

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

For the month of February 2019

Commission File Number 001-37626

Mesoblast Limited

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

Silviu Itescu

Chief Executive Officer and Executive Director

Level 38

55 Collins Street

Melbourne 3000

Australia

(Address of principal executive offices)

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

Form 20-F Form 40-F

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

Yes No

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

Yes No

On February 21, 2019, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement and investor presentation, which are attached hereto as Exhibit 99.1 and Exhibit 99.2, and is incorporated herein by reference.

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 organized.

MESOBLAST LIMITED

/s/ Charlie Harrison

Charlie Harrison
Company Secretary

Dated: February 21, 2019

INDEX TO EXHIBITS

Item _____

- 99.1 Press release of Mesoblast Ltd, dated February 21, 2019.
- 99.2 Investor presentation of Mesoblast Ltd, dated February 21, 2019.

**MESOBLAST REPORTS FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS
FOR THE FIRST HALF ENDED DECEMBER 31, 2018**

Strong cash reserves as Company prepares for potential US launch of remestemcel-L

Melbourne, Australia, February 21, 2019 and New York, USA, February 20, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported its financial results and operational highlights for the six months ended December 31, 2018. Pro-forma cash on hand at December 31, 2018 was US\$92.0 million (A\$130.0 million).

Chief Executive Dr Silviu Itescu said: "The highlights from the half year include completion of enrollment in our major cardiovascular Phase 3 trial, execution of our cardiovascular partnership in China, and continued revenue growth from product sales by our licensee in Japan for treatment of acute graft versus host disease (aGVHD). Our focus in the coming period is on obtaining FDA approval for and ensuring a successful commercial launch of remestemcel-L for aGVHD in the United States."

Corporate Highlights for the Six Months Ended December 31, 2018 (first half FY2019):

- After demonstrating strong survival benefits through Day 180, Mesoblast held two successful end-of-phase meetings with the FDA covering clinical and manufacturing aspects of the upcoming Biologics License Application (BLA) for remestemcel-L in the US for use in children with steroid-refractory aGVHD.
- The Company now has a meeting scheduled with the FDA in April 2019 and is on track to subsequently initiate a BLA filing for marketing authorization.
- Mesoblast's Phase 3 trial in chronic heart failure completed patient enrollment, with 566 patients randomized to receive Revascor or placebo. The study, conducted across 55 centers in North America, will complete when sufficient primary endpoint events have accrued, which is likely to be within 12 months.
- Mesoblast completed its transaction with Tasy Pharmaceutical Group (Tasy) to establish a strategic cardiovascular partnership in China, and received US\$40 million on closing.
- Mesoblast and Tasy held their first Joint Steering Committee meeting, with a shared objective to initiate a clinical study in China using similar clinical endpoints and targeting a similar patient population as in Mesoblast's North American Phase 3 trial. Tasy and Mesoblast will leverage each other's clinical trial results to support their respective regulatory submissions.
- The National Institutes of Health (NIH) sponsored 159-patient trial of Revascor in end-stage heart failure patients with a left ventricular assist device (LVAD) achieved a 76% reduction in major gastrointestinal (GI) bleeding events and a 65% reduction in associated hospitalizations. Under the Regenerative Medicine Advanced Therapy (RMAT) designation for this indication, Mesoblast has received guidance from the FDA that reduction in GI bleeding and related hospitalizations is a clinically meaningful outcome that could support product registration.
- Mesoblast has expanded its partnership with Japan's JCR Pharmaceuticals Co. Ltd. (JCR) for the treatment of wound healing in epidermolysis bullosa (EB). Having been granted Orphan Regenerative Medical Product designation for EB in October, JCR now intends to seek a label extension for TEMCELL®1 HS. Inj. in Japan for EB beyond its existing approval for the treatment of aGVHD.
- Management has been expanded to build a commercial team to support the Company's launch plans for remestemcel-L and operational leadership to drive product life cycle management, commercial manufacturing and regulatory interactions.

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- The Board of Directors is undergoing a structured succession plan and has brought on two new US-based Directors with proven expertise in product commercial launches, reimbursement and health system economics.

Upcoming Milestones in Second Half FY2019:

- Mesoblast intends to initiate BLA filing for marketing authorization of remestemcel-L following its FDA meeting scheduled for April 2019.
- Mesoblast's partner Tasly is planning to meet with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China.
- Mesoblast intends to meet with the FDA to discuss the pathway for approval of Revascor for the reduction in GI bleeding in patients with LVADs.
- All patients in Mesoblast's Phase 3 trial in MPC-06-ID for chronic lower back pain will complete their 12-month assessment for safety and efficacy.

Key Financial Highlights for First Half FY2019:

- Pro forma cash of US\$92.0 million at December 31, 2018.
 - o This includes US\$15.0 million received in January 2019 from Hercules Capital, Inc. (Hercules) after having successfully achieved the clinical milestone of reduction in major GI bleeding events and related hospitalizations in the NIH trial of Revascor in end stage heart failure patients with LVADs;
 - o Additional non-dilutive capital of US\$35.0 million may be available under existing arrangements with Hercules and NovaQuest Capital Management, L.L.C. (NovaQuest), subject to certain milestones.
- 43% increase in royalty income on sales of TEMCELL for aGVHD in Japan.
- Stable revenue of US\$13.5 million, compared with US\$14.6 million in the first half of FY2018.
- Increased investment in commercial manufacturing of US\$8.0 million in preparation for potential aGVHD approval.
- 50% reduction in net operating cash outflows in the first half of FY2019 to US\$17.5 million.

Detailed Financial Results for the Six Months Ended December 31, 2018 (first half FY2019):

- **Revenues** were US\$13.5 million for the first half FY2019, compared with US\$14.6 million for the first half FY2018, a decrease of US\$1.1 million primarily due to:
 - o US\$10.0 million milestone revenue recognized in the first half FY2019 in relation to establishing a partnership with Tasly in China, compared with US\$11.8 million milestone revenue recognized in the first half FY2018 in relation to the patent license agreement with Takeda Pharmaceutical Company Limited.
 - o US\$3.2 million royalties and milestones revenue recognized in the first half FY2019 from sales of TEMCELL by our licensee in Japan, JCR, compared with US\$2.6 million in the first half FY2018, an increase of US\$0.6 million. Royalty income from TEMCELL increased by 43% for the first half FY2019.
- **Research and Development** expenses were US\$34.0 million for the first half FY2019, compared with US\$31.6 million for the first half FY2018, an increase of US\$2.4 million (8%) as the Company invested in its lead clinical programs.

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- **Manufacturing** expenses were US\$9.7 million for the first half FY2019, compared with US\$1.7 million for the first half FY2018, an increase of US\$8.0 million due to an increase in commercial manufacturing in preparation for GVHD approval.
- **Management and Administration** expenses were US\$10.7 million for the first half FY2019, compared with US\$10.6 million for the first half FY2018, an increase of only US\$0.1 million (1%).
- **Finance Costs** of US\$5.1 million related to loan and security agreements entered into with Hercules in March 2018 and NovaQuest in June 2018. No interest expense was recognized in the first half FY2018.

Additional components of loss after income tax also include movements in other items which did not impact current cash reserves, such as income tax benefits, fair value remeasurement of contingent consideration, remeasurement of borrowing arrangements and foreign exchange movements within other operating income and expenses.

In the first half FY2019 the Company reported a US\$44.1 million loss after tax compared to a profit after tax of US\$6.7 million for the first half FY2018. The increase in the loss is primarily due to, in the current period, investment in commercial manufacturing of US\$8.0 million in preparation for GVHD approval, and an increase of US\$5.1 million in finance costs; and in comparison period of first half FY2018 the Company recognized a one-off non-cash income tax benefit of US\$23.0 million due to a revaluation of tax liabilities given changes in tax rates and a non-cash US\$8.7 million gain on contingent consideration for reduction of future payments to third parties. The net loss attributable to ordinary shareholders was 9.08 cents loss per share, for the first half FY2019, compared with 1.46 cents earnings per share, for the first half of FY2018.

ITEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

Conference Call Details

There will be a webcast today on the financial results beginning at 4.30pm on Wednesday, February 20 EST; 8:30am on Thursday, February 21, 2019 AEDT.

The live webcast can be accessed via <https://webcasting.boardroom.media/broadcast/5c6107137e5a7b7d6e8941e4>

To access the call only, dial 1 855 881 1339 (U.S.), 1 800 558 698 (toll-free Australia) or +61 2 9007 3187 (outside of the U.S. and Australia). The conference identification code is 774100.

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). www.mesoblast.com

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Forward-Looking Statements

This announcement 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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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 U.S. dollars, in thousands, except per share amount)	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
Revenue	1,870	13,397	13,507	14,571
Research & development	(15,488)	(16,222)	(33,975)	(31,590)
Manufacturing commercialization	(5,401)	(801)	(9,717)	(1,678)
Management and administration	(5,126)	(5,643)	(10,742)	(10,655)
Fair value remeasurement of contingent consideration	(11)	(793)	(634)	8,702
Other operating income and expenses	(827)	423	(978)	1,091
Finance costs	(2,486)	—	(5,139)	—
Loss before income tax	(27,469)	(9,639)	(47,678)	(19,559)
Income tax benefit	2,865	23,342	3,575	26,240
(Loss)/profit attributable to the owners of Mesoblast Limited	(24,604)	13,703	(44,103)	6,681
(Losses)/earnings per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents	Cents	Cents
Basic - (losses)/earnings per share	(5.00)	2.91	(9.08)	1.46
Diluted - (losses)/earnings per share	(5.00)	2.91	(9.08)	1.46

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
(Loss)/profit for the period	(24,604)	13,703	(44,103)	6,681
Other comprehensive (loss)/income				
<i>Items that may be reclassified to profit and loss</i>				
Changes in the fair value of financial assets	108	47	195	67
Exchange differences on translation of foreign operations	(160)	(385)	(183)	(500)
Other comprehensive (loss)/income for the period, net of tax	(52)	(338)	12	(433)
Total comprehensive (losses)/income attributable to the owners of Mesoblast Limited	(24,656)	13,365	(44,091)	6,248

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Consolidated Statement of Balance Sheet

(in U.S. dollars, in thousands)	As of December 31, 2018	As of June 30, 2018
Assets		
Current Assets		
Cash & cash equivalents	77,022	37,763
Trade & other receivables	3,934	50,366
Prepayments	16,845	12,942
Total Current Assets	97,801	101,071
Non-Current Assets		
Property, plant and equipment	871	1,084
Financial assets at fair value through other comprehensive income	2,516	2,321
Other non-current assets	3,330	3,361
Intangible assets	583,815	584,606
Total Non-Current Assets	590,532	591,372
Total Assets	688,333	692,443
Liabilities		
Current Liabilities		
Trade and other payables	25,120	18,921
Provisions	5,594	5,082
Borrowings	3,095	—
Total Current Liabilities	33,809	24,003
Non-Current Liabilities		
Deferred tax liability	16,504	20,079
Deferred consideration	10,000	—
Provisions	43,076	42,956
Borrowings	60,387	59,397
Total Non-Current Liabilities	129,967	122,432
Total Liabilities	163,776	146,435
Net Assets	524,557	546,008
Equity		
Issued Capital	909,235	889,481
Reserves	39,617	36,719
(Accumulated losses)/retained earnings	(424,295)	(380,192)
Total Equity	524,557	546,008

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Six months ended December 31,	
	2018	2017
Cash flows from operating activities		
Commercialization revenue received	2,101	1,080
Milestone payment received	26,409	6,125
Research and development tax incentive received	1,654	—
Payments to suppliers and employees (inclusive of goods and services tax)	(46,186)	(42,593)
Interest received	293	192
Interest paid	(1,783)	—
Income taxes (paid)/refunded	(3)	(25)
Net cash (outflows) in operating activities	(17,515)	(35,221)
Cash flows from investing activities		
Investment in fixed assets	(112)	(137)
Payments for contingent consideration	—	(543)
Net cash (outflows) in investing activities	(112)	(680)
Cash flows from financing activities		
Proceeds from borrowings	28,950	—
Payments of transaction costs from borrowings	(1,546)	—
Proceeds from issue of shares	30,258	40,532
Payments for share issue costs	(607)	(2,603)
Net cash inflows by financing activities	57,055	37,929
Net increase in cash and cash equivalents	39,428	2,028
Cash and cash equivalents at beginning of period	37,763	45,761
FX (losses) on the translation of foreign bank accounts	(169)	(403)
Cash and cash equivalents at end of period	77,022	47,386

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Operational Highlights and Financial Results for the Half Year Ended December 31, 2018

February 2019

Nasdaq: MESO ASX: MSB

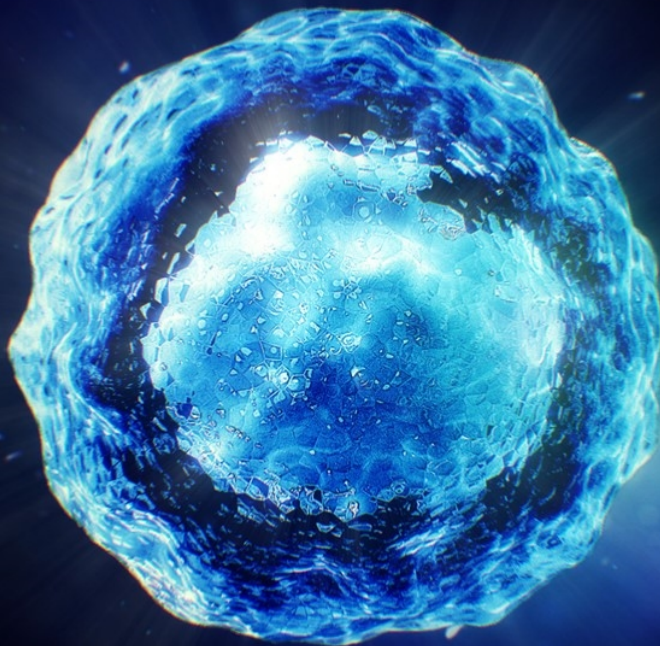


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, recent changes in regulatory laws, 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 current and potential future business partners 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.

Our Mission

Mesoblast is committed to bring to market innovative cellular medicines to treat serious and life-threatening illnesses



Premier Global Cellular Medicines Company



Innovative Technology Platform ¹	Late Stage Pipeline	Commercialization
<ul style="list-style-type: none">▪ Innovative technology targets the most severe disease states refractory to conventional therapies▪ Well characterized multimodal mechanisms of action▪ Underpinned by extensive, global IP estate	<ul style="list-style-type: none">▪ Upcoming BLA submission for Steroid-Refractory Acute GVHD▪ 2 blockbuster product candidates completed Phase 3 trial enrollment - heart failure and back pain▪ China cardiovascular partnership established	<ul style="list-style-type: none">▪ Building focused U.S. sales force for GVHD product launch▪ Industrial-scale manufacturing to meet commercial demand▪ First approved products commercialized by licensees in Japan² and Europe³▪ Increasing revenues and milestone payments

1. Mesenchymal precursor cells (MPCs) and their culture-expanded progeny mesenchymal stem cells (MSCs).

2. Licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan and markets this product under its trademark, TEMCELL® Hs Inj.

3. Licensee Takeda received first central marketing authorization approval from the European Commission for an allogeneic stem cell therapy and markets this product under its trademark, Alofisel®.

Corporate Highlights for the Half Year



Remestemcel-L for Steroid Refractory Acute Graft Versus Host Disease

- After demonstrating strong survival benefits through Day 180, held two successful end-of-phase meetings with the FDA covering clinical and manufacturing aspects of the upcoming BLA filing
- Meeting scheduled with the FDA in April 2019 and on track to subsequently initiate filing
- Building an efficient and targeted sales force for product launch

Revascor for Advanced and End-Stage Heart Failure

- Phase 3 trial in chronic heart failure completed patient enrollment, with 566 patients randomized, and will complete when sufficient primary endpoint events have accrued, which is likely to be within 12 months
- First Joint Steering Committee meeting held with Tasly, objective to initiate a clinical study in China using similar clinical endpoints and targeting a similar patient population as in Mesoblast's North American Phase 3 trial
- NIH sponsored 159-patient trial of Revascor in end-stage heart failure patients with an LVAD achieved a 76% reduction in major GI bleeding events and a 65% reduction in associated hospitalizations
- FDA provided guidance that reduction in GI bleeding and related hospitalizations is a clinically meaningful outcome that could support product registration

Corporate Highlights for the Half Year



Financial

- Strengthened cash position through both corporate transactions and strategic financing
 - US\$92 million pro forma cash on hand
- Completed transaction with Tasly to establish a cardiovascular partnership in China, and received US\$40 million
- Ramp up of manufacturing investment in preparation for registration and launch of remestemcel-L
- Increased product royalties from licensees

Board of Directors – Structured Succession Plan to Bring Complementary Skills

- Proven FDA product approval capabilities, commercial launch expertise, reimbursement and health system expertise and extensive global transactional record

Management – Expand to Support Commercial Launch Plans

- Commercial leadership with proven track record to roll out launch team
- Operational leadership to drive product life cycle management, commercial manufacturing and regulatory interactions



Financials

Pro Forma Cash Position of US\$92 million

US\$m	December 31, 2018	June 30, 2018
Reported Cash on Hand	77.0	37.8
NovaQuest financing agreement	-	39.0
Tasly strategic partnership	-	40.0
Hercules – 2 nd tranche	15.0	-
Pro forma cash on hand	92.0	116.8

- Pro forma cash on hand at December 31, 2018 includes US\$15.0 million received in January 2019 from Hercules Capital, Inc. after having successfully achieved the clinical milestone of reduction in major gastrointestinal bleeding (GI) events and related hospitalizations in the 159 patient trial of Mesoblast's product candidate Revascor in end stage heart failure patients with LVADs
- An additional US\$35.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones

Significant reduction in Operating Net Cash Outflows

For the six months ending (US\$m)	December 31, 2018	December 31, 2017
Operating net cash outflows	(17.5)	(35.2)
Investing net cash outflows	(0.1)	(0.7)
Financing net cash inflows	57.0	37.9
Net increase in cash	39.4	2.0

- 50% (US\$17.7 million) reduction in net operating cash outflows for the six months ended December 31, 2018, primarily due to the timing of receipts of milestone payments
- Increase in financing net cash inflows from strategic transactions with Tasly and Novaquest

Revenues – continued growth in royalties and substantial milestone revenues from corporate transactions

For the six months ending (US\$m)	December 31, 2018	December 31, 2017
Milestone revenue	11.0	12.8
Commercialization revenue	2.2	1.6
Interest revenue	0.3	0.2
Total revenue	13.5	14.6

- 43% growth in commercialization revenue from royalty income on sales of TEMCELL® HS. Inj.¹
- Corporate transactions drive milestone revenues
 - US\$10.0 million of milestone revenue from licensee Tasly Pharmaceutical Group in first half FY2019
 - US\$11.8 million of milestone revenue from licensee Takeda Pharmaceuticals in first half FY2018

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

Increased loss due to investment in manufacturing and financing, and non-cash gains in comparable period from revaluation of tax and contingent consideration

Profit and Loss for the six months ending (US\$m)	December 31, 2018	December 31, 2017
Total Revenue	13.5	14.6
Research and development	(34.0)	(31.6)
Manufacturing	(9.7)	(1.7)
Management & administration	(10.7)	(10.7)
Contingent consideration	(0.6)	8.7
Other operating income & expenses	(1.0)	1.1
Finance costs	(5.1)	-
(Loss)/Profit before tax	(47.7)	(19.6)
Income tax benefit	3.6	26.2
(Loss)/Profit after tax	(44.1)	6.7

- Increase in loss primarily due to the following items in the current period:
 - increased investment in commercial manufacturing by US\$8.0 million in preparation for GVHD approval;
 - incurred US\$5.1 million of increased finance costs;
- And the following items in the comparative period:
 - a one-off non-cash income tax benefit of US\$23.0 million due to a revaluation of tax liabilities given changes in tax rates
 - non-cash US\$8.7 million gain on contingent consideration for reduction of future payments to third parties;



Operational highlights for
the half year ended
December 31, 2018



Commercial and Late-Stage Product Pipeline

PLATFORM	PRODUCT	THERAPEUTIC AREA	APPROVAL	COMMERCIAL RIGHTS
MSC (Bone Marrow)	TEMCELL® HS Inj ¹	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	JCR Japan
MSC (Adipose)	Alofisel ^{®2}	Perianal Fistula	1st allogeneic regen med approved in Europe	Takeda Global

MARKETED

	PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL	PHASE 2	PHASE 3	COMMERCIAL RIGHTS
TIER 1	MSC	Remestemcel-L	Acute Graft Versus Host Disease	[Progress bar]			mesoblast the regenerative medicine company
	MPC	Revascor	Advanced HF (Class II/III) End-Stage HF (Class III/IV) ³	[Progress bar]			mesoblast the regenerative medicine company TASLY China ⁴
	MPC	MPC-06-ID	Chronic Low Back Pain	[Progress bar]			mesoblast the regenerative medicine company
	MPC	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy	[Progress bar]			mesoblast the regenerative medicine company
TIER 2	Includes remestemcel-L (Crohn's disease – biologic refractory), MPC-25-IC (Acute Cardiac Ischemia), MPC-25-Osteo (Spinal Fusion) and MPC-75-IA (Knee Osteoarthritis)						

IN DEVELOPMENT

1. Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® HS Inj, product in Japan
 2. Mesoblast will receive royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae
 3. Study funded by the United States National Institutes of Health (NIH) and the Canadian Health Research Institute; conducted by the NIH-funded Cardiothoracic Surgical Trials Network
 4. Tasly's rights are limited to China; Tasly also has rights to develop MPC-25-IC for AMI

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

Remestemcel-L: for SR Acute Graft Versus Host Disease (aGVHD)

Burden of Illness

- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMT)¹
- Steroid-refractory aGVHD is associated with **mortality rates as high as 95%¹ and significant extended hospital stay costs²**

Minimal Treatment Options

- There are **no approved treatments for SR-aGVHD outside Japan**
- In Japan, Mesoblast's licensee has received the only product approval for SR-aGVHD in both children and adults

Market Opportunity

- >30,000 allogeneic BMTs performed globally (>20K US/EU) annually, ~20% pediatric^{3,4}
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL[®] HS Inj.⁵ in Japan for SR-aGVHD in 2016; reimbursed up to ~\$USD195k⁶
- **SR-aGVHD represents USD > \$700m USA/EU market opportunity^{4,7}**



1. Westin, J., Saibba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 2012 and a SWOT analysis of the Worldwide Network for Blood and Marrow Transplantation Group including the global survey. 4. Source: CIBMTR. Current Uses and Outcomes of Hematopoietic Cell Transplantation 2017 Summary. Passweg JR, Baldomero, H (2016) Hematopoietic stem cell transplantation in Europe 2014: more than 40,000 transplants annually. 5. TEMCELL is the registered trademark of JCR Pharmaceuticals Co. Ltd. 6. Based on a ¥/PY = \$USD 0.009375 spot exchange rate on market close on November 11, 2016. Amounts are rounded. Source: Bloomberg. 7. Data on file

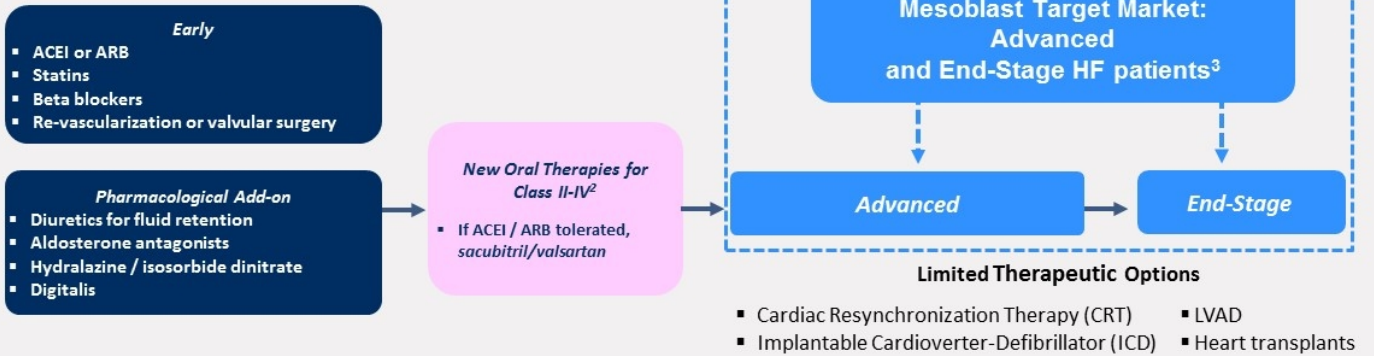
Remestemcel-L for SR Acute Graft Versus Host Disease: Commercial strategy overview

- TEMCELL® HS Inj. sales experience in Japan helps inform commercial strategy for the U.S.
- Fast Track designation provides eligibility for FDA priority review
- Commercialization strategy in place for product launch
- Building out efficient, targeted sales force

**FDA Biologics License Application submission on track for
early 2019**

Revascor: Targeting patients with progressive heart failure despite maximal standard of care

Common Treatment Pathway in Progressive Heart Failure¹



Class I Progressive Vascular (Endothelial) Dysfunction and Heart Failure **Class IV**

1. Source: Simon-Kucher & Partners 2017. Primary research 2017; Payers n=35, KOLs n=15, Cath lab managers n=4.
 2. Corlanor® (ivabradine) approved by FDA (April 2015). ENTRESTO® (sacubitril/valsartan) approved by FDA (July 2015).
 3. GlobalData-PharmaPoint Heart Failure (2016); McMurray et al., 2012; Yancy et al., 2013, 2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure.

Revascor: Commercial Opportunity for Advanced Heart Failure Market

Burden of Illness/Limited Options

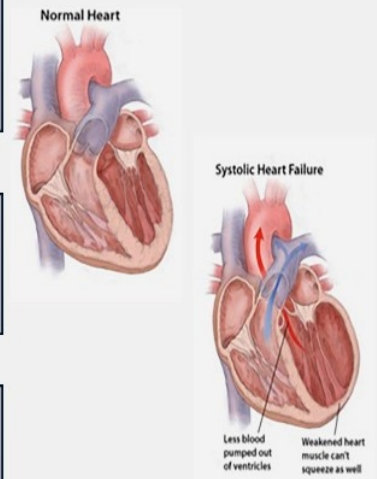
- ~ 8 million patients with chronic heart failure by 2030 in USA alone¹
- 17-45% globally die within 1 year of hospital admission¹
- Majority of advanced heart failure patients die within 5 years¹
- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure²

Unmet Need

- New therapies to reduce hospitalizations and mortality in patients with advanced heart failure who have failed other therapies
- Greatest need is in NYHA class III/IV where event rate is highest

Market Opportunity

- US healthcare costs for NYHA class II-IV patients \$115bn/year⁵
- Hospitalizations account for ~69% of expenditure³⁻⁵
- **Multi-billion dollar annual market opportunity in USA^{4,5}**



1. Heart Failure: Preventing disease and death worldwide – European Society of Cardiology. 2014. 2. ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. 3. 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. 4. A Reevaluation of the Costs of Heart Failure and its Implications for Allocation of Health Resources in the United States. Voigt J. Clinl Cardiol. 37, 5, 312-321 (2014). 5. The Medical and Socioeconomic Burden of Heart Failure: A Comparative Delineation with Cancer. Dimitrios, F. International Journal of Cardiology (2015). doi: 10.1016/j.ijcard.2015.10.172.

Revascor: Phase 3 Trial for Advanced Heart Failure Fully Enrolled



- Events-driven Phase 3 trial completes enrollment of 566 patients
- Evaluating a single dose of Revascor to reduce recurrent heart failure-related major adverse cardiac events such as heart failure-related hospitalizations and cardiac death
- Target patient population enriched for those likely to be both highest-risk for events and greatest responders to MPC therapy
- Trial will complete when sufficient primary endpoint events accrued, likely to be within 12 months from last patient dosed
- Trial design is 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America

Revascor: Commercial Opportunity for Use in End-Stage Heart Failure Patients with LVADs to Reduce Hospitalizations from GI Bleeding

Burden of Illness

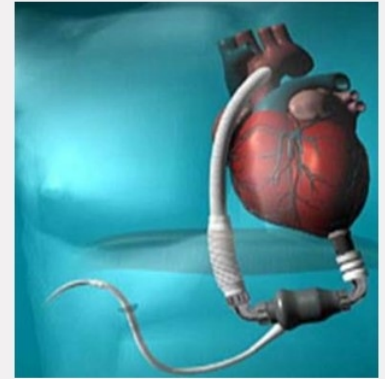
- In the USA, there are approximately 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class III–IV).¹
- Despite optimal medical therapy, mortality exceeds 50% in class IV patients.¹

Ongoing Unmet Need

- LVADs have improved survival, but morbidity remains high with patients on average experiencing greater than two hospitalization annually.²
- Gastrointestinal (GI) bleeding is the leading cause of non-surgical hospitalizations in LVAD patients²
- **Device attributable major adverse events (DAEs) can cost on average from up to \$46.5k per hospitalization²**

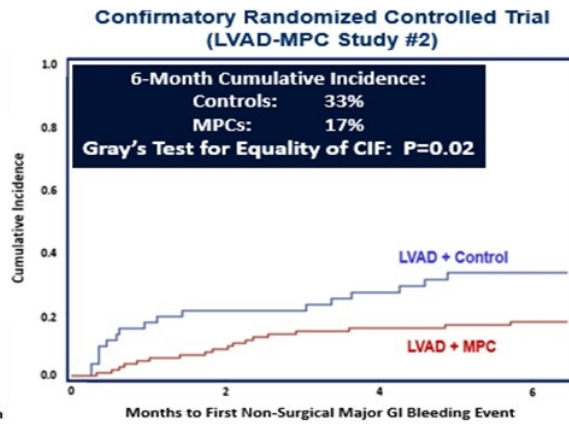
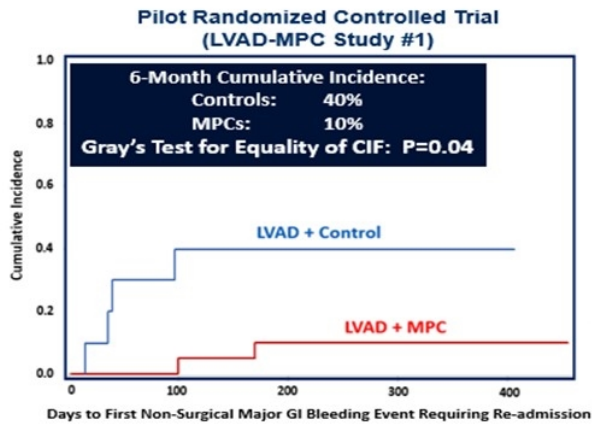
Market Opportunity

- ~4,500 – 5,500 assist devices are implanted annually in the United States.^{3, 4}
- **US LVAD market is growing double-digit CAGR and represents significant market growth opportunity^{3, 4}**
- US targeted commercial footprint provides low cost market entry



¹Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, ² Mehra, MR, Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure, ³Agency for Healthcare Research and Quality – Healthcare Cost and Utilization Project – claims analysis using ICD-937.6 implantation of heart and circulatory assist systems, ⁴ Data on File

MPCs Prolong Time-to-First Major GI Bleeding Event and Reduce Cumulative Major GI Bleeding Events in Two Confirmatory Randomized Controlled Trials in LVAD Patients^{1,2}



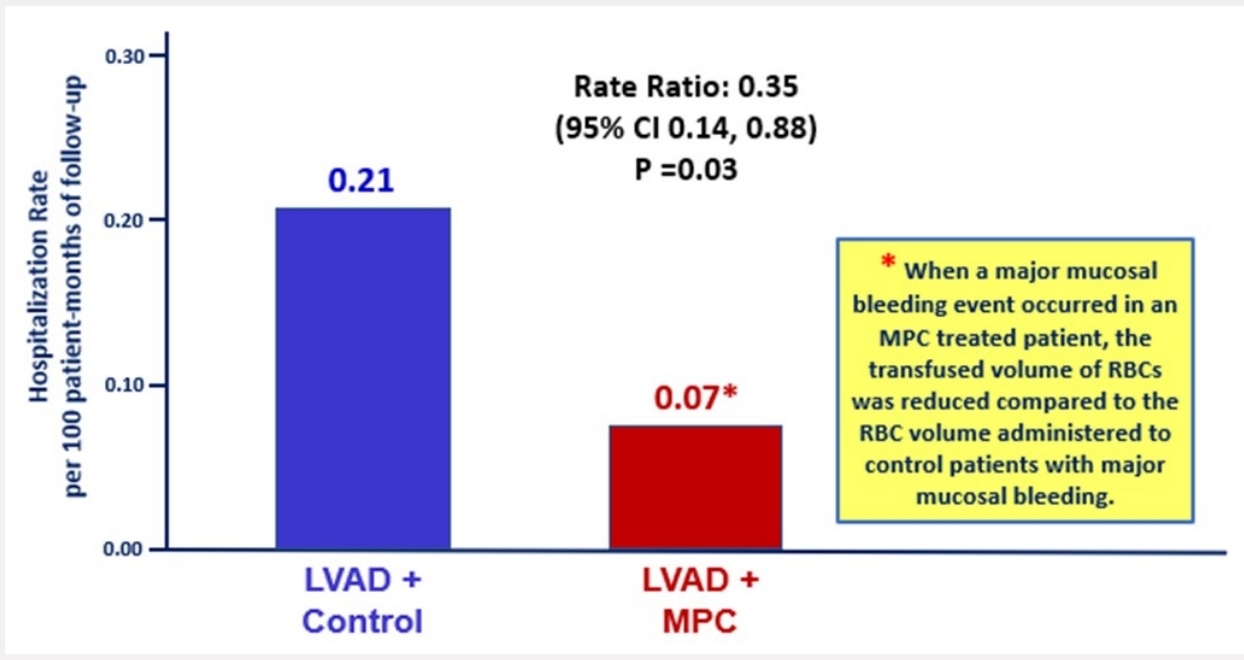
MPC (n = 20)	Control (n = 10)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
4.2	14.2	0.06

MPC (n = 106)	Control (n = 53)	P-value
Event Rate (100-Pt-Months)	Event Rate (100-Pt-Months)	
3.8	15.9	<0.001

Rate of major GI bleeding events over 6 months in LVAD patients reduced by 70% and 76% with MPCs in two randomized controlled trials

1. Mesoblast internal data post-hoc analysis 2017 (clinicaltrials.gov, identifier: NCT01442129). 2. Presented at American Heart Association Scientific Sessions 2018.

MPCs Reduce Hospitalization Rate from GI Bleeding by 65% in 159-Patient Phase 2 Trial¹



¹ Presented at American Heart Association Scientific Sessions 2018.



Revascor (MPC-150-IM) Has Received RMAT Designation for Use In End-Stage Heart Failure Patients with LVADs

- Key benefits of the RMAT designation include:
 - Potential eligibility for priority review and accelerated approval
 - Potential to utilize surrogate endpoints for accelerated approval
 - Potential to utilize patient registry data and other sources of “real world evidence” for post approval studies, subject to approval by the FDA
- Mesoblast received guidance from FDA that reduction in major GI bleeding
 - is a clinically meaningful outcome
 - could be used as an endpoint to support product approval
- Mesoblast plans to meet with FDA in 1H 2019 to discuss pathway to filing for Biologics License Application (BLA)



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

Burden of Illness

- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system,¹ including excessive use of opioids in this patient population²

Minimal Treatment Options

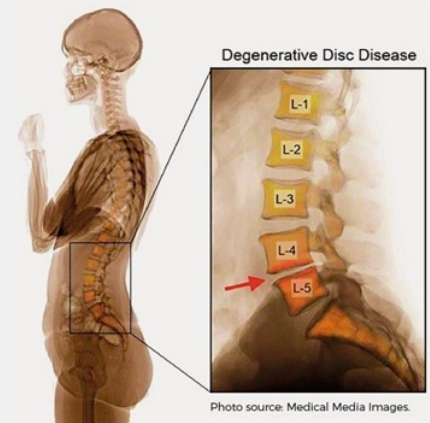
- Treatment options for patients with CLBP who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for chronic low back pain (CLBP)²

Unmet Need

- Novel therapeutic approach for durable improvement in pain and function
- Potential alternative for opioid use or surgical intervention

Market Opportunity

- MPC-06-ID development focused on over ~3.2m patients with CLBP due to degenerative disc disease (DDD) in US alone^{3,4,5}
- **USA market opportunity >USD \$1 billion**^{3,4,5,6}

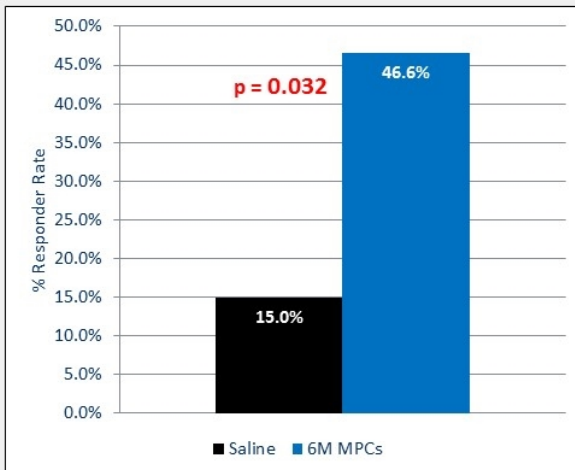


1. Williams, J., NG, Nawi, Peltzer, K. (2015) Risk factors and disability associated with low back pain in older adults in low- and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PLoS One. 2015; 10(6): e0127880. 2. Decision Resources: Pain Management Study, Chronic Pain December 2013. 3. Decision Resources: Chronic Pain December 2015. 4. LEK & NCI opinion leader interviews, and secondary analysis. 5. Navigant Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014. 6. Data on File.

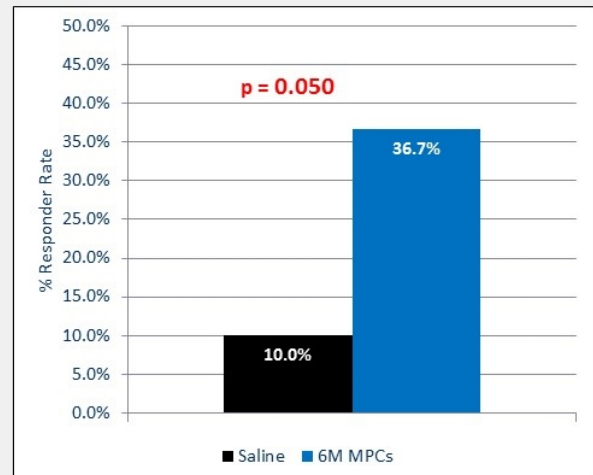
Chronic Low Back Pain MPC-06-ID

Post-Hoc Phase 2 results over 24 months provide target endpoints for Phase 3 trial

**A: Phase 2: Treatment Success Responders^{1,2}
at 12 Months**



**B: Phase 2: Treatment Success Responders^{1,2}
at both 12 & 24 Months**



**404 patient 2:1 randomized Phase 3 trial completed enrollment March 2017
All patients to complete 12 month assessment for safety and efficacy in H1 2019**

1. Subjects with missing data are classified as non-responders.
2. Treatment Success Responders have a 50% reduction in LBP as measured by VAS AND a 15 point improvement in function as measured by ODI at a) 12 months, and b) both 12 and 24 months and no intervention through 24 months.

Key Milestones

Remestemcel-L for Acute Graft Versus Host Disease

- Successfully met all efficacy and safety endpoints through six months ✓
- Initiate BLA filing for marketing authorization following FDA meeting scheduled for April 2019
- Build out efficient and targeted sales force for product launch

Revascor for Advanced and End-Stage Heart Failure

- Phase 3 events-driven trial in advanced heart failure in North America completed 566 patient enrollment ✓
- Primary endpoint events continue to accrue; likely to complete within 12 months
- Mesoblast's partner Tasly plans to meet in H1 CY19 with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China
- Mesoblast plans to meet with FDA in H1 CY19 to discuss pathway for approval of Revascor for reduction in GI bleeding in patients with LVADs

MPC-06-ID for Chronic Low Back Pain

- Phase 3 trial completed enrollment (Q1 CY18) ✓
- All 404 patients in Mesoblast's Phase 3 trial in MPC-06-ID for chronic lower back pain will have completed their 12-month assessments for safety and efficacy in H1 CY19

Establish additional global and regional strategic and commercial licensing arrangements

