

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 November 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 November 26, 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 are 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: November 27, 2019

INDEX TO EXHIBITS

Item _____

- 99.1 Press release of Mesoblast Ltd, dated November 26, 2019.
- 99.2 Investor presentation of Mesoblast Ltd, dated November 26, 2019

MESOBLAST FINANCIAL RESULTS FOR THE QUARTER ENDED SEPTEMBER 30, 2019
Continued Increase in Revenues and Strong Balance Sheet

Melbourne, Australia, November 26, 2019 and New York, USA, November 25, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported operational highlights and financial results for the first quarter ended September 30, 2019.

Mesoblast Chief Executive Dr Silviu Itescu stated: "The Company's financial results for the quarter reflect continued growth in revenues from product sales in Japan and ongoing strategic partnering activities, and a reduction in R&D expenditures. Our balance sheet positions us well as we prepare for first product approval and launch in the United States market."

Financial Highlights for the First Quarter FY2020

- 46% growth in revenues due to:
 - 43% increase in milestone revenues from strategic partnerships (US\$15.0 million compared with US\$10.5 million for the first quarter of FY2019).
 - 85% growth in revenues from sales of TEMCELL^{®1} HS. Inj. by Mesoblast's licensee for steroid-refractory acute graft versus host disease (aGVHD) in Japan compared to the first quarter of FY2019.
- 72% reduction in loss after tax compared to the first quarter FY2019 (US\$5.5 million compared with US\$19.5 million) driven by:
 - 33% decrease in research and development spend (US\$12.4 million compared with US\$18.5 million for the first quarter FY2019).
 - 46% increase in revenues from milestones and commercialization, as noted above.
- At September 30, 2019, cash on hand was US\$34.5 million and pro forma cash on hand was US\$100.0 million. Pro forma cash on hand has been adjusted for US\$15.0 million upfront received on October 1, 2019 from Grünenthal GmbH and US\$50.5 million of gross cash proceeds from the capital raise on October 3, 2019.
- Over the coming 12 months, Mesoblast may have access to an additional US\$65.0 million in non-dilutive capital under existing strategic partnerships and financial arrangements.

Operational Highlights for the First Quarter FY2020

- The continued growth in commercialization revenues reflects successful aGVHD market adoption in Japan and provides insight into the projected uptake of our product candidate remestemcel-L for aGVHD in the United States.
- In October, Mesoblast entered into an agreement with Lonza for commercial product manufacture in line with the corporate strategy to facilitate appropriate inventory build ahead of the planned launch of remestemcel-L.
- Mesoblast entered into a strategic partnership with Grünenthal, a global leader in pain management, to develop and commercialize MPC-06-ID, Mesoblast's Phase 3 allogeneic product candidate for the treatment of chronic low back pain due to degenerative disc disease. Under the partnership, Grünenthal will have exclusive commercialization rights to MPC-06-ID for Europe and Latin America.

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- Under the Grünenthal agreement, Mesoblast will receive up to US\$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments. Cumulative milestone payments could exceed US\$1 billion depending on the outcome of Phase 3 studies and patient adoption. Mesoblast will also receive tiered double-digit royalties on product sales.
- Mesoblast and the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York have agreed on the protocol for a confirmatory Phase 3 trial of Revascor in the treatment of patients with end-stage heart failure and a left ventricular assist device (LVAD), in line with US Food and Drug Administration (FDA) guidance on a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.
- Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designations.

Key Milestones

Remestemcel-L for aGVHD

- Upcoming filing of the completed Biologic License Application (BLA) submission to the US Food and Drug Administration (FDA).
- Within a maximum of 60 days after receipt of the complete application, Mesoblast will be informed by FDA of acceptance of the filing, and whether the BLA has received Priority Review under its existing Fast Track designation.
- If approved, the US launch of remestemcel-L is expected to occur next year.

Revascor for advanced and end-stage heart failure

- Full accrual of primary endpoints events in the Phase 3 trial of Revascor for advanced heart failure around the end of this year.
- Data read-out for this Phase 3 trial planned in H1 CY20.
- Results will be considered pivotal to support regulatory approval in the US, as well as China through the Tasty partnership.
- Initiation of confirmatory Phase 3 trial of Revascor for the reduction of mucosal bleeding in end-stage heart failure patients implanted with an LVAD.

MPC-06-ID for chronic low back pain

- Last patient last visit at 24-months of follow up in the Phase 3 trial of MPC-06-ID for chronic low back pain H1 CY20, with the primary endpoint being a composite outcome of pain and function at 12 and 24 months.
- Results will be considered pivotal to support regulatory approval in the US, as well as Europe through the Grünenthal partnership.

Strategic partnerships

- In active discussions to enter into further global and regional strategic partnering transactions.²

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Financial Results for the Three Months Ended September 30, 2019 (first quarter FY2020)

Loss after tax reduced by US\$14.0 million to US\$5.5 million for the first quarter FY2020 compared to US\$19.5 million for the first quarter FY2019 as detailed below:

- **Revenues** increased US\$5.4 million to US\$17.0 million for the first quarter FY2020, compared to US\$11.6 million for the first quarter FY2019.
 - Milestone revenues increased by US\$4.5 million as we recognized the up-front milestone payment of US\$15.0 million for the strategic partnership with Grünenthal in first quarter FY2020. In the first quarter of FY2019 we recognized US\$10.0 million of milestone revenue in relation to establishing a partnership with Tasy in China and US\$0.5 million of cumulative sales milestones for sales of TEMCELL in Japan.
 - Royalty revenue on sales of TEMCELL in Japan increased US\$0.9 million (85%) to US\$1.9 million for the first quarter FY2020 compared with US\$1.0 million for the first quarter FY2019.
- **Research and Development** expenses decreased by US\$6.1 million to US\$12.4 million for the first quarter FY2020, compared to US\$18.5 million for the first quarter FY2019. This US\$6.1 million decrease was due to a reduction in third party costs for our Phase 3 clinical trials as enrollment is now complete and activities are decreasing.
- **Manufacturing** expenses decreased by US\$1.6 million to US\$2.7 million for the first quarter FY2020, compared to US\$4.3 million for the first quarter FY2019 due to a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for remestemcel-L.
- **Management and Administration** expenses decreased US\$0.1 million to US\$5.5 million for the first quarter FY2020, compared with US\$5.6 million for the first quarter FY2019.
- **Finance Costs** for our borrowing arrangements with Hercules and NovaQuest were US\$3.5 million for the first quarter FY2020, compared to US\$2.7 million for the first quarter FY2019, an increase of US\$0.8 million.
- **Income tax benefit** increased by US\$1.2 million to US\$1.9 million in the first quarter FY2020, compared with US\$0.7 million in the first quarter FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 1.10 cents per share for the first quarter FY2020, compared with 4.07 cents for the first quarter FY2019.

Cash on hand was US\$34.5 million at September 30, 2019, pro forma cash on hand was US\$100.0 million after adjusting for US\$15.0 million upfront received on October 1, 2019 from Grünenthal GmbH and US\$50.5 million of gross cash proceeds from the capital raise on October 3, 2019.

Webcast

There will be a webcast today on the financial results beginning at 8.30am on Tuesday November 26, 2019 AEDT; 4.30pm Monday November 25, 2019 EST.

The live webcast can be accessed via <https://webcasting.boardroom.media/broadcast/5dcd529dbec873524b6116b>

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

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1. TEMCELL HS. Inj.® is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. Mesoblast does not make any representation or give any assurance that such partnering transactions will be concluded

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 cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast has initiated submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial, and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com.
LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

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 September 30,	
	2019	2018
Revenue	17,048	11,637
Research & development	(12,389)	(18,489)
Manufacturing commercialization	(2,698)	(4,317)
Management and administration	(5,463)	(5,614)
Fair value remeasurement of contingent consideration	(288)	(622)
Other operating income and expenses	(169)	(151)
Finance costs	(3,457)	(2,653)
Loss before income tax	(7,416)	(20,209)
Income tax benefit	1,932	711
Loss attributable to the owners of Mesoblast Limited	(5,484)	(19,498)
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:	Cents	Cents
Basic - losses per share	(1.10)	(4.07)
Diluted - losses per share	(1.10)	(4.07)

Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Three Months Ended September 30,	
	2019	2018
Loss for the period	(5,484)	(19,498)
Other comprehensive (loss)/income		
<i>Items that may be reclassified to profit and loss</i>		
Financial assets at fair value through other comprehensive income	(365)	87
Exchange differences on translation of foreign operations	(332)	(23)
Other comprehensive income/(loss) for the period, net of tax	(697)	64
Total comprehensive losses attributable to the owners of Mesoblast Limited	(6,181)	(19,434)

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

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Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Three months ended September 30,	
	2019	2018
Cash flows from operating activities		
Commercialization revenue received	1,739	1,095
Milestone payment received	—	500
Research and development tax incentive received	1,499	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(17,539)	(22,039)
Interest received	173	136
Interest and other costs of finance paid	(1,427)	(887)
Income taxes (paid)/refunded	(3)	(3)
Net cash (outflows) in operating activities	(15,558)	(19,544)
Cash flows from investing activities		
Investment in fixed assets	(153)	(39)
Payments for licenses	(100)	—
Net cash (outflows)/inflows in investing activities	(253)	(39)
Cash flows from financing activities		
Proceeds from borrowings	—	28,950
Payments of transaction costs from borrowings	—	(1,534)
Proceeds from issue of shares	299	10,048
Payments for share issue costs	—	(358)
Payment of lease liabilities	(335)	—
Net cash inflows by financing activities	(36)	37,106
Net increase/(decrease) in cash and cash equivalents	(15,847)	17,523
Cash and cash equivalents at beginning of period	50,426	37,763
FX (losses)/gains on the translation of foreign bank accounts	(43)	(143)
Cash and cash equivalents at end of period	34,536	55,143

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**Global Leader in Allogeneic Cellular
Medicines for Inflammatory Diseases**

First Quarter Ended September 30, 2019

Nasdaq: MESO ASX: MSB

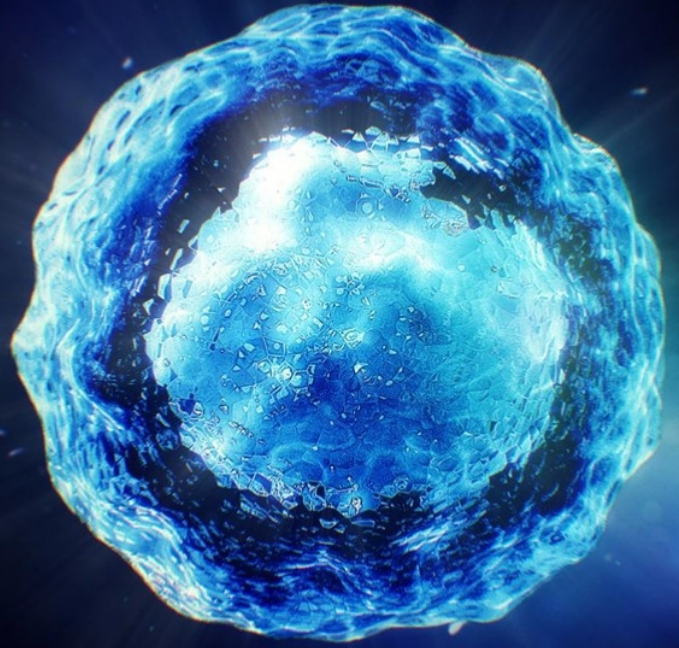


CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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.

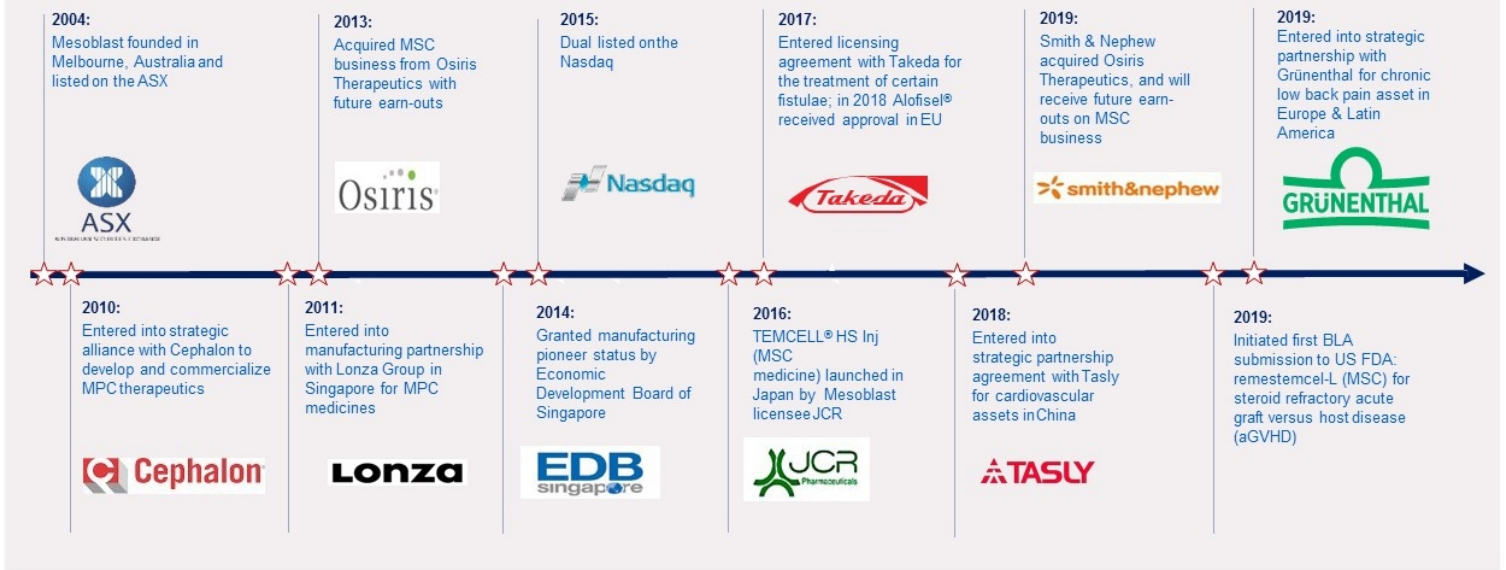
Our Mission

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



Corporate History

Over a decade of scientific, manufacturing, clinical development and corporate development experience targeted at bringing to market allogeneic, off-the-shelf cellular medicines for inflammatory diseases





Innovative Technology Platform ¹	Late Stage Pipeline	Commercialization
<ul style="list-style-type: none">▪ Innovative technology targets some of 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">▪ Initiated rolling filing with US FDA for approval for steroid-refractory aGVHD▪ Two Phase 3 product candidates – heart failure and back pain – with near term US trial readouts▪ Back pain Phase 3 product candidate partnered in Europe & Latin America with Grünenthal▪ Heart failure Phase 3 product candidate partnered in China	<ul style="list-style-type: none">▪ Building US sales force for potential aGVHD product launch▪ Industrial-scale manufacturing to meet commercial demand▪ First approved products commercialized by licensees in Japan² and Europe³▪ Continued growth in royalty revenues from strategic partnerships

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®.

Commercial Scale Manufacturing Capability

- Scalable allogeneic “off-the-shelf” cellular medicine platform
- Manufacturing meets stringent criteria set by international regulatory agencies including FDA and EMA
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Culture expansion scalable for near term commercial needs
- Proprietary xeno-free technologies being developed to enable sufficient yields for long term global commercial supply
- Next generation processes using 3D bioreactors to reduce labor and drive down cost of goods



Lonza contract manufacturing facility in Singapore

Global IP Estate Provides Substantial Competitive Advantage

- ~1,000 patents and patent applications (68 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Enables licensing to third parties for different indications, when in alignment with our corporate strategy e.g. TiGenix (subsequently acquired by Takeda)
- Provides strong global protection against competitors seeking to develop products in areas of core commercial focus



Markets
U.S., Europe, China, and Japan

Sources
Allogeneic, Autologous, (Bone Marrow, Adipose, Dental Pulp, Placenta), Pluripotent (iPS)

Diseases
All Tier 1 & Tier 2 Indications, and multiple additional conditions

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

PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL	PHASE 2	PHASE 3	COMMERCIAL RIGHTS
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease	[Progress bars]			BLA submission to FDA underway mesoblast the regenerative medicine company
		Crohn's Disease	[Progress bars]			
		Knee Osteoarthritis	[Progress bars]			
MPC suite	Revascor	Advanced HF (Class II/III) End-Stage HF (Class III/IV)	[Progress bars]			TASLY China mesoblast ROW
	MPC-06-ID	Chronic Low Back Pain	[Progress bars]			GRUNENTHAL Europe Lat Am mesoblast ROW
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy	[Progress bars]			mesoblast the regenerative medicine company

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

1. TEMCELL® HS, Inj. is a registered trademark of JCR Pharmaceuticals Co Ltd
 2. Alofisel® is a registered trademark of Takeda Pharmaceuticals

Partnerships and License Agreements



- Strategic partnership to develop and commercialize MPC-06-ID for chronic low back pain due to degenerative disc disease in patients who have exhausted conservative treatment options
- Grünenthal will have exclusive commercialization rights for Europe and Latin America
- Mesoblast will receive up to US\$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments
- Cumulative milestone payments could exceed US\$1 billion depending on the final outcome of Phase III studies and patient adoption. Mesoblast will also receive tiered double digit royalties on product sales



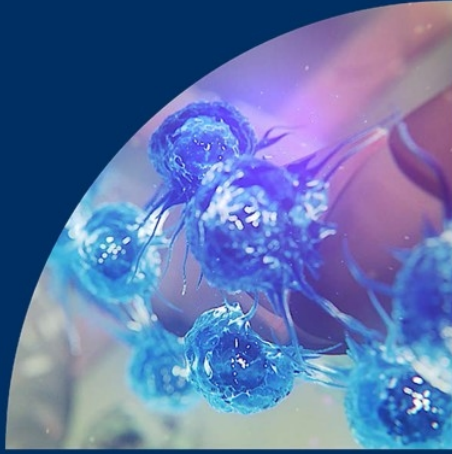
- JCR has rights to use our MSC technology to treat acute GVHD in Japan
- Its product TEMCELL® HS Inj. was the first fully approved allogeneic cellular medicine in Japan
- Royalties and milestones received in last 12 months exceed US\$6.0 million
- License expanded to cover use in epidermolysis bullosa (EB), a highly debilitating and sometimes lethal skin disease and hypoxic ischemic encephalopathy (HIE) in newborns



- Patent license agreement entered in Dec 2017 with Takeda (formerly TiGenix NV) providing exclusive access to certain IP for local treatment of perianal fistulae
- Mesoblast received €10 million in payments and is eligible to receive up to an additional €10 million in milestone payments (€20 million in total payments) plus royalties upon commercial sales of Alofisel® worldwide



- Exclusive cardiovascular rights in China
- Mesoblast received US\$40 million on closing, and is eligible to receive additional milestones and royalties



Financials
First Quarter FY2020



Substantial Increase in Revenues

For the quarter ending (US\$m)	September 30, 2019	September 30, 2018	September 30, 2017
Upfront/milestone revenue	15.0	10.5	0.5
Commercialization revenue	1.9	1.0	0.6
Interest revenue	0.1	0.1	0.1
Total revenue	17.0	11.6	1.2

- Strategic partnerships drive upfront and milestone revenues
 - US\$15.0 million for an upfront milestone payment for the strategic partnership with Grünenthal GmbH in the first quarter FY2020
 - US\$10.0 million from licensee Tasly Pharmaceutical Group in the first quarter FY2019
 - US\$0.5 million from licensee JCR in the first quarter FY2019
- 85% growth in commercialization revenue from royalty income on sales of TEMCELL® HS. Inj.¹

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

Loss After Tax Reduced by 72% (US\$14.0 million)

Profit and Loss for the quarter ending (US\$m)	September 30, 2019	September 30, 2018
Total Revenue	17.0	11.6
Research and development	(12.4)	(18.5)
Manufacturing	(2.7)	(4.3)
Management & administration	(5.4)	(5.6)
Contingent consideration	(0.3)	(0.6)
Other operating income & expenses	(0.2)	(0.2)
Finance costs	(3.4)	(2.6)
Loss before tax	(7.4)	(20.2)
Income tax benefit	1.9	0.7
Loss after tax	(5.5)	(19.5)

Loss after tax reduced by US\$14.0 million (72%) predominantly due to:

- US\$6.1 million reduction in R&D expenditure; and
- US\$5.4 million increase in milestone revenues from strategic partnerships and increased commercialization revenues from product sales in Japan.

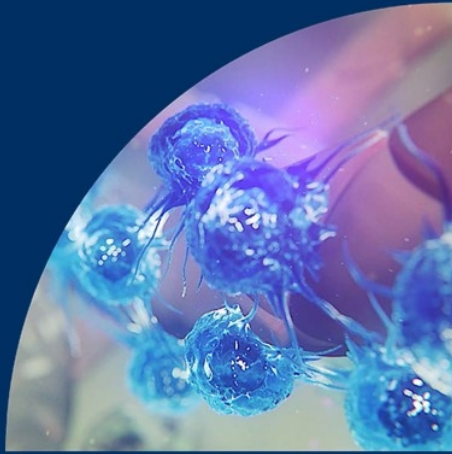
Strong Balance Sheet and 20% Reduction in Operating Net Cash Outflows

As of (US\$m)	September 30, 2019	June 30, 2019
Cash on Hand	34.5	50.4
Pro forma cash on hand	100.0	50.4

- Pro forma cash on hand at September 30, 2019 includes a US\$15.0 million upfront payment for the strategic partnership with Grünenthal received on October 1, 2019 and US\$50.5 million of gross cash proceeds from an institutional capital raise received on October 3, 2019.
- Over the next 12 months, we may receive up to an additional US\$30.0 million in milestone payments under the strategic partnership with Grünenthal and a further US\$35.0 million under the arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.

For the quarter ending (US\$m)	September 30, 2019	September 30, 2018	September 30, 2017
Operating net cash outflows	(15.6)	(19.5)	(20.4)

- 20% (US\$3.9 million) reduction in net operating cash outflows for the three months ended September 30, 2019.



Operational Highlights
First Quarter FY2020



Acute Graft Versus Host Disease (aGVHD)

Significant market opportunity for Remestemcel-L



Burden of Illness

- aGVHD is a life-threatening complication that occurs in ~50% of patients receiving allogeneic bone marrow transplants (BMTs)¹
- Steroid-refractory aGVHD is associated with **mortality rates as high as 90%**^{1,7} and **significant extended hospital stay costs**²

Minimal Treatment Options

- There is only one approved treatment for SR-GVHD and **no approved treatment for children under 12 years old, 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 US/EU market opportunity**^{4,8}



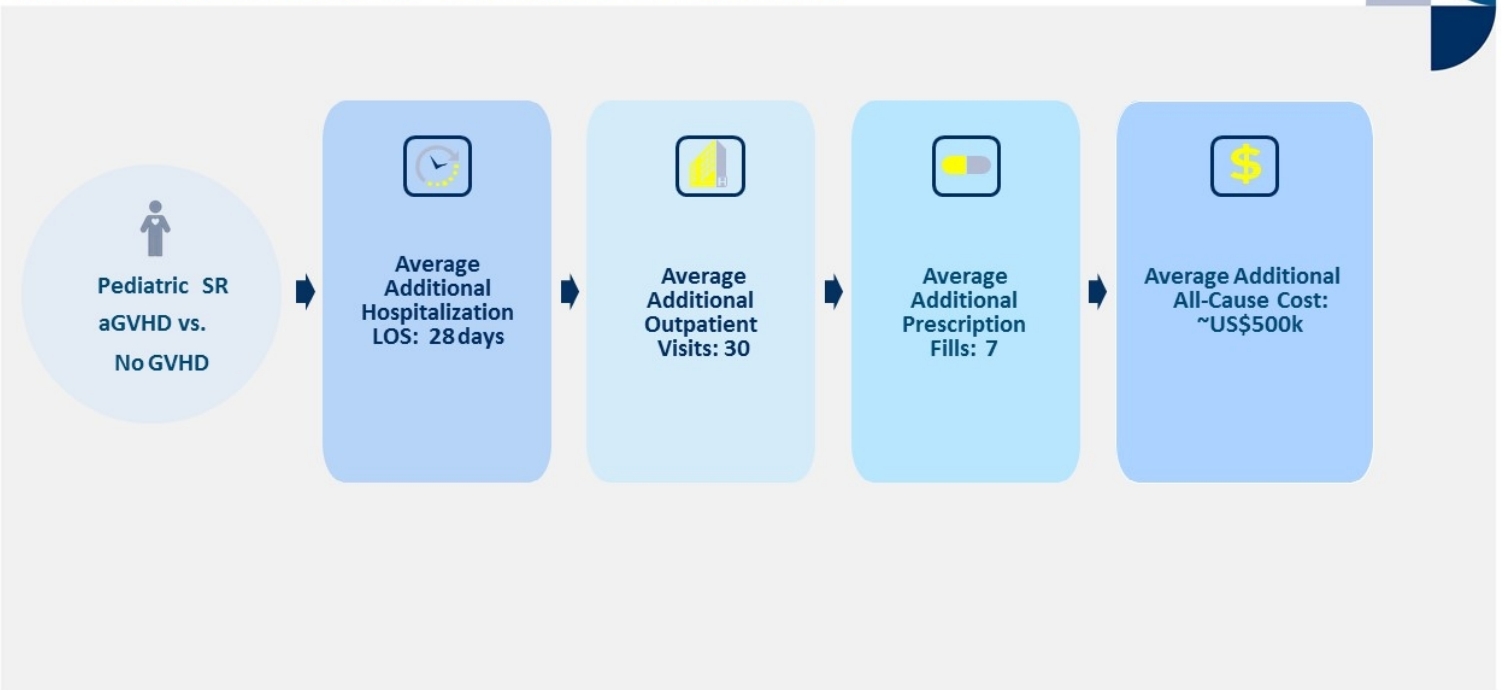
1. Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. *Advances in Hematology*. 2. Anthem-HealthCore/Mesoblast claims analysis (2016). Data on file 3. Niederwieser D, Baldomero H, Szer J. (2016) Hematopoietic stem cell transplantation activity worldwide in 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 ¥JPY = \$USD 0.009375 spot exchange rate on market close on November 11, 2016. Amounts are rounded. Source: Bloomberg. 7. Axt L, Naumann A, Toennies J (2019) Retrospective single center analysis of outcome, risk factors and therapy in steroid refractory graft-versus-host disease after allogeneic hematopoietic cell transplantation. *Bone Marrow Transplantation*. 8. Data on file

Remestemcel-L: U.S. Regulatory and Commercial Strategy



- US strategy for remestemcel-L informed by TEMCELL sales experience in Japan
- Rolling BLA submission to FDA
- Fast Track designation provides eligibility for FDA priority review
- Commercialization strategy in place for product launch
- Ramp-up for inventory build
- Building out efficient, targeted sales force - 15 centers account for ~50% of patients

Remestemcel-L: SR-aGVHD is Associated with Significant Burden of Illness in Children in the U.S.¹



1. European Hematology Association 2019 Congress Meeting: Abstract PF718, The economic and humanistic burden of graft-versus-host disease (GVHD) in pediatric patients: A systematic literature review (SLR)

Remestemcel-L: Results from Providers/Payers Indicate Near Maximal Rating on Product Attributes¹



(n=20)

0

Reaction to
Tested Target Profile²

Median
Response

6

7

Max Rating Product
Attributes

Most Significant Value Drivers for Remestemcel-L

- Day 28 overall response rate (especially grade C/D)
- Day 100 & Day 180 Survival rates
- No increase in infections
- Large clinical data set (n~300)
- Ability to administer the drug outpatient
- Significant reduction in ICU stay

1. Data on file.

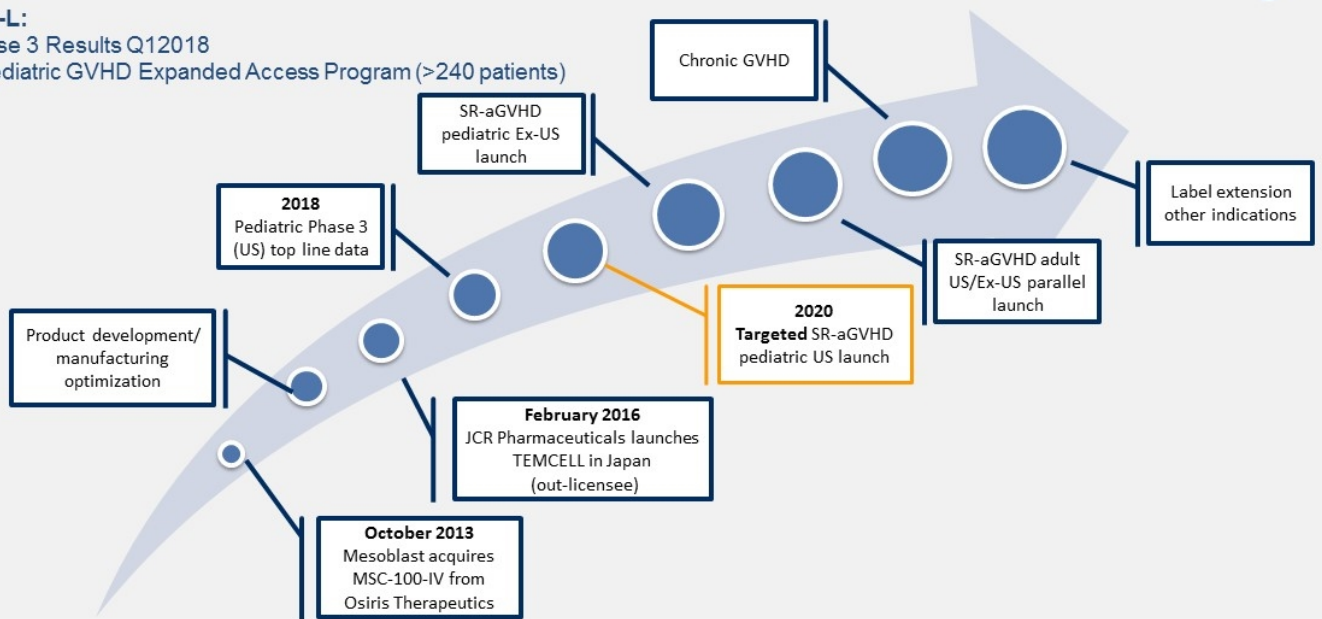
2. ZS Associates June 2018 Qualitative Market Research: MCO Medical Directors n=5, Transplant Center Directors n=5, Hospital Pharmacy Directors n=5, AMC-based Hem/Oncs / KOLs n=3

Remestemcel-L: Life Cycle Strategy

Mesoblast has over 10 years of experience in hematology-oncology space

Remestemcel-L:

- Positive Phase 3 Results Q12018
- Large US Pediatric GVHD Expanded Access Program (>240 patients)



Remestemcel-L for Acute GVHD



Recent Highlights

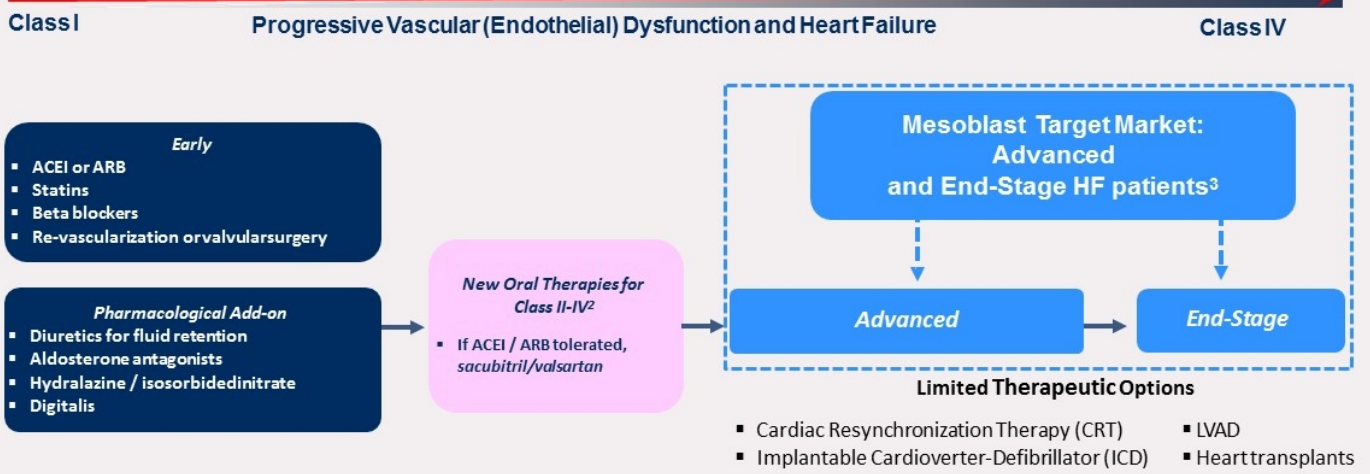
- Continued growth in revenues from royalties on sales of TEMCELL in Japan for steroid refractory aGVHD
 - Product adoption and reimbursement seen in the Japan GVHD market for TEMCELL informs Mesoblast US commercial strategy for remestemcel-L in aGVHD
 - US addressable market for SR aGVHD in children and adults is expected to be approximately 8-fold larger than Japan, a major commercial opportunity due to greater patient numbers, incidence and pharmacoeconomics
- Mesoblast entered into an agreement with Lonza for commercial product manufacture in line with the corporate strategy to facilitate appropriate inventory build ahead of the planned launch of remestemcel-L

Key milestones

- Upcoming filing of completed Biologic License Application (BLA) submission to the US Food and Drug Administration (FDA)
- Within a maximum of 60 days after receipt of the complete application, Mesoblast will be informed by FDA of acceptance of the filing, and whether the BLA has received Priority Review under its existing Fast Track designation
- If approved, the US launch of remestemcel-L is expected to occur next year

Advanced and End-Stage Heart Failure

Common Treatment Pathway in Progressive Heart Failure¹



1. Source: Simon-Kucher & Partners 2017. Primary research 2017; Payers n=35, KOLs n=15, Cath lab managers n=4.

2. Corlanort® (vabradine) 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.

Advanced Heart Failure

Revascor – Commercial opportunity

Burden of Illness

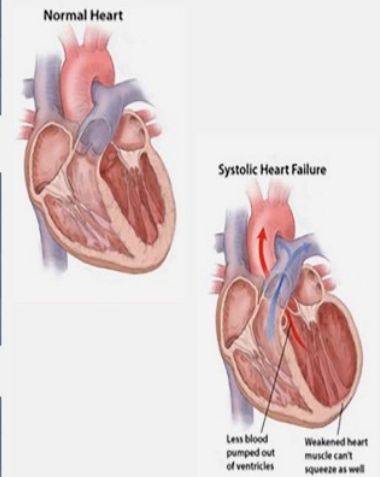
- ~ 8 million patients with chronic heart failure by 2030 in US alone¹
- 17-45% globally die within 1 year of hospital admission¹
- Majority of advanced heart failure patients die within 5 years¹

Limited Options / Unmet Need

- Despite recent advances in newly approved drugs, limited treatment options are available for patients with advanced heart failure²
- New therapies to reduce hospitalizations and mortality in patients with advanced heart failure who have failed other therapies
- Area of great need: NYHA class III-IV where event rate is highest

Market Opportunity

- US healthcare costs for NYHA class II-IV patients \$US115bn/year⁴
- Hospitalizations account for ~69% of expenditure³⁻⁵
- **Multi-billion dollar annual market opportunity in US**^{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. Gunvitz 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. Clin.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.

Advanced Heart Failure

Revascor - Phase 3 trial fully enrolled



- Trial design is 1:1 randomized, controlled, double blinded; conducted over 55 sites across North America using 150 million cell dose vs control
- Events-driven Phase 3 trial completed enrollment of 566 patients in February 2019
- Primary endpoint: reduction in recurrent heart failure-related major adverse cardiac events such as heart failure-related hospitalizations and cardiac death
- Secondary endpoint: reduction in terminal cardiac events
- Target patient population enriched for those likely to be both highest risk for events and greatest responders to Revascor therapy

Revascor for Advanced Heart Failure



Key milestones

- Full accrual of primary endpoints events in the Phase 3 trial of Revascor for advanced heart failure around the end of CY19
- Data read-out for this Phase 3 trial planned in H1 CY20
- Results will be considered pivotal to support regulatory approval in the US, as well as China through the Tasly partnership

End-Stage Heart Failure

Revascor – Commercial opportunity in reducing GI bleeding in patients with LVADs

Burden of Illness

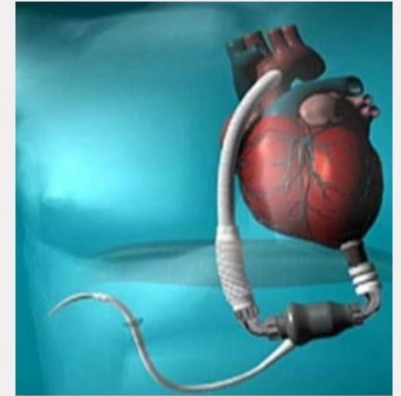
- In the US there are ~ 250,000–300,000 patients annually who suffer from advanced systolic heart failure (NYHA Class III–IV)¹
- Despite optimal medical therapy, mortality exceeds 50% in class IV patients¹

Ongoing Unmet Need

- LVADs have improved survival, but morbidity remains high with patients on average experiencing greater than two hospitalizations annually²
- Gastrointestinal (GI) bleeding is the leading cause of non-surgical hospitalizations in LVAD patients²
- **Device attributable major adverse events (DAEs) can cost on average \$USD46.5k per hospitalization²**

Market Opportunity

- ~ 4,500 – 5,500 assist devices are implanted annually in the US^{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

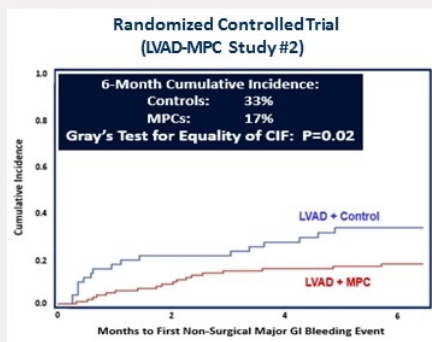
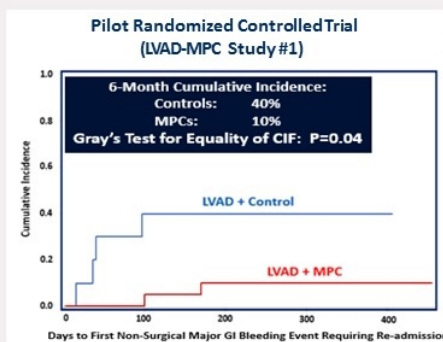


¹Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes, ²Mehra, MR Salerno C, Cleveland JC (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure, ³Agency for Healthcare Research and Quality – Healthcare Cost and Utilization Project – claims analysis using ICD-9 37.6 implantation of heart and circulatory assist systems, ⁴Data on File

End-Stage Heart Failure in LVAD Patients

Revascor reduced GI bleeding events causing hospitalizations in two randomized trials

MPCs prolong time-to-first major GI bleeding event and reduced cumulative major GI bleeding events in two 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 six 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.

Revascor for End-Stage Heart Failure in LVAD Patients



Recent Highlights

- Mesoblast and the International Center for Health Outcomes Innovation Research (InCHOIR) at the Icahn School of Medicine at Mount Sinai in New York have agreed on the protocol for a confirmatory Phase 3 trial of Revascor
- In line with FDA guidance, the primary endpoint will be reduction in major mucosal bleeding events, and key secondary endpoints will be improvement in various parameters of cardiovascular function
- Revascor is being developed for these patients under existing FDA Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug Designations

Key milestones

- Initiation of confirmatory Phase 3 trial of Revascor for the reduction of mucosal bleeding in end-stage heart failure patients implanted with an LVAD
 - Results will be considered pivotal to support regulatory approval in the US

MPC-06-ID: A New Paradigm for Treatment of Chronic Low Back Pain Due to Degenerative Disc Disease

Burden of Illness

- Back pain causes more disability than any other condition¹
- Inflicts substantial direct and indirect costs on the healthcare system^{1,2}, including excessive use of opioids in this patient population

Minimal Treatment Options

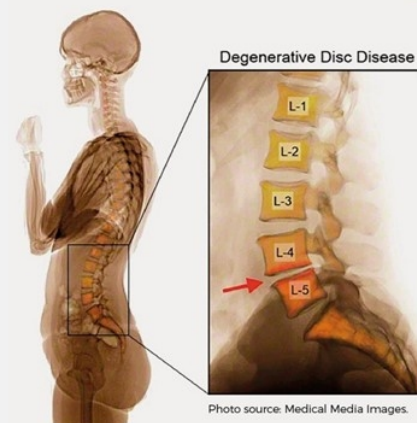
- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

Unmet Need

- Disease modifying therapy for durable improvement in pain and function has potential to prevent progression to opioid use or surgical intervention

Market Opportunity

- Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.³⁻⁶
- MPC-06-ID development program targets over 3.2m patients in U.S. and 4m in E.U.5 with moderate to severe disease



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. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014) 305-317. 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. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US - Anthem/HealthCore.

MPC-06-ID – Development Strategy for US & Europe



- Phase 3 trial in chronic low back pain completed enrolment in March 2018 with 404 patients randomized to receive MPC-06-ID or placebo
- Initiate confirmatory Phase 3 trial in Europe in partnership with Grünenthal
- Complete commercial manufacturing in partnership with Grünenthal
- Results of confirmatory Phase 3 clinical trials in US and Europe, together with commercial manufacturing, expected to support regulatory approval and commercial launches in both Europe and US for MPC-06-ID in chronic low back pain due to degenerative disc disease

Key Terms of the Strategic Partnership with Grünenthal



Grünenthal has obtained

- An exclusive license for Europe and Latin America to develop and commercialize MPC-06-ID in the treatment of chronic low back pain due to degenerative disc disease

In consideration, Mesoblast will receive

- Up to US\$150 million in upfront and milestone payments prior to product launch, as well as further commercialization milestone payments
- Payments include commitments up to US\$45 million within the first year comprising US\$15 million on signing, US\$20 million on receiving regulatory approval to begin a confirmatory Phase 3 trial in Europe, and US\$10 million on certain clinical and manufacturing outcomes
- Cumulative milestone payments could exceed US\$1 billion depending on the final outcome of Phase 3 studies and patient adoption
- Mesoblast will also receive tiered double digit royalties on product sales
- Mesoblast retains the rights for the rest of world, including the US and Japan markets

Transaction Benefits to Mesoblast



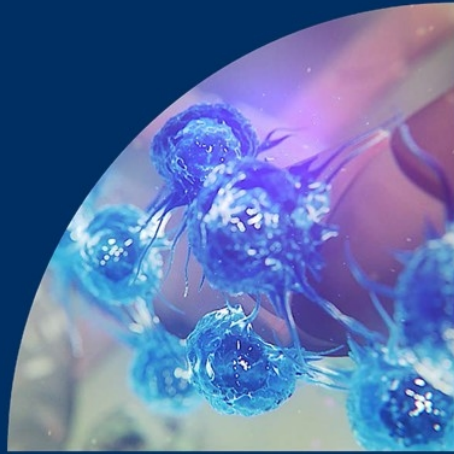
- ✓ **Strong commercial partner**
 - Delivers commercialization, distribution, sales & marketing
 - Field force comprises around 1,600 people across Europe, Latin America & US – overall focus is on pain – visited nearly 300,000 stakeholders in 2018 (physicians, pharmacists & health administrators)
 - Provides knowledge and knowhow in manufacturing, regulatory affairs (Europe in particular)
- ✓ **Advances approval pathway**
 - Provides funding for Phase 3 trial in Europe reducing Mesoblast cash outflow
 - Mesoblast and Grünenthal will collaborate on the study design for a confirmatory Phase 3 trial in Europe
 - Confirmatory European and US (currently ongoing) Phase 3 trials are expected to support regulatory approval in both Europe and US
- ✓ **Transaction focuses on Europe**
 - Mesoblast maintains rights to all other geographic markets, including US, Japan and China for additional partnering opportunities to maximize shareholder return
- ✓ **Third party endorsement provides validation of technology platform**

MPC-06-ID for Chronic Low Back Pain



Key Milestones

- Last patient last visit at 24-months of follow up in the Phase 3 trial of MPC-06-ID for chronic low back pain H1 CY20, with the primary endpoint being a composite outcome of pain and function at 12 and 24 months
- Obtain clearance in CY20 from European regulatory authorities to begin European Phase 3 trial
- Results from the Phase 3 trials will be considered pivotal to support regulatory approval in the US, as well as Europe through the Grünenthal partnership



 **mesoblast**



Questions

