty related to our ability to sustainably implement planned cost reductions and defer programs on a timely basis while achieving expected outcomes.

The continuing viability of us and our ability to continue as a going concern and meet our debts and commitments as they fall due are dependent upon either entering into an arrangement with a third party partner on one or more of our four key Tier 1 programs that would result in non-dilutive funding, or raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects and operational streamlining.

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 ("PCAOB") standards. For our audited financial statements, see "Item 18 Financial Statements" included in our Form 20-F.

Cash flows

(in thousands)	Three months ended September 30, 2016	2015	$ Change	% Change
Cash Flow Data:				
Net cash (outflows) in operating activities	$ (20,827)	$ (28,067)	7,240	(26%)
Net cash (outflows) in investing activities	(290)	(1,507)	1,217	(81%)
Net cash inflows in financing activities	(55)	169	(224)	(133%)
Net (decrease) in cash and cash equivalents	**$ (21,172)**	**$ (29,405)**	**8,233**	**(28%)**

Net cash outflows in operating activities

Net cash outflows for operating activities were $20.8 million for the three months ended September 30, 2016, compared with $28.1 million for the three months ended September 30, 2015, a decrease of $7.2 million. Outflows decreased by $6.9 million due to operational streamlining efforts that reduced full time equivalents and salary and other associated costs and a decrease in payments to suppliers in relation to research and development costs. This was offset by interest receipts which reduced by $0.1 million as we held a higher proportion of cash reserves in US$ compared with A$ in the three months ended September 30, 2016, when compared with the three months ended September 30, 2015. Inflows from commercialization payments received increased by $0.4 million for royalty income earned on sales of TEMCELL® HS Inj. in Japan during the three months ended September 30, 2016.

Net cash outflows in investing activities

Net cash outflows for investing activities were $0.3 million for the three months ended September 30, 2016, compared with $1.5 million for the three months ended September 30, 2015, a decrease of $1.2 million. This decrease was primarily due to a $0.8 million reduction in payments for investments, a decrease of $0.2 million for payments for licenses and a decrease of $0.2 million related to lower payments for fixed assets, such as plant and equipment for our clinical trials as well as office and computer equipment for our staff in the three months ended September 30, 2016.

Net cash inflows in financing activities

Net cash outflows for financing activities were $0.1 million for the three months ended September 30, 2016, compared with cash inflows for financing activities of $0.1 million for the three months ended September 30, 2015, a decrease of $0.2 million. This decrease was due to $0.1 million decrease in receipts from employee share option exercises and an increase of $0.1 million for share issue costs in the three months ended September 30, 2016.

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 incident 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 as well as management and administration expenses will decrease in the short term. Subject to us achieving successful regulatory approval we expect an increase in our total expenses driven by an increase in our 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 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

Lease and sub-lease commitments

We lease various offices under non-cancellable operating leases expiring within 1 to 5 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 operating lease. There have been no material updates to our lease commitments disclosure included in our Form 20-F.

Contingent liabilities

We will be required to make a milestone payment to Central Adelaide Local Health Network Incorporated, or CALHNI, of $0.25 million on completion of each Phase 3 (human) clinical trial and $0.35 million on each United States Food and Drug Administration ("FDA") marketing approval for products in the orthopedic field. We will pay CALHNI a commercial arm's length royalty based on net sales by us of licensed products in the orthopedic field each quarter.

We may also be required to pay consideration to CALHNI upon successful completion of subsequent clinical milestones in fields other than orthopedic.

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. As of September 30, 2016 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, 2016.

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 21 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

We are not exposed to typical interest rate risk, which is the impact of interest rates on the cost of servicing and repaying debt. Our exposure to interest rate arises through movements in regards to 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 spreading the maturity date of our deposits across various periods. Our strategy of entering into new deposits as old deposits mature and reinvesting surplus funds ensures that we spread the timing of new deposits which assists us to achieve the average interest rates available in the market throughout the year. We also ensure that sufficient funds are available, in at-call accounts, to meet our cash flow requirements.

Foreign currency exchange risk

We have foreign currency amounts owing primarily in our Australian parent entity, whose functional currency is the A$, 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.

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

Revenues comprise the fair value of the consideration received or receivable.

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.

Where such arrangements can be divided into separately identifiable components (each component constituting a separate earnings process), the arrangement consideration is allocated to the different components based on their relative fair values and recognized over the respective performance period in accordance with IAS 18 Revenue. Where the components of the arrangement cannot be divided into separate units, the individual deliverables are combined as a single unit of accounting and the total arrangement consideration is recognized over the estimated collaboration period. Such analysis requires considerable estimates and judgments to be made by us, including the relative fair values of the various elements included in such agreements and the estimated length of the respective performance periods.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as

deferred revenue, within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, within non-current liabilities.

Cephalon arrangement

In December 2010, we entered into a development and commercialization agreement ("DCA"), with Cephalon, Inc., now a wholly-owned subsidiary of Teva, which allowed for Teva to obtain world-wide rights to commercialize specific products based on our proprietary adult stem cell technology platform. As part of the DCA, we received $130.0 million as a non-refundable up-front payment. In the month of June 2016, Teva exercised a contractual right under the DCA to end the joint development of the lead asset in our cardiovascular portfolio, product candidate MPC-150-IM, and we regained full world-wide rights on this product candidate.

As the joint development of product candidate MPC-150-IM was ended in the month of June 2016, we brought the remaining full amounts of deferred revenues to account. During the period from the initial recognition date until June 2016, the revenue was being recognized on a straight line basis over the estimated development period of product candidate, MPC-150-IM. For the three months ended September 30, 2015, we recognized $3.8 million of revenue, being the amortization of the initial payment over the estimated development program term. The recognition of commercialization revenue relating to the deferred revenue amounts in the three months ended September 30, 2015 had no impact to cash flows as the cash receipt pertaining to this revenue recognized was received in the year ended June 30, 2011. Our policy of reviewing the estimated development program term was on a quarterly basis.

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 model 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, 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 development and 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. Royalty revenue is recognized upon the sale of the related products provided we have no remaining performance obligations under the arrangement.

In the three months ended September 30, 2016, we recognized $0.3 million in commercialization revenue relating to royalty income earned on sales of TEMCELL® HS Inj. in Japan since the launch of the product on February 24, 2016, by our licensee JCR, compared to $Nil for the three months ended September 30, 2015. This amount was recorded in revenue as there are no further performance obligations required in regards to this item.

In the three months ended September 30, 2015, we recognized $3.5 million in milestone revenue from JCR for the receipt of full regulatory approval of TEMCELL® HS Inj. in Japan, which is a substantive milestone under our agreement with JCR, compared to $Nil in milestone revenue recognized in the three months ended September 30, 2016. This amount was recorded in revenue as there are no further performance obligations required in regards to these milestones.

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 45% for periods prior to June 30, 2016 and an expected rate of 43.5% for periods from July 1, 2016. We have assessed our research and development activities and expenditure to determine which of these spending 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.

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 assets from Osiris 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 on May 31. 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 Form 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® HS Inj. 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 have suspended further patient enrolment of the Phase IIa MPC-MICRO-IO clinical trial and the Phase III MPC-CBE clinical trial as we prioritize the funding of our Tier 1 product candidates. The remaining carrying amount of in-process research and development as at September 30, 2016 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 at May 31 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.

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

Management 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.

We have reclassified $24.0 million from in-process research and development to current marketed products upon the TEMCELL® HS Inj. 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 Impairment of Assets 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 Form 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.

As a consequence of the June 2016 strategic review we recognized non-cash impairment charges of $61.9 million in 2016 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 of June 30, 2016 we had completed the Phase IIa MPC-MICRO-IO clinical trial and MPC-CBE was in a Phase III clinical trial. In June 2016, we suspended further patient enrolment of both programs as we prioritized the funding of our Tier 1 product candidates. Existing and future cash resources will be deployed on delivery of Tier 1 product candidates for the foreseeable future and therefore we are unable to ascertain when MPC-MICRO-IO and MPC-CBE patient enrolment will be restarted. Accordingly impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in June 2016 in line with our accounting policy. These product candidates will remain technically viable and available to consider for future resource allocation and on this basis we have not abandoned the programs. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future. This accounting charge was non-cash and has not impacted our liquidity or cash flows from our operating activities.

Excluding the abovementioned impairment charges, the recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts in the impairment testing completed 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, 2016 and 2015, 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 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, and trading and available-for-sale 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 of September 30, 2016 and 2015.

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 of September 30, 2016 and 2015. 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 thousands, except percent data) Description	Fair value as of September 30, 2016	Fair value as of June 30, 2016	Valuation technique	Unobservable Inputs[1]	Range of inputs (weighted average) for Three Months Ended September 30, 2016	Range of inputs (weighted average) for Year Ended June 30, 2016	Relationship of unobservable inputs to fair value
Contingent consideration provision	64,691	63,716	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Three months ended September 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%. Year ended June 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%.
				Expected unit revenues	n/a	n/a	Three months ended September 30, 2016: A 10% increase in the price assumptions adopted would increase the fair value by 6%. Year ended June 30, 2016: A 10% increase in the price assumptions adopted would increase the fair value by 6%.

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

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 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 to retain existing intellectual property assets in their relative jurisdictions as we are no longer planning to consolidate intellectual property assets at September 30, 2016.

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 enrolment 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

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. For the three months ended September 30, 2016, we had a comprehensive loss of $19.1 million. Our net loss for the three months ended September 30, 2016 was $19.8 million. As of September 30, 2016, we have an accumulated deficit of $287.9 million since our inception. We do not know whether or when we will become profitable. Our losses have resulted principally from costs incurred in our manufacturing and clinical development activities.

We anticipate that our expenses will increase in the future as we move toward commercialization, including the scaling up of our manufacturing activities. 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 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 anticipate generating revenues from product sales for the foreseeable future (other than licensing revenue from sales of TEMCELL® HS. Inj. by JCR Pharmaceuticals Co. Ltd. ("JCR") in Japan), and we may never generate product sales. Our ability to generate future revenues from product sales depends heavily on our success in a number of areas, including:

- completing research 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 infrastructure;
- 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 and know-how;

- 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 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, domestic or foreign, 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, 2016, our cash and cash equivalents were $60.4 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 Congestive Heart Failure ("CHF")), MPC-06-ID (Chronic Low Back Pain ("CLBP")), MSC-100-IV (acute Graft versus Host Disease ("aGVHD")) and MPC-300-IV (inflammatory conditions) product candidates;
- initiate and advance our product candidates into larger and more expensive 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 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; and
- seek to attract and retain skilled personnel.

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. 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 collaborations, 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(ii) 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 either entering into an arrangement with a third party partner on one or more of our four key Tier 1 programs that would result in non-dilutive funding, or otherwise raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects and operational streamlining.

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 may lose some or all of their investment in us.

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 cells ("MLC") 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 stem cell products have been approved in the United States.

Other than with respect to sales of TEMCELL® HS. Inj. by our licensee JCR in Japan, we have not commercially marketed, distributed or sold any products, either ourselves or through a licensee. 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 MLC 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 MLC 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 than other, better known or extensively studied pharmaceutical or other product candidates to develop. 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. At the moment, no other industrially manufactured stem cell products have been approved in the United States, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or elsewhere.

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

Other than with respect to TEMCELL® HS. Inj., our licensed product in Japan, we have not obtained any regulatory approvals for a product, either ourselves or through a licensee. We must conduct extensive testing of our product candidates to demonstrate their safety and efficacy, including both preclinical animal testing and 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 we or they 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 collaborator may be prevented or delayed in obtaining marketing approval for our product candidates.

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, enrolment or completion of clinical development include:

- problems which may arise as a result of our transition of the Phase 3 CHF trial from Teva Pharmaceutical Industries Ltd;
- 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 prospective clinical 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;
- 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 the testing, validation, manufacturing and delivery of the product candidates to the clinical 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 the product candidates 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 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, especially for indications such as aGVHD which are designated as orphan or niche markets, 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. More specifically, certain of our product candidates, including MSC-100-IV for aGVHD, target indications with relatively small patient populations, which can prolong the clinical trial timeline for the regulatory process if sufficient patients cannot be enrolled in a timely manner. As a result, 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.

In addition, our planned clinical trials targeting more prevalent indications, such as our product candidates for CLBP, MPC-06-ID, and CHF, MPC-150-IM, may require the recruitment of several thousand patients. If there are delays in accumulating the required number of trial subjects or, in trials where clinical events are a primary endpoint, 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 enrolment 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 enrolment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- the degree of treatment effect in event-driven trials.

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 participate in 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 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 and CROs;
- standards within different jurisdictions for conducting clinical trials and resulting patients;
- our inability to locate 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
- 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.

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 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 labelling 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 labelling 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, even 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 other 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 treat 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 MSC-100-IV, which will focus on steroid-refractory 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 during our Phase 3 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.

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 (other than TEMCELL® HS. Inj., our licensed product in Japan), even if we expend substantial time and resources seeking such approval.

Further, regulatory requirements governing stem cell therapy products in particular have changed frequently and may continue to change in the future. For example, in November 2014, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or PMD Act, establishes a framework for expedited approval in Japan for certain regenerative medical products. As this is a new regulation, it is not clear yet what impact it will have on the operation of our business. 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;
- the inability to obtain sufficient quantities of the product candidates for use in clinical trials;
- 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. In addition, regulatory approval does not specify pricing or reimbursement which may not match our expectations based on the results of our clinical data.

Even if we obtain regulatory approval for a product candidate, 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;
- 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;
- product seizure or detention, or refusal to permit the import or export of products; and
- 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 MLCs, is frequently misunderstood by the public. Negative public attitudes toward stem cell therapy could also result in greater governmental regulation of stem cell therapies, which could harm our business. The use of these 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. 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 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.

Fast track designation by the FDA may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

If a drug is intended for the treatment of a serious or life-threatening condition or disease and the applicable nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast

track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. We may in the future seek fast track designation for our product candidates as appropriate in the United States. For any product candidate that receives fast track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 a patient population of fewer than 200,000 in the United States, or 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. 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 European Union 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 MSC-100-IV product candidate has received orphan drug designation for the treatment of aGVHD by the FDA. If we seek orphan drug designations for this or other product candidates in other indications or in other jurisdictions, such as for MSC-100-IV in the EU, 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.

Breakthrough therapy designation by the FDA may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We have in the past and may in the future apply for breakthrough therapy designation for our product candidates, as appropriate, in the United States. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the applicant can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may, in some cases, also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our products or product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree. In any event, the receipt of a breakthrough therapy designation for a product or product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. We have in the past been denied breakthrough designation for certain of our product candidates. In addition, even if one or more of our products or product candidates does qualify as a breakthrough therapy, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

We may face competition from biosimilars due to the changing 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 new pathway could allow competitors to reference data from innovator biological products already approved after 12 years from the time

of approval. In his proposed budget for fiscal year 2017, President Obama proposed to cut this 12-year period of exclusivity down to seven years. The President has also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." 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, with the attendant competitive pressure and consequences.

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 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 other 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 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 MLC product candidates in our 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 cells, 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.

Further, we have made significant advances in the development of 3-dimensional ("3D"), bioreactor based production for MLCs, the goal of which is to allow us to produce our products at commercial scale. There is no guarantee that we will successfully complete this process, 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 two-dimensional, or 2D, manufacturing processes. In the event our transition to 3D manufacturing is unsuccessful, we may not be able to produce 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 certain 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 MLC 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 MLC product candidates. Relying on Lonza as our sole source to manufacture our MLC 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 foreign 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; 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 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 MLC-containing bone marrow from donors, for which we currently rely on Lonza. MLCs 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 will 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 general market availability third parties to provide various "devices" or "carriers" for some of our programs (e.g., the catheter for use with MPC-150-IM, the collagen sponge used in spinal fusion, 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. As a result, 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 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 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 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.

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 for cell count, viability and appearance. 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 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 labelling 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 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; and
- the effectiveness of our, and our collaborators', sales and marketing efforts.

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 no sales and marketing infrastructure and, as a company, have limited sales, marketing or distribution 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 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 lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more diversified product lines; 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 clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. 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 the stem cell industry and/or those with collaboration arrangements and other third party payors. 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.

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 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 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 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 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 therapy, 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 do not clearly demonstrate the efficacy of our product candidates, 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 patients and achieve a significant market share to maintain profitability and growth.

Certain of our research and product development focuses on treatments for small patient populations, including orphan or niche markets. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with 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. 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 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, and we have a collaborator, JCR, with rights to develop and distribute products based on our MSC technology 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 into such markets. We may, therefore, 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, a referendum was held on the United Kingdom's membership in the European Union, the outcome of which was a vote in favor of leaving the European Union. 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 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;
- 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, 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 labelling, 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.

On September 16, 2011, the *Leahy-Smith America Invents Act*, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has and continues to develop and implement regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act. The full effect of these changes are currently unclear as the USPTO has not yet adopted all pertinent final rules and regulations, the courts have yet to address these provisions and the applicability of the Leahy-Smith Act and new regulations on specific patents, including our patents discussed herein, have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. As a result, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

On June 13, 2013, the U.S. Supreme Court decision in Association for *Molecular Pathology v. Myriad Genetics, Inc.*, held that isolated DNA sequences are not patentable because they constitute a product of nature. The Supreme Court did not address stem cells in particular, and as a result, it is not yet clear what, if any, impact this recent Supreme Court decision or future decisions will have on the operation of our business.

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 during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and 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 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 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, 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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 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 laws. 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. ("Osiris") 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, 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 Australian corporate taxation. As of September 30, 2016, our cumulative operating losses have a total potential tax benefit of $87.6 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. 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. Our carry forward net operating losses in the U.S. first start to expire in 2032. In addition, we are eligible for certain research and development tax incentive refundable credits in Australia which may increase our available cash flow. We currently project to benefit from these incentives in future taxable years. 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. If these incentives are revoked or modified or if we are no longer eligible for such incentives, our business, results of operations and financial condition may be adversely affected.

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 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* ("HITECH"), 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*, as amended, the ACA, 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 labelling 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.

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

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

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

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

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. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. 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 United States and (c) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the *Exchange Act* reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and NASDAQ listing standards. Further, we would be required to comply with United States generally accepted accounting principles, 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 establish and 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, beginning with our annual report for the year ending June 30, 2017, 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. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we have opted to rely on the exemptions provided to us by virtue of being a foreign private issuer, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until we file our annual report for the fiscal year ended June 30, 2017 with the SEC.

Our first Section 404(a) assessment will take place beginning with our annual report for the year ending June 30, 2017. As of the date of this filing, we have not designed and implemented controls to maintain appropriate segregation of duties in our manual and computer based business processes which could have a pervasive impact over the preparation of the financial statements. Specifically, we have limited accounting personnel to enable effective segregation of duties to allow for appropriate monitoring of financial reporting matters and internal control over financial reporting. Consequently we have determined there is a material weakness in the internal control over financial reporting. This material weakness did not result in material adjustments to the financial statements, however there is a reasonable possibility that a material misstatement of the annual financial statements would not have been prevented or detected on a timely basis due to the failure to design and implement appropriate segregation of duty controls. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. We have commenced the process of reviewing and improving our internal controls over financial reporting for compliance with Section 404(a) of the Sarbanes-Oxley Act. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, and entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal 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.

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 new compliance initiatives.

As a company whose ADSs have recently begun to be publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, *Dodd-Frank Wall Street Reform* and *Consumer Protection Act* and related rules implemented by the SEC 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 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 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 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 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 Global Select Market 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 stocks; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

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 will be influenced by the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on our company, to the extent such coverage currently exists, or in other cases, may never publish research on our company. If no or 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. In the event securities or industry analysts initiate coverage, 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. 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 and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

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 68% of our cash and cash equivalents as of September 30, 2016 were denominated in U.S. dollars and 32% 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.

Further, any significant change in the value of the Australian dollar may have a material adverse effect on the value of our ADSs in U.S. dollars. 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.

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 Global Select Market, we will be permitted to, and plan to, follow certain home country corporate governance practices in lieu of certain NASDAQ Global Select Market 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 *Securities Exchange Act of 1934*, as amended (the "Exchange Act"), that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, the information may not be disseminated in as timely a manner, or there may be less information publicly available concerning us generally than there is for a company that files as a domestic issuer.

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

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

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

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

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail or email and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon. As soon as practicable after receiving notice from us of any such meeting, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions

may be given by ADS holders. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted. Under Australian law and our Constitution, any resolution to be considered at a meeting of the shareholders shall be decided on a show of hands unless a poll is demanded by the shareholders at or before the declaration of the result of the show of hands. Under voting by a show of hands, multiple "yes" votes by ADS holders will only count as one "yes" vote and will be negated by a single "no" vote, unless a poll is demanded.

We may be or become classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to U.S. holders of our ADSs or ordinary shares.

Based on our business projections and the anticipated composition of our income and assets for the current and future years, we believe that we were a "passive foreign investment company," or PFIC, for the taxable year ending June 30, 2016. However, if there is a change in the type or composition of our gross income, or our actual business results do not match our projections, it is possible that we may become a PFIC in future taxable years. We will be a PFIC for any taxable year if either: (i) 75% or more of our gross income for the taxable year is passive income (such as certain dividends, interest, rents or royalties and certain gains from the sale of shares and securities or commodities transactions, including amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares or ADSs), or (ii) the average percentage value of our gross assets during the taxable year that produce passive income or are held for the production of passive income is at least 50% of the value of our total assets. For purposes of the PFIC asset test, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing, debt instruments or bank deposits that is readily convertible into cash. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC income and asset tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of Australian research and development tax incentive credits and other revenue, and there can be no assurances that such tax incentive credit programs will not be revoked or modified, that we will continue to conduct our operations in the manner necessary to be eligible for such incentives or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. The value of our assets for purposes of the PFIC asset test will generally be determined by reference to our market capitalization, which may fluctuate. Under circumstances where our gross income from activities that produce passive income significantly increases relative to our gross income from activities that produce non-passive income or where we decide not to deploy significant amounts of cash for active purposes, our risk of becoming classified as a PFIC may substantially increase. Since a separate factual determination as to whether we are or have become a PFIC must be made each year (after the close of such year), we cannot assure you that we will not be or become a PFIC in the current or any future taxable year. If we are treated as a PFIC for any taxable year, then U.S. holders generally would be subject to adverse U.S. federal income tax consequences (regardless of whether we continued to be a PFIC) unless a U.S. holder makes a "mark-to-market" election or a "Qualified Electing Fund" election. Upon request, we intend to provide U.S. holders with the information necessary to make and maintain a "Qualified Electing Fund" election if we are treated as a PFIC for any taxable year.

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

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

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

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

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

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

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

Several of our officers and directors are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. 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 United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the 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 United States 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 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 14, 2016

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

Exhibits

Furnished as Exhibit 99.1 to this Report on Form 6-K is the press release of the Company dated November 14, 2016, announcing the Company's unaudited consolidated financial results for the three months ended September 30, 2016.

Furnished as Exhibit 99.2 of this Report on Form 6-K is an investor presentation of the Company dated November 14, 2016.

Exhibit 99.1

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PROVIDES CORPORATE UPDATE AND FINANCIAL RESULTS FOR THE FIRST QUARTER ENDED SEPTEMBER 30, 2016

Melbourne, Australia; November 15, 2016; and New York, USA, November 14, 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today provided a quarterly corporate update on its operational highlights, including its key milestone achieved in its acute graft versus host disease Phase 3 clinical trial. Mesoblast also reported its consolidated financial results for the three months ended September 30, 2016.

In line with previous guidance, the Company implemented operational streamlining measures during the quarter while achieving, and continuing to maintain progress towards, key milestones in its Tier 1 clinical programs.

In recognition of the Company's continued clinical achievements, it was recently awarded the Frost & Sullivan Asia Pacific 2016 Cell Therapy Company of the Year award. The Frost & Sullivan awards identify and honor the best-in-class companies that have demonstrated excellence in their industry.

Financial Highlights

At September 30, 2016, the Company had cash reserves of $60.4 million. As previously announced, a fully discretionary equity facility has been established for up to $A120 million/$US90 million over 36 months.

In order to absorb the incremental costs of the MPC-150-IM program in advanced heart failure in FY17, the Company has executed its planned operational streamlining and re-prioritization of projects. Cash outflows for Q1 FY17 were $21.2 million, a reduction of 28% from $29.4 million in the comparable FY16 quarter. This was achieved principally through reduced spend on commercial manufacturing, deprioritized Tier 2 clinical projects and reduced labor costs.

Operational Highlights

MSC-100-IV for steroid-refractory acute graft versus host disease (aGVHD):

- The Phase 3 trial of Mesoblast's intravenous product candidate MSC-100-IV, used as front-line therapy in children with steroid-resistant aGVHD, was successful in a pre-specified interim futility analysis conducted by the independent Data Safety Monitoring Board (DSMB).

- The interim analysis showed that the predefined Bayesian futility rule used to determine the probability of the trial's success using the trial's primary endpoint of Day 28 overall response had been passed. The analysis method determined the likelihood of obtaining a statistically significant treatment effect at study completion, based on the data observed at this interim time point.

- Enrollment in the 60-patient open label Phase 3 trial is ongoing across multiple sites in the United States, trial completion is expected in the first half of 2017, and commercial launch activities are underway.

- Based on guidance from the United States Food and Drug Administration, Mesoblast believes that positive data from this Phase 3 trial may be sufficient for filing for accelerated approval of MSC-100-IV in the United States.

- Mesoblast plans to broaden its use in adult patients with high-risk steroid-refractory aGVHD.

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MPC-300-IV for biologic refractory rheumatoid arthritis (RA):

- The Phase 2 trial of Mesoblast's intravenous product candidate, MPC-300-IV, in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released in August 2016. An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks.

- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit.

- The responses to date in this 48-patient, randomized, placebo-controlled Phase 2 trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned early as a treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent.

- Given the large market opportunity, the Company believes that MPC-300-IV is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis.

- With respect to other indications of the MPC-300-IV product candidate, positive results from the randomized, placebo-controlled Phase 2 trial of MPC-300-IV in patients with diabetic nephropathy were published in the peer-reviewed journal *EBioMedicine.*

MPC-150-IM for advanced chronic heart failure (CHF):

- More than 300 patients have been enrolled to date in the Phase 3 trial evaluating MPC-150-IM in advanced CHF patients. After reviewing patient data in April and October 2016, the trial's DSMB has maintained its recommendation that the study should continue as planned.

- The trial's primary endpoint is a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) in advanced CHF patients receiving either MPC-150-IM by catheter injection into the left ventricular heart muscle, or control.

- Based on observed HF-MACE event rates in the trial to date, the Company has decided to bring forward to Q1 CY2017 a previously planned Interim Analysis to assess the trial's primary endpoint.

MPC-06-ID for chronic low back pain:

- The current 360 patient Phase 3 trial is actively recruiting across US sites.

- The 24-month results from the Company's 100-patient Phase 2 trial of MPC-06-ID for treatment of chronic low back pain were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award.

Vice Chair: Mr William (Bill) A. Burns, former CEO of Roche Pharmaceuticals was appointed Vice Chair of Mesoblast after serving as a Mesoblast Non-Executive Director since 2014. In this new role, he will focus his considerable pharmaceutical industry expertise on activities relating to execution of major strategic partnerships and corporate transactions.

Intellectual Property: The Company's intellectual property portfolio was further strengthened by the granting of a key patent by the United States Patent and Trademark Office covering the use of its MPCs in the treatment of rheumatic diseases.

Upcoming Milestones

- During the first half of CY2017, the Company expects to have interim analyses from its Phase 3 trials in advanced heart failure and chronic low back pain trials, and to complete enrollment in the Phase 3 acute graft versus host disease trial.

- The Company is in advanced discussions to establish potential strategic partnerships to commercialize its lead products.

Financial Results for the Three Months Ended September 30, 2016 (first quarter) (in U.S. Dollars)

The main items which impacted the loss before income tax movement were as follows:

- **Research and Development:** Research and development (R&D) expenses increased by $2.9 million. This increase was driven by increased costs for the MPC-150-IM chronic heart failure product. Within R&D expenses, labor costs have been reduced through a 28% reduction in FTEs from a labor restructure, as well as additional cost reductions in consultancy and travel. Additionally there has been a reduction in certain clinical trial costs due to the completion of enrollment for the Company's heart attack study using MPC-25-IC, and the deprioritization of the previously-specified Tier 2 clinical programs.

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $3.3 million for the first quarter of FY2017 compared with $6.2 million for the first quarter of FY2016, a decrease of $2.9 million as the Company had sufficient clinical grade product on hand to enable it to manage costs by reducing the number of production runs in the period.

- **Revenue:** The decrease in revenue for the first quarter of FY2017 compared with the first quarter of FY2016 was due to a decrease in non-cash commercialization revenue, as the Company had fully recognized its remaining deferred revenue balance for its MPC-150-IM product in June 2016, and to having received a one-time milestone payment for TEMCELL® HS Inj. in the first quarter of FY2016.

The overall increase in loss before income tax also includes movements in other items which did not impact the Company's current cash reserves, such as: remeasurement of contingent consideration, R&D tax incentive revenue and foreign exchange movements within other operating income and expenses.

Conference Call Details

Australia: 9:00 am AEDT on Tuesday, November 15, 2016

T: 1800 558 698 and 1800 809 971 (toll-free Australia)

USA: 5:00 pm ET on Monday, November 14, 2016
T: 1855 8811 339 (toll-free US)

Ex USA and Australia: +612 9007 3187

Passcode: 912575

The live webcast can be accessed via
http://webcasting.boardroom.media/broadcast/58214386d5f1311b35bd36a6

The archived webcast will be available in the Events and Presentations section of the Investor page in the Mesoblast website.

About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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Forward-Looking Statements
This press release 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. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

For further information, please contact:

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Consolidated Income Statement

(in thousands, except per share amount)	Note	Three Months Ended September 30, 2016	2015
Revenue	3	395	7,513
Research & development		(14,004)	(11,089)
Manufacturing commercialization		(3,295)	(6,203)
Management and administration		(5,459)	(5,535)
Fair value remeasurement of contingent consideration		24	3,729
Other operating income and expenses		473	849
Finance costs		(1,037)	(2,424)
Loss before income tax	3	**(22,903)**	**(13,160)**
Income tax benefit/(expense)	4	3,105	—
Loss attributable to the owners of Mesoblast Limited		**(19,798)**	**(13,160)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**
Basic - losses per share		(5.24)	(3.94)
Diluted - losses per share		(5.24)	(3.94)

Consolidated Statement of Comprehensive Income

(in thousands)	Note	Three Months Ended September 30, 2016	2015
(Loss)/profit for the year		**(19,798)**	**(13,160)**
Other comprehensive income			
Items that may be reclassified to profit and loss			
Changes in the fair value of available-for-sale financial assets		31	—
Exchange differences on translation of foreign operations		703	(3,593)
Other comprehensive (loss)/income for the period, net of tax		**734**	**(3,593)**
Total comprehensive (loss)/income is attributable to the owners of Mesoblast Limited		**(19,064)**	**(16,753)**

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Consolidated Statement of Balance Sheet

(in thousands)	Note	As of September 30, 2016	As of June 30, 2016
Assets			
Current Assets			
Cash & cash equivalents	5(a)	60,355	80,937
Trade & other receivables	5(b)	4,583	4,054
Prepayments	5(b)	5,759	3,832
Total Current Assets		**70,697**	**88,823**
Non-Current Assets			
Property, plant and equipment		2,925	3,063
Available-for-sale financial assets	5(d)	1,997	1,966
Other non-current assets		2,362	2,343
Intangible assets	6(a)	587,463	587,823
Total Non-Current Assets		**594,747**	**595,195**
Total Assets		**665,444**	**684,018**
Liabilities			
Current Liabilities			
Trade and other payables	5(c)	28,119	27,155
Provisions		3,202	2,260
Total Current Liabilities		**31,321**	**29,415**
Non-Current Liabilities			
Deferred tax liability	6(b)	59,588	62,693
Provisions		64,663	63,749
Total Non-Current Liabilities		**124,251**	**126,442**
Total Liabilities		**155,572**	**155,857**
Net Assets		**509,872**	**528,161**
Equity			
Issued Capital	8	770,289	770,272
Reserves		27,468	25,976
(Accumulated losses)/retained earnings		(287,885)	(268,087)
Total Equity		**509,872**	**528,161**

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Consolidated Statement of Cash Flows

(in thousands)	Note	Three months ended September 30, 2016	2015
Cash flows from operating activities			
Commercialization revenue received		361	—
Payments to suppliers and employees (inclusive of goods and services tax)		(21,369)	(28,355)
Interest received		181	288
Net cash (outflows) in operating activities	7(b)	**(20,827)**	**(28,067)**
Cash flows from investing activities			
Payments for investments		—	(805)
Payments for licenses		—	(200)
Investment in fixed assets		(290)	(502)
Net cash (outflows) in investing activities		**(290)**	**(1,507)**
		—	
Cash flows from financing activities			
Proceeds from issue of shares		—	169
Payments for share issue costs	8	(55)	—
Net cash (outflows) / inflows by financing activities		**(55)**	**169**
Net (decrease)/increase in cash and cash equivalents		(21,172)	(29,405)
Cash and cash equivalents at beginning of period		80,937	110,701
FX (losses)/gains on the translation of foreign bank accounts		590	(3,535)
Cash and cash equivalents at end of period	7(a)	**60,355**	**77,761**

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Exhibit 99.2

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Financial Results for the First Quarter Ended September 30, 2016

November 2016

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation 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. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are 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. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with JCR Pharmaceuticals Co., Ltd, and Lonza and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Agenda

FINANCIAL RESULTS

OPERATIONAL UPDATE

TIMELINES

Agenda

FINANCIAL RESULTS

Q1 FY 17 Financial Highlights US$m

- At September 30, 2016, the Company had cash reserves of $60.4 million
- As previously announced, a fully discretionary equity facility has been established for up to $A120 million/$US90 million over 36 months
- In order to absorb the incremental costs of the MPC-150-IM program in advanced heart failure in FY17, the Company has executed its planned operational streamlining and re-prioritization of projects
- Cash outflows for Q1 FY17 were $21.2 million, a reduction of 28% from $29.4 million in the comparable FY16 quarter
- This was achieved principally through reduced spend on commercial manufacturing, deprioritized Tier 2 clinical projects and reduced labor costs

Operational Streamlining and Re-Prioritization of Assets US$m

As previously indicated in July, the Company is planning to absorb the incremental costs of the MPC-150-IM program in FY17 through a range of cost reduction initiatives. To date, the following initiatives have been executed:

Within R&D:

- A 28% reduction in FTEs was achieved primarily through a labor restructure. This, combined with the cost containment of consultants and travel have reduced product support costs within R&D by $1.9 million (29%) in comparison with Q1 FY16
- Enrollment has been completed for our heart attack study using MPC-25-IC, reducing future expenditure on this Tier 2 program
- Previously-specified Tier 2 programs have been deprioritized

Within Manufacturing Commercialization:

- A labor restructure, combined with cost containment of consultants and travel have reduced manufacturing support costs for the function by $0.3 million (36%) in comparison with Q1 FY16
- Overall MPC/MSC platform technology costs were reduced by $2.6 million (49%) as the Company had sufficient clinical grade product on hand to reduce the number of production runs in this period

Reductions to office accommodation and laboratory space have also been executed

FY17 Cash Flows and Cash Position US$m

	30 Sep 2016	30 Sep 2015	$ Change	%
Cash on hand	**60.4**	**77.8**	**(17.4)**	
Cash flows for the quarter:				
Operating cash outflows	(20.8)	(28.1)	7.3	(26%)
Investing cash outflows	(0.3)	(1.5)	1.2	(81%)
Financing cash (outflows)/inflows	(0.1)	0.2	(0.3)	(133%)
Net decrease in cash outflows	**(21.2)**	**(29.4)**	**8.2**	**(28%)**
Foreign exchange	0.6	(3.5)	4.1	(117%)
Net decrease in cash after FX	**(20.6)**	**(32.9)**	**12.3**	**(37%)**

- Cash outflows have been reduced by 28% ($8.2 million) primarily due to operational streamlining, re-prioritization of projects and reduced manufacturing costs in order to absorb the ongoing and incremental costs associated with the MPC-150-IM chronic heart failure program

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FY17 Profit and Loss US$m

	30 Sep 2016	30 Sep 2015	$ Change	%
Revenue	**0.4**	**7.5**	**(7.1)**	**(95%)**
Research and Development	(14.0)	(11.1)	(2.9)	26%
Manufacturing Commercialization	(3.3)	(6.2)	2.9	(47%)
Management & Administration	(5.5)	(5.5)	0.1	(1%)
Contingent Consideration	—	3.7	(3.7)	(100%)
Other Operating Income & Expenses	0.5	0.8	(0.3)	(44%)
Finance Costs	(1.0)	(2.4)	1.4	(57%)
Loss Before Tax	**(22.9)**	**(13.2)**	**(9.7)**	**74%**

- The overall increase in loss before income tax is primarily attributable to items that did not impact the Company's current cash reserves, such as remeasurement of contingent consideration and reduction in revenue
- Revenue was reduced as the Company has fully recognized its remaining non-cash deferred revenue balance for its MPC-150-IM product in June 2016, and due to having received a one-time milestone payment for TEMCELL® HS Inj. in the first quarter of FY2016
- R&D expenses: increased by $2.9 million (26%) - the incremental costs of the MPC-150-IM program were partially offset by cost reductions achieved from the operational streamlining and the re-prioritization of assets
- Manufacturing Commercialization: decreased by $2.9 million (47%) – sufficient clinical grade product on hand enabled the number of production runs to be reduced in this period vs the comparative quarter

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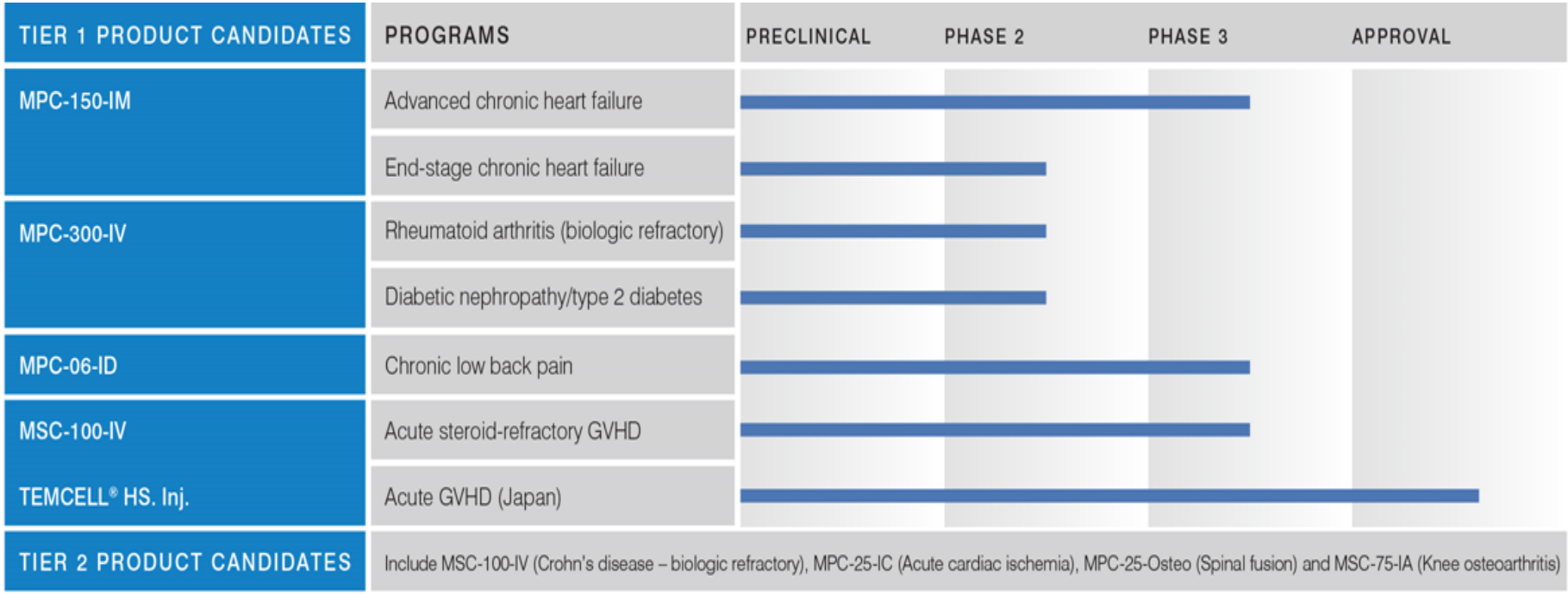
Agenda

OPERATIONAL UPDATE

Diversified Pipeline of Product Candidates for High Unmet Needs

First Product on market - Three Tier 1 Product Candidates in Phase 3



This chart is figurative and does not purport to show individual trial progress within a clinical program.
For product registration purposes, Phase 3 programs may require more than one trial.

MPC-150-IM: Chronic Heart Failure (CHF) – Market Opportunity

MPC-150-IM is in development for patients with New York Heart Association Class II-IV CHF

Market opportunity	▪ 5.7m patients (prevalence rate of 2% of the population) diagnosed with CHF in the US[1] ▪ 915,000 new cases diagnosed in the US each year[1] – Growing by 2% per annum ▪ ~1.9m CHF NYHA Class II-IV patients with low ejection fraction (LVEF<40%) in the US alone[2]
Gap in treatment options	▪ Class II / III CHF patients with low ejection fraction continue to be at high risk of repeated hospitalizations and mortality, despite standard of care pharmacological treatments[3] ▪ Class III / IV CHF patients only have heart transplant and mechanical support as treatment options
Targeted physician population	▪ Specialists: Targeted physician audience & commercial footprint – Heart failure specialists – Interventional cardiologists – Cardiac Surgeons

We believe MPC-150-IM is positioned to fill the significant treatment gap in patients with advanced CHF

1. AHA Heart disease and stroke statistics—2016 update: a report from the American Heart Association. Circulation. 2016;133:e38-e360 (P e308).
2. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary Prevalence and Correlates of Incident Heart Failure with Preserved Ejection Fraction. *The American journal of medicine*. 2013;126(5):393-400. Derived by applying a HF-REF prevalence rate of 32.6% to the U.S. rate of 5.7m U.S. patients.
3. European Heart Journal (2012) 33, 1750–1757 Figure 3

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MPC-150-IM: Operational Update

- Phase 3 trial for 600 patients with advanced heart failure is recruiting well across North American sites; over 300 patients enrolled
- After reviewing patient data in April and October 2016, the trial's DSMB has maintained its recommendation that the study should continue as planned
- The trial's primary endpoint is a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) in advanced CHF patients receiving either MPC-150-IM by catheter injection into the left ventricular heart muscle, or control
- Based on observed HF-MACE event rates in the trial to date, the Company has decided to bring forward to Q1 CY2017 a previously planned Interim Analysis to assess the trial's primary endpoint

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MPC-06-ID: CLBP Due to Degenerative Disc Disease – Market Opportunity

MPC-06-ID is in development for the treatment of chronic low back pain (CLBP) lasting >6 months as a result of moderate degenerative intervertebral disc disease

Market opportunity	▪ Over approximately 7m patients in the US are estimated to suffer from CLBP due to degenerative disc disease (DDD) in 2016[1,2,5] ▪ Current MPC-06-ID development program targets over approximately 3.2m patients
Gap in treatment options	▪ For patients who fail conservative treatment (rest, analgesia, opioids, and epidural steroids), treatment options are limited to highly invasive therapies such as spinal fusion or artificial disc replacement[3] ▪ Surgeons report ~40% of patients ultimately fail back surgery[3]
Targeted physician population	▪ Specialists: Targeted physician audience & commercial footprint[4] – Pain management specialists and anesthesiologists – Orthopedic / spine surgeons

We believe MPC-06-ID is positioned to fill the significant treatment gap in patients with moderate to severe CLBP after conservative treatment options have failed

1. Decision Resources: Chronic Pain December 2015
2. LEK & NCI opinion leader interviews, and secondary analysis
3. Simon et al – Discogenic Low Back Pain Phys Med Rehabil Clin N Am 25 (2014) 305–317
4. Shapiro CM Phys Med Rehabil Clin N Am 2014
5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

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MPC-06-ID: Operational Update

- The current 360 patient Phase 3 trial is actively recruiting across US sites
- The 24-month results from the Company's 100-patient Phase 2 trial of MPC-06-ID for treatment of chronic low back pain were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award
- FDA has provided written guidance:
  - Use of a composite primary endpoint is acceptable for approval
  - Agreed thresholds for pain (50% decrease in VAS) and function (15 point improvement in ODI)
  - Two time points (12 and 24 months) for meeting pain and functional improvement criteria
  - No intervention at the treated level through 24 months

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) – Market Opportunity

Ongoing randomized, controlled Phase 2 Trial in 48 patients with biologic refractory rheumatoid arthritis, comparing two doses of MPC-300-IV against placebo

Market opportunity

- There are approximately 5.3 million prevalent cases in the US, Japan, and EU5, of which there were 2.4 million in the US alone in 2014[1]
- Incidence increases with age – 8.7 per 100,000 for ages 18-34 vs. 89 per 100,000 for ages 65-74[2]
- RA treatment is a approximately $15 billion global market in 2014 projected to grow to over $18 billion in 2024. primarily due to sales of the anti-TNF agents[1]
- In the US, the anti-TNF refractory population is the fastest growing branded market segment, projected to increase by approximately 8% annually and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars[1]

Gap in treatment options

- One third of RA patients do not respond or cannot tolerate current biologic therapies[3]
  - Sustained remission defined by ACR 70 only occurs in 5-15% of patients on biologics[5]
  - Biologics are associated with increased incidence of opportunistic infections and malignancies[4]
- Indications for currently approved biologics target either a single cytokine or immune cell pathway even though RA involves multiple signals / pathways[4]
- Need for disease-modifying therapies that are well tolerated and induce remission in a greater percentage of patients (ACR 70) as early as possible in the disease management[3]

1. Decision Resources Rheumatoid Arthritis – Disease Landscape & Forecast - January 2016; Market Forecast Methodology; Access & Reimbursement – August 2016.
2. GlobalData©: Rheumatoid Arthritis Therapeutic – Pipeline Oct 2011
3. Decision Resources Rheumatoid Arthritis – Unmet Need – April 2016.
4. Information listed in the package insert of anti-TNF-α therapies such as Enbrel® (etanercept), Rituxan® (rituximab), Remicade® (infliximab), and Humira® (adalimumab).
5. Alivernini, S et. al. Arthritis Research & Therapy 2009, 11:R163

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MPC-300-IV: Operational Update

- The Phase 2 trial of Mesoblast's intravenous product candidate, MPC-300-IV, in biologic refractory rheumatoid arthritis has completed enrollment and results of the 12 week primary endpoint were released in August 2016. An intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks

- A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function, and disease activity, with the 2 million MPCs/kg dose providing the greatest benefit

- The responses to date in this 48-patient, randomized, placebo-controlled Phase 2 trial provide support for the potential of Mesoblast's allogeneic MPCs to be positioned early as a treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent

- Given the large market opportunity, the Company believes that MPC-300-IV is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis

- With respect to other indications of the MPC-300-IV product candidate, positive results from the randomized, placebo-controlled Phase 2 trial of MPC-300-IV in patients with diabetic nephropathy were published in the peer-reviewed journal *EBioMedicine*

MSC-100-IV / TEMCELL® HS Inj. : Acute Graft vs Host Disease

MSC-100-IV / TEMCELL® HS Inj. is targeting pediatric and adult patients with acute Graft Versus Host Disease (aGVHD) following allogeneic Bone Marrow Transplant (BMT)

Market opportunity	▪ ~30,000 allogeneic BMTs performed globally (~20K US/EU5) each year, ~20% pediatric[1,2] ▪ ~3,700 allogeneic BMTs performed in Japan each year[3] ▪ ~50% of all US patients develop aGVHD (Grades II-IV)[4]
Unmet Need	▪ Steroid-resistant acute GvHD have a dismal prognosis, with mortality rates in excess of 85% ▪ No currently approved therapies for steroid refractory patients (ex Japan) ▪ Off-label options have mixed efficacy with high toxicity ▪ Significant need for a new treatment with a favorable risk / benefit profile
Path to market	▪ Japan product (TEMCELL® HS Inj.) launched; reimbursed up to ~$195K for full treatment course[5] ▪ US product candidate (MSC-100-IV) currently in 60 patient open-label Phase 3 registration pediatric trial ▪ Highly targeted physician audience and commercial footprint for pediatric launch in US ▪ High risk adult population identified for Phase 3 trial ▪ Planned Interim Analysis Q4 2016, enrollment complete 1H 2017

We believe MSC-100-IV has potential to be first allogeneic non-hemotopoietic stem cell products approved in USA, triggering a "halo" effect for Mesoblast's other Tier 1 products

1. Gratwohl A et al Quantitative and qualitative differences in use and trends of hematopoietic stem cell transplantation: a Global Observational Study. Haematologica. 2013 Aug;98(8):1282-90.
2. CIBMTR, Decision resources GVHD Epi Nov 2012.
3. APBMT Annual Report Dec 2012; Assumes a growth rate of approximately 3% per year
4. Jagasia et al Risk factors for acute GVHD and survival after hematopoietic cell transplantation. 2012 January vol 119 (1).
5. Based on a ¥JPY = $USD 0.009375 spot exchange rate on as of the market close on November 11, 2016. Amounts are rounded. Source: Bloomberg.

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MSC-100-IV North America aGVHD Market Opportunity

	Target Population	2015	Source
Epidemiology	Allogeneic Hematopoietic Stem Cell Transplants	10,200	• US: estimated from 2013 CIBMTR (table 6) • Canada: estimate based on general population size and US transplant activity per 10m
Epidemiology	Acute GVHD Grades II-IV	5,400	• Estimated 53% Rate: Jagasia, M., Arora, M., Flowers, M. (2012) Risk Factors for acute GVHD and Survival after Hematopoietic Cell Transplantation. Blood, 5 January (119):296-307
Epidemiology	Steroid Refractory Acute GVHD Grades II-IV	2,900	• Estimated 54% Rate: Westin, J., Saliba, RM., Alousi, A. (2011) Steroid Refractory Acute GVHD: Predictors and Outcomes. Advances in Hematology (2011); 1-8
Target Population	Pediatric SR aGHVD Grades II-IV	600	• Pediatric: estimated from Center for International Blood and Marrow Transplant Research -Transplant Activity Report Covering 2009-2013

Target Population	First-Line High Risk Adults with aGVHD	1,900	• Adult High Risk:
			  • MacMillan, ML., Robin, M., Harris, AC. (2015) A refined risk score for acute graft-versus-host disease that predicts response to initial therapy, survival, and transplant-related mortality. Biol Blood Marrow Transplant. Apr;21(4):761-7
			  • Jagasia, M., Arora, M., Flowers, M. (2012) Risk Factors for acute GVHD and Survival after Hematopoietic Cell Transplantation. Blood, 5 January (119):296-307
			  • CIBMTR: Current uses and outcomes of hematopoietic stem cell transplantation 2015 summary slides

Target Population	Total North America aGHVD Target Population	~2,500	

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MSC-100-IV: Concentrated High Volume Centers Provide Compelling Low Cost Commercial Structure[1]

Top Pediatric Transplant Centers

- There are 65 centers in the country that conduct allogeneic transplants in pediatrics
- ~ 50% of all of these transplants happen at 13 influential centers
- Broad overlap between high volume pediatric centers and influential adult centers

Top Adult Transplant Centers

- There are 108 centers in the country that conduct adult allogeneic transplants
- ~50% of all of these transplants happen at 19 influential centers

1. Source: Center for International Blood & Marrow Transplant Research.

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MSC-100-IV: Product Development Strategy

- **Manufacturing**
  - Optimised process – modernized and harmonized
  - Commercial readiness for launch

- **Pediatrics**
  - Complete targeted Phase 3, 60 patient open label clinical trial in SR-aGVHD for accelerated approval pathway (US)
  - Market development and access work in parallel
  - Launch pediatric product in 2018 in US

- **Adults**
  - Complete targeted Phase 3 study in high - risk subset of adult patients with aGVHD (with liver and gut disease)
  - Market development and access work in parallel
  - Launch adult product in 2021 in major markets

- **Life cycle management and label expansion**
  - Prophylaxis
  - Acute GVHD, first-line

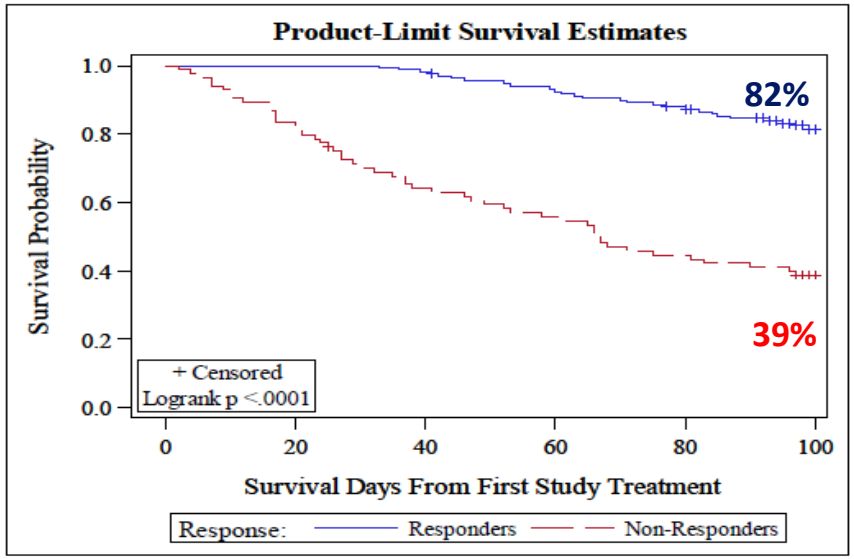
MSC-100-IV: Phase 3 Trial in Children with Steroid Refractory Acute Graft vs Host Disease (SR-aGVHD)

MSC-100-IV as first line therapy in children with SR-aGVHD (Day 28 response)

Response at Day 28	Randomized Placebo Controlled Trial		Open-label Expanded Access Program
	Placebo	MSC-100-IV	MSC-100-IV
Responder	3/14 (21.4%)	9/14 (64.3%)	29/36 (81%)
Non-responder	11/14 (78.6%)	5/14 (35.7%)	7/36 (19%)
	p-value = 0.0014		

Compared with placebo control patients, MSC-100-IV produced markedly superior overall response at day 28, a clinically meaningful endpoint (p=0.0014).

MSC-100-IV in children with SR-aGVHD who failed multiple other modalities (Day 100 survival)



Survival at Day 100 of pediatric patients treated with MSC-100-IV stratified by 28-Day responders vs non-responders, n=241

- Evidence that MSC-100-IV is effective when used as first line therapy in children with SR-aGVHD
- FDA agreement on 60 patient open label Phase 3 trial for accelerated US approval pathway
- Enrollment criteria: MSC-100-IV offered as first line therapy in children with SR-aGVHD

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MSC-100-IV: Graft vs Host Disease: Pediatric GVHD001/GVHD002 Phase 3 Study

- Phase 3 study ongoing, ~ 40 sites planned[1]
  - Multi-center, Single-Arm, Open-Label to evaluate efficacy and safety to day 100 (study 001) and from day 100 to day 180 (study 002)
  - At least 60 pediatric patients (2 months to 17 years inclusive)
  - aGVHD following allogeneic HSCT failing systemic corticosteroid therapy
  - Grades C and D aGVHD involving skin, liver and/or GI tract
  - Grade B aGVHD involving liver and/or GI tract with or without concomitant skin disease

Endpoints[1]:

- Primary endpoint: Overall response at Day 28
- Key secondary endpoint: Survival at Day 100 in responders at Day 28
- Subjects evaluated at Days 28, 56 and 100 in study 001, and out to Day 180 in study 002

1. Clinicaltrials.gov identifier: NCT02652130.

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GVHD001 Interim Futility Analysis Method and Results- November 2016

- Predefined Bayesian futility rule that determined the predictive probability of success using the primary endpoint of Day 28 overall response
- Method determined the likelihood of obtaining a statistically significant treatment effect at study completion, conditional on the data observed at this interim time point
- **DSMB notified Mesoblast that analysis was successful**
- Interim analysis outcome is consistent with what has previously been demonstrated for the product used in this indication under both expanded access protocol and earlier placebo-controlled trial
- Enrollment in the study is ongoing across multiple sites in the United States and will continue
  - Completion is expected in mid-2017
  - Commercial launch activities are underway

Other Operational Highlights

- **Award**: In recognition of the Company's continued clinical achievements, it was awarded the Frost & Sullivan Asia Pacific 2016 Cell Therapy Company of the Year award. The Frost & Sullivan awards identify and honor the best-in-class companies that have demonstrated excellence in their industry.

- **Vice Chair:** Mr William (Bill) A. Burns, former CEO of Roche Pharmaceuticals was appointed Vice Chair of Mesoblast after serving as a Mesoblast Non-Executive Director since 2014. In this new role, he will focus his considerable pharmaceutical industry expertise on activities relating to execution of major strategic partnerships and corporate transactions.

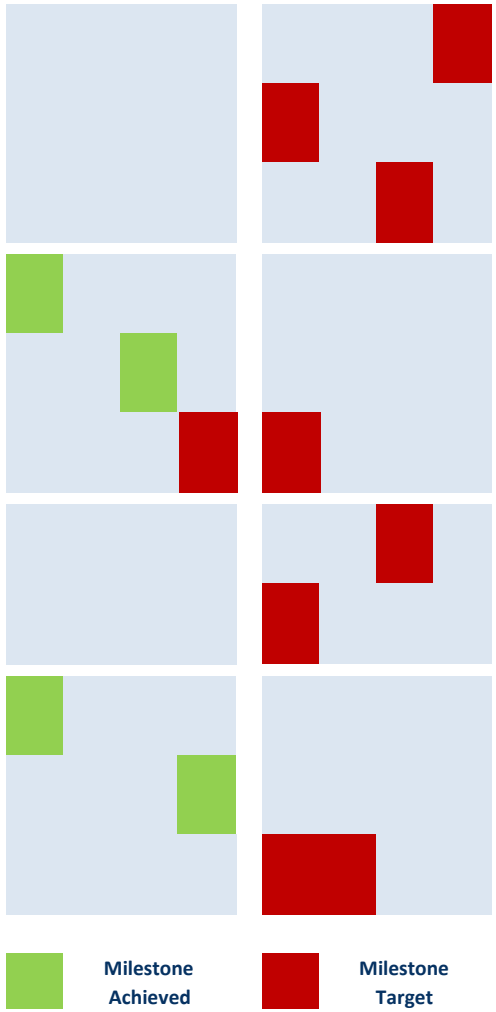
- **Intellectual Property:** The Company's intellectual property portfolio was further strengthened by the granting of a key patent by the United States Patent and Trademark Office covering the use of its MPCs in the treatment of rheumatic diseases.

Agenda

TIMELINES

Tier 1 Product Candidate Deliverables (Calendar Year)

Product Candidate	Programs	Milestones
MPC-150-IM	Class II and III Heart Failure Class IV Heart Failure Requiring LVAD	Phase 3 Enrollment Complete Interim Results Phase 2b trial results
MPC-300-IV	Rheumatoid Arthritis (Biologic Refractory)	Top line results first cohort Full trial results 6/9 month trial results
MPC-06-ID	Chronic Low Back Pain Due to Degenerative Disc Disease	Phase 3 Enrollment Complete Phase 3 Interim Analysis
MSC-100-IV / Temcell® HS Inj.	Acute Graft Versus Host Disease	TEMCELL® HS Inj. Launched in Japan Interim Results Phase 3 Enrollment Complete



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Thank You and Questions