#### **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 August 2018

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):

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):

#### INFORMATION CONTAINED ON THIS REPORT ON FORM 6-K

On August 30, 2018, 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.

On August 29, 2018, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement, which is attached hereto as Exhibit 99.3. 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: August 30, 2018

#### INDEX TO EXHIBITS

#### Item

99.1 99.2 99.3 Press release of Mesoblast Ltd, dated August 30, 2018. Investor presentation of Mesoblast Ltd, dated August 30, 2018. Press release of Mesoblast Ltd, dated August 29, 2018.





#### MESOBLAST REPORTS FOURTH QUARTER AND FULL-YEAR 2018 FINANCIAL RESULTS AND OPERATIONAL HIGHLIGHTS

Melbourne, Australia; August 30, 2018; and New York, USA, August 29, 2018: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported strong financial results and provided operational highlights for the fourth quarter and full-year ended June 30, 2018 (FY2018)

#### Key financial results for the 12 months ended June 30, 2018

- Revenues significantly increased to US\$17.3 million in FY2018 compared with US\$2.4 million in FY2017 Commercialization revenues from sales of TEMCELL  $^{\otimes 1}$  HS Inj. in Japan increased by 152%
- Significant reduction in loss after tax by US\$41.5 million (54%) to US\$35.3 million in FY2018 from US\$76.8 million in FY2017 Substantial reduction in operating cash outflows in FY2018 of US\$20.5 million (21%) compared with FY2017
- - Pro-forma cash on June 30, 2018 was US\$116.8 million including:

    - US\$37.8 million balance sheet cash
      US\$37.8 million from NovaQuest Capital Management through a strategic financing agreement in July 2018, and
  - O US\$40.0 million from Tasly Pharmaceutical Group through agreements entered into in July 2018, subject to filing with the State Administration of Foreign Exchange An additional US\$50.0 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones.

#### Corporate highlights

Mesoblast entered into a strategic alliance with Tasly Pharmaceutical Group for the development, manufacture and commercialization of MPC-150-IM and MPC-25-IC in the treatment and prevention of chronic heart failure and heart attacks in China.

Mesoblast granted TiGenix NV (now fully owned by Takeda Pharmaceutical Co. Ltd) exclusive access to certain of its patents to support global commercialization of Alofisel® in the local treatment of fistulae. This product is the first allogeneic mesenchymal stem cell therapy to receive approval from the European Commission. As consideration, Mesoblast will receive up to €20 million in payments, as well as single digit royalties on net sales.

 $Me soblast\ accessed\ non-dilutive\ capital\ for\ commercialization\ of\ MSC-100-IV\ (remestemcel-L)\ through\ credit\ facilities\ with\ Hercules\ Capital\ and\ NovaQuest\ accessed\ non-dilutive\ capital\ for\ commercialization\ of\ MSC-100-IV\ (remestemcel-L)\ through\ credit\ facilities\ with\ Hercules\ Capital\ and\ NovaQuest\ non-dilutive\ capital\ and\ NovaQuest\ non-dilutive\ capital\ for\ commercialization\ of\ MSC-100-IV\ (remestemcel-L)\ through\ credit\ facilities\ with\ Hercules\ Capital\ and\ NovaQuest\ non-dilutive\ capital\ non-dilutive\ non-diluti\ non-dilutive\ non-diluti\ non-diluti\ non-dilu$ 

New non-executive Directors Joseph R. Swedish and Shawn Cline Tomasello joined the Board of Directors, bringing substantial commercial and transactional healthcare expertise.

#### Operational highlights and anticipated upcoming milestones

MSC-100-IV (remestemcel-L) for pediatric steroid-refractory acute Graft Versus Host Disease (SR-aGVHD):

- The Phase 3 primary endpoint was successfully met
- The primary endpoint of Day 28 overall response rate to remestemcel-L treatment was 69%, a statistically significant increase compared to the protocol-defined historical control rate of 45% (p=0.0003) Day 100 survival results demonstrated 87% survival rate for Day 28 responders (33/38), and an overall survival rate of 75% (41/55)

Mesoblast Limited ABN 68 109 431 870

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- These results were presented at the 2018 annual meeting of the International Society for Stem Cell Research
- The multi-infusion regimen of remestemcel-L was safe and well tolerated Day 180 survival results are expected shortly
- Based on discussions with the United States Food and Drug Administration (FDA), Mesoblast believes that successful results from the completed Phase 3 trial may provide sufficient clinical evidence to initiate filing of a marketing authorization for this product candidate in the United States.

#### MPC-150-IM for Advanced and End-Stage Heart Failure:

- Upcoming 12 month database lock for Phase 2b trial in 159 patients with end-stage heart failure and a left ventricular assist device
- Mesoblast is in active discussions with the FDA on the regulatory pathway under the granted Regenerative Medicine Advanced Therapy (RMAT) designation for MPC therapy in this indication granted in December 2017.
- Enrollment completion for the Phase 3 events-driven trial for Advanced Heart Failure Class II/III anticipated Q4 CY18
  Trial received a recommendation from the Independent Data Monitoring Committee to continue without modification after an evaluation of clinical safety data in the first 465 randomized patients
- Mesoblast plans to leverage results of this Phase 3 trial from complementary global trials performed by strategic partners.

#### MPC-06-ID for Chronic Low Back Pain:

- Enrollment was completed during FY2018 in Mesoblast's Phase 3 trial in patients with chronic low back pain who have failed conservative therapy A total of 404 patients across 48 sites are being followed for evaluation of treatment-related improvement in pain and function over two years.

#### Financial Results for the Three Months Ended June 30, 2018 (fourth quarter) (in U.S. Dollars)

Loss after tax was significantly reduced by US\$6.3 million (23%) for the fourth quarter of FY2018, compared with the fourth quarter of FY2017 due to the items below:

- Revenues were US\$1.7 million in the fourth quarter of FY2018, of which US\$1.6 million was due to sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Revenues increased by US\$1.1 million (200%) compared with the fourth quarter of FY2017.
- Research and Development expenses were US\$1.5 million for the fourth quarter of FY2018, compared with US\$1.5 million for the fourth quarter of FY2017, an increase of US\$1.6 million (10%) as the Company invested in Tier 1 clinical programs.
- Manufacturing expenses were US\$2.1 million for the fourth quarter of FY2018, compared with US\$1.2 million for the fourth quarter of FY2017, an increase of US\$0.9 million (84%) primarily due to an increase in process validation activities for MSC-based manufacturing
- Management and Administration expenses were US\$5.2 million for the fourth quarter of FY2018, compared with US\$7.1 million for the fourth quarter of FY2017, a decrease of US\$1.9 million (27%) due to an overall decrease in corporate
- Finance Costs of US\$1.4 million in interest expenses were recognized in the fourth quarter of FY2018 in relation to the Company's loan and security agreement entered into with Hercules in March 2018. No interest expense was recognized in the fourth quarter of FY2017

Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia United States Operations 505 Fifth Avenue Third Floor New York, NY 10017 USA Mesoblast Limited ABN 68 109 431 870 www.mesoblast.com т +61 3 9639 6036 т +1 212 880 2060 т +65 6570 0635 The overall increase in loss after income tax also includes movements in other items which did not impact current cash reserves, such as: fair value remeasurement of contingent consideration, and foreign exchange movements within other operating income and expenses.

A non-cash income tax benefit of US\$1.0 million was recognized in the fourth quarter of FY2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, compared to US\$4.1 million in the fourth quarter of FY2017

The net loss attributable to ordinary shareholders was US\$20.8 million, or 4.39 cents loss per share, for the fourth quarter of FY2018, compared with US\$27.2 million, or 6.34 cents loss per share, for the fourth quarter of FY2017.

At June 30, 2018, the Company had cash reserves of US\$37.8 million. As of June 30, 2018, the Company recognized funds receivable from debt financing and unissued capital of US\$39.0 million pursuant to a financing facility with NovaQuest. On July 10, 2018 the net proceeds from the financing facility of US\$39.0 million were received and recognized in cash reserves. The Company will also receive US\$40.0 million from Tasly on closing of the strategic alliance that the two companies announced in July 2018 for cardiovascular therapies in China. This transaction has been approved by the Tianjin Bureau of Ministry of Commerce and the Tianjin Bureau of National Development Reform Commission, and is subject to filling with the State Administration of Foreign Exchange.

Mesoblast retains an equity facility for up to A\$120 million/US\$90 million, to be used at its discretion over the next 12 months to provide additional funds as required.

#### Financial Results for the Year Ended June 30, 2018 (in U.S. Dollars)

Loss after tax was significantly reduced by US\$41.5 million (54%) for FY2018, compared with FY2017.

The main items which reduced loss after income tax were:

- Revenues were US\$17.3 million for FY2018, compared with US\$2.4 million for FY2017, an increase of US\$14.9 million. These revenues primarily consisted of US\$11.8m from our patent license agreement with TiGenix (now fully owned by Takeda) in December 2017 and US\$5.1 million in royalties and milestones from sales of TEMCELL by our licensee in Japan, JCR Pharmaceuticals Co. Ltd. Royalties from TEMCELL increased by 152% for FY2018 compared with FY2017.
- Research and Development expenses were US\$65.9 million for FY2018, compared with US\$58.9 million for FY2017, an increase of US\$7.0 million (12%) as the Company invested in its phase 3 clinical programs.
- Manufacturing expenses were US\$5.5 million for FY2018, compared with US\$12.1 million for FY2017, a decrease of US\$6.6 million (54%) due to a reduction in manufacturing activity because sufficient quantities of clinical grade product were previously manufactured for all ongoing clinical trials.
- Management and Administration expenses were US\$21.9 million for FY2018, compared with US\$23.0 million for FY2017, a decrease of US\$1.1 million (5%) primarily due to decreased legal activities and corporate overhead expenses such as rent, IT costs and depreciation. This decrease was partially offset by an increase in labor costs primarily for recruitment and short term incentives.
- Finance Costs of US\$1.8 million in interest expenses were recognized in FY2018 in relation to the Company's loan and security agreement entered into with Hercules in March 2018. No interest expense was recognized in FY2017.

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T +65 6570 0635 F +65 6570 0176 The overall decrease in loss after income tax also includes movements in other items which did not impact current cash reserves, such as: fair value remeasurement of contingent consideration, and foreign exchange movements within other operating income and expenses.

A non-cash income tax benefit of US\$30.7 million was recognized in FY2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, primarily due to a revaluation of our deferred tax assets and liabilities recognized as a result of changes in tax rates. On December 22, 2017, the United States signed into law the Tax Cuts and Jobs Act (the Tax Act), which changed many aspects of United States corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%.

A non-cash income tax benefit of US\$13.4 million was recognized in FY2017 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was US\$35.3 million, or 7.58 cents loss per share, for FY2018, compared with US\$76.8 million, or 19.25 cents loss per share, for FY2017.

 $^1\mathrm{TEMCELL} ^{\circledR}$  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 6:00 pm EDT on Wednesday, August 29, 2018; 8:00 am Thursday, August 30, 2018 AEST.

The live webcast can be accessed via

 $\underline{http://webcasting.boardroom.media/broadcast/5b7512acb14eaa0d350808c4}$ 

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 471961.

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). <a href="https://www.mesoblast.com">www.mesoblast.com</a>

#### 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 timing, progress and results of Mesoblast's preclinical and clinical studies; the timing or likelihood of regulatory filings and approvals; 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

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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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(in II C. dallare in the country of a country of the country of		Three Months End 2018	ed June 30, 2017	Year Ended Ju 2018	me 30, 2017
(in U.S. dollars, in thousands, except per share amount) Revenue		1,700	566	17,341	2,412
Research & development		(17,539)	(15,939)	(65,927)	(58,914)
Manufacturing commercialization		(2,121)	(1,150)	(5,508)	(12,065)
Management and administration		(5,219)	(7,148)	(21,907)	(23,007)
Fair value remeasurement of contingent consideration		2,661	(7,908)	10,541	(130)
Other operating income and expenses		69	321	1,312	1,489
Finance costs		(1,406)	-	(1,829)	
Impairment of intangible assets		(1,100)	_	(1,025)	_
Loss before income tax		(21,855)	(31,258)	(65,977)	(90,215)
Income tax benefit/(expense)		1,021	4,076	30,687	13,400
Loss attributable to the owners of Mesoblast Limited		(20,834)	(27,182)	(35,290)	(76,815)
Loss attributable to the owners of Mesoblast Ellinted		(20,034)	(27,102)	(33,230)	(70,013)
Losses per share from continuing operations attributable					
to the ordinary equity holders of the Group:		Cents	Cents	Cents	Cents
Basic - losses per share		(4.39)	(6.34)	(7.58)	(19.25)
Diluted - losses per share		(4.39)	(6.34)	(7.58)	(19.25)
Consolidated Statement of Comprehensive Income		(unaudite	q)	(audited	1
		Three Months End	,	Year Ended Ju	,
(in U.S. dollars, in thousands)		2018	2017	2018	2017
Loss for the year		(20,834)	(27,182)	(35,290)	(76,815)
Other comprehensive (loss)/income		(_0,000,0)	(=:,===,	(00,200)	(10,010)
Items that may be reclassified to profit and loss					
Changes in the fair value of available-for-sale financial					
assets		183	86	324	31
Exchange differences on translation of foreign operations		(334)	(52)	(903)	316
Other comprehensive (loss)/income for the period,			_		
net of tax		(151)	34	(579)	347
Total comprehensive losses attributable to the					
owners of Mesoblast Limited		(20,985)	(27,148)	(35,869)	(76,468)
Mesoblast Limited ABN 68 109 431 870	Corporate Headquarters Level 38	United States Operations 505 Fifth Avenue	Asia 20 Biopolis Wa		
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			As of June 30,	
(in U.S. dollars, in thousands)			2018	2017
Assets				
Current Assets				
Cash & cash equivalents			37,763	45,761
Trade & other receivables			50,366	3,743
Prepayments			12,942	14,105
Total Current Assets			101,071	63,609
Non-Current Assets				
Property, plant and equipment			1,084	1,814
Available-for-sale financial assets			2,321	1,997
Other non-current assets			3,361	1,916
Intangible assets			584,606	586,350
Total Non-Current Assets			591,372	592,077
Total Assets			692,443	655,686
Liabilities				
Current Liabilities				
Trade and other payables			18,921	21,805
Provisions			5,082	14,865
Total Current Liabilities			24,003	36,670
Non-Current Liabilities				
Deferred tax liability			20,079	49,293
Provisions			42,956	52,957
Borrowings			59,397	_
Total Non-Current Liabilities			122,432	102,250
Total Liabilities			146,435	138,920
Net Assets			546,008	516,766
Equity				
Issued Capital			889,481	830,425
Reserves			36,719	31,243
(Accumulated losses)/retained earnings			(380,192)	(344,902)
Total Equity			546,008	516,766
Mesoblast Limited ABN 68 109 431 870	Corporate Headquarters Level 38 55 Collins Street	United States Operations 505 Fifth Avenue Third Floor	Asia 20 Biopolis Way #05-01 Centros	
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	Year ended June	30,
(in U.S. dollars, in thousands)	2018	2017
Cash flows from operating activities		
Commercialization revenue received	3,019	1,332
Milestone payment received	7,125	500
Research and development tax incentive received	_	2,813
Payments to suppliers and employees (inclusive of goods and services tax)	(84,682)	(100,598)
Interest received	367	483
Interest paid	(816)	_
Income taxes (paid)/refunded	(25)	(1)
Net cash (outflows) in operating activities	(75,012)	(95,471)
		<u> </u>
Cash flows from investing activities		
Payments for contingent consideration	(952)	_
Investment in fixed assets	(201)	(311)
Rental deposits received	_	453
Payments for investments	_	_
Payments for licenses	<u></u>	
Net cash (outflows)/inflows in investing activities	(1,153)	142
Cash flows from financing activities		
Proceeds from borrowings	31,704	
Payments of transaction costs from borrowings	(392)	_
Proceeds from issue of shares	40,566	61,932
Payments for share issue costs	(3,265)	(1,927)
Net cash inflows by financing activities	68,613	60,005
Net decrease in cash and cash equivalents	(7,552)	(35,324)
Cash and cash equivalents at beginning of period	45,761	80,937
FX (losses)/gains on the translation of foreign bank accounts	(446)	148
Cash and cash equivalents at end of period	37,763	45,761

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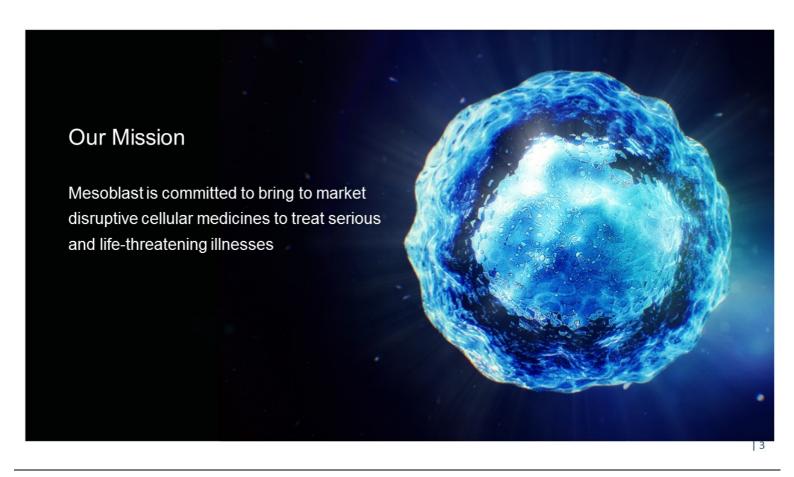
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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 of historical facts contained in this presentation are forward-looking statements. When the Private Securities Lidigation Reform Act of 1995 and other federal securities laws. All 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," "ilkely," "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 or 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 anticipated in these f



## Premier global cellular medicines company

## **Disruptive Technology** Platform<sup>1</sup>

## **Industrial Scale** Manufacturing

## **Multiple Revenue Generating Products** & Phase 3 Assets

- Immuno-selected, culture expanded cellular medicines
- Well characterized mechanisms of action targeting multiple
- Extensive, robust IP estate
- Targeting the most severe disease states refractory to conventional therapies
- Unique cell properties enable large scale expansion and use in unrelated recipients
- Proprietary media formulations meet industrial scale needs
- 'Off the shelf' delineated products with batch to batch consistency and reproducibility
- 2 approved products commercialized by licensees in Japan<sup>2</sup> and Europe<sup>3</sup>
- 3 product candidates in U.S. Phase 3
- Major near-term data readouts
- Revenue from approved and late-stage assets will help fund deep product pipeline

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

  TEMCELL® Hs Inj licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan.

  Alofisel® licensee Takeda received first central marketing authorization (MA) approval from the European Commission (EC) for an allogeneic stem cell therapy.

## Disruptive cellular medicine technology

- STRO-1<sup>+</sup> Mesenchymal Precursor Cells (MPCs) are at the apex of the hierarchy of mesenchymal lineage cells
- STRO-1/STRO-3 immuno-selection provides a homogeneous population of MPCs with receptors that respond to activating inflammation and damaged-tissue signals
- In response to activating signals present in the endogenous environment, MPCs secrete a diverse variety of biomolecules responsible for immunomodulation and tissue repair
- Targeting multiple pathways may result in greater therapeutic benefits in complex diseases



- Simmons PJ, et al, Blood. 1991;78:55-62
   Gronthos S, et al, J Cell Sci. 2003;116(Pt 9):1827-35

- See F, et al, J Cell Mol Med. 2011;15:2117-29
   Psaltis PJ, et al, J Cell Physiol. 2010;223(2):530-40

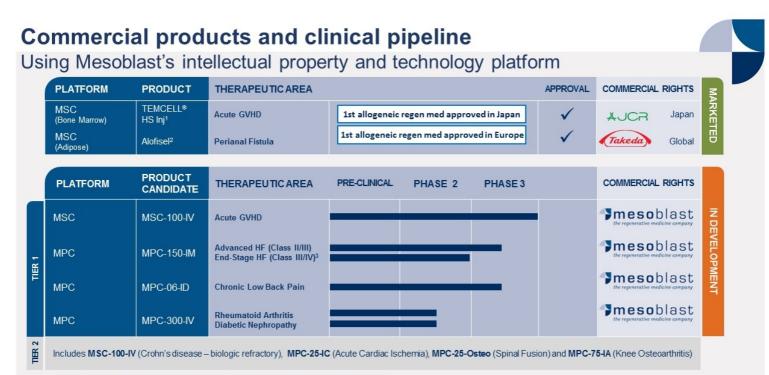
## **Commercial translation capabilities**

## Technology positioned for scalable, industrialized manufacturing

- Immune privileged nature of mesenchymal lineage cells enables allogeneic "off the shelf" product candidates
- Culture expansion scalable to produce anticipated commercial quantities
- Management know-how in regulatory activities necessary for product approval and commercial launch
- If successful, we believe MSC-100-IV (remestemcel-L) will likely be the first allogeneic mesenchymal lineage cell product registered for sale in the USA



Lonza contract manufacturing facility in Singapore



 Mesoblast receives royalty income on sales of TEMCELL® in Japan by its licensee JCR Pharmaceuticals Co Ltd.
 Mesoblast will receive royalty income on world wide sales of Alofise® in the local treatment of perianal fistulae by its licensee Takeda Pharmaceuticals.
 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. This chart is figurative and does not purport to show individual trial progress within a clinical program

## Strategic partnership in cardiology in China



- Tasly Pharmaceuticals to receive exclusive rights and will fund all development, manufacturing and commercialization activities for MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction in China
- Mesoblast to receive US\$40 million on closing
  - US\$20 million upfront technology access fee
  - US\$20 million in equity at AU\$1.86 per share
- Mesoblast to receive US\$25 million on product regulatory approvals in China
- Mesoblast will receive double-digit escalating royalties on net product sales and six escalating milestone payments upon product candidates reaching certain sales thresholds in China
- Partners will leverage each other's clinical trial results to support their respective regulatory submissions in the US and China

Transaction approved by Tianjin Bureau of Ministry of Commerce and Tianjin Bureau of National Development Reform Commission, subject to filing with State Administration of Foreign Exchange



## Significant increase in revenue

Revenue for the year ending June 30, 2018 (US\$m)

For the year ending	June 30, 2018	June 30, 2017	\$Change	%
Commercialization revenue	3.6	1.4	2.2	152%
Milestone revenue	13.3	0.5	12.8	NM
Interestrevenue	0.4	0.5	(0.1)	(22%)
Total revenue	17.3	2.4	14.9	NM

## 2018 revenue increased by US\$14.9 million vs 2017 revenue due to:

- 152% increase in commercialization revenue from royalty income on sales of TEMCELL® 1 HS. Inj.
- An upfront payment of US\$5.9 million (€5.0 million) received upon execution of our patent license agreement with TiGenix NV (now fully owned by Takeda Pharmaceuticals) in December 2017
- A future payment from Takeda of US\$5.9 million (€5.0 million), due by December 2018, was recognized in FY 2018
- An increase of US\$1.0 million in sales milestones recognized on sales of TEMCELL

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

# Significant reduction in loss after tax

Profit and Loss for the year ending June 30, 2018 (US\$m)

For the year ending	June 30, 2018	June 30, 2017	\$Change	%
Total revenue	17.3	2.4	14.9	NM
Research and development	(65.9)	(58.9)	(7.0)	12%
Manufacturing	(5.5)	(12.1)	6.6	(54%)
Management & administration	(21.9)	(23.0)	1.1	(5%)
Contingent consideration	10.5	(0.1)	10.6	NM
Other operating income & expenses	1.3	1.5	(0.2)	(12%)
Finance costs	(1.8)	-	(1.8)	NM
Loss before tax	(66.0)	(90.2)	24.2	(27%)
Income tax benefit	30.7	13.4	17.3	NM
Loss after tax	(35.3)	(76.8)	41.5	(54%)

Loss after tax reduced by US\$41.5 million (54%) for the year ended June 30, 2018 versus the comparative period of FY17 due to:

- Increased revenue
- Reduced spend on manufacturing for R&D
- Non-cash items including an income tax benefit from the revaluation of deferred tax assets and liabilities after US corporate tax rates changes

# Significant reduction in operating cash outflows

Cash flow highlights (US\$m)

For the year ending	June 30, 2018	June 30, 2017	\$Change	%Change
Operating net cash outflows	(75.0)	(95.5)	20.5	(21%)
Investing net cash (outflows)/inflows	(1.2)	0.1	(1.3)	NM
Financing net cash inflows	68.6	60.0	8.6	14%
Forex	(0.5)	0.2	(0.7)	NM
Net increase/(decrease) in cash	(8.1)	(35.2)	27.1	(77%)

 Operating net cash outflows reduced by 21% for the year ended June 30, 2018 versus the prior period due to increased revenue and decreased spend on manufacturing for R&D

## Cash position strengthened through strategic transactions

Balance sheet cash (US\$m)

	June 30, 2018	June 30, 2017	\$Change
Reported Cash on Hand	37.8	45.8	(8.0)
NovaQuest financing agreement	39.0	-	39.0
Tasly strategic alliance	40.0	-	40.0
Pro forma Cash on Hand	116.8	45.8	71.0

- Pro forma Cash on Hand at June 30 includes material financing and partnering agreements executed prior to reporting date
- US\$39 million cash received in July 2018 from NovaQuest Capital Management through a strategic financing agreement
- US\$40 million to be received at closing from Tasly Pharmaceutical Group through a strategic alliance executed in July 2018. This transaction has received certain government approvals from the People's Republic of China and is subject to filing with the State Administration of Foreign Exchange
- An additional US\$50 million may be available under existing arrangements with Hercules Capital and NovaQuest, subject to achievement of certain milestones

## Strategic financing transactions







- US\$75 million non-dilutive, four-year credit facility
- US\$35 million drawn on closing in March 2018
- US\$15 million may be drawn on or before Q4
   CY2018, and a further US\$25 million on or before Q3 CY2019, as certain milestones are met
- Interest 9.95% per annum with interest only period up to 30 months upon satisfaction of certain conditions
- US\$40 million non-dilutive, eight-year credit facility and US\$10 million equity investment in June 2018
- US\$30 million drawn and US\$10 million equity at closing
- Interest only period 48 months
- Interest and principal payments deferred until after first commercial sale of remestemcel-L for pediatric patients with steroid-refractory acute Graft versus Host Disease
- Interest 15% per annum, payable from product sales

No warrants with either facility; NovaQuest is subordinated to the senior creditor Hercules



# **Remestemcel-L (MSC-100-IV):** market opportunity for 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

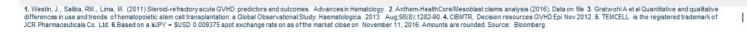
#### Minimal Treatment Options

- 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

- $^{\bullet}$  ~30,000 allogeneic BMTs performed globally (~20K US/EU5) annually, ~22% pediatric  $^{3,4}$
- Our licensee, JCR Pharmaceuticals Co., Ltd launched TEMCELL® HS Inj.<sup>5</sup> in Japan for SR-aGVHD in 2016; reimbursed up to ~\$USD195k<sup>6</sup>
- USD \$700m US/EU5 market opportunity.



## **Operational Update:**

MSC-100-IV (remestemcel-L) product candidate for steroid refractory aGVHD

- Phase 3 study evaluated remestemcel-L in 55 children to improve overall response rate and survival
  - 89% of children had grade C/D disease, the most severe form and historically associated with up to 90% mortality
- Study successfully met the primary endpoint of improved Day 28 Overall Response (OR)
  - 69% vs 45% protocol-defined historical control rate (p=0.0003)
- Day 100 Overall Survival 75%, with 87% survival in Day 28 responders
- Day 180 survival results expected shortly
- Remestemcel-L safe and infusions well tolerated1
- Findings consistent with previous results in 241 SR-aGVHD children under expanded access who failed to respond to multiple biologic agents<sup>2</sup>

## **GVHD** pathway to market

# 4

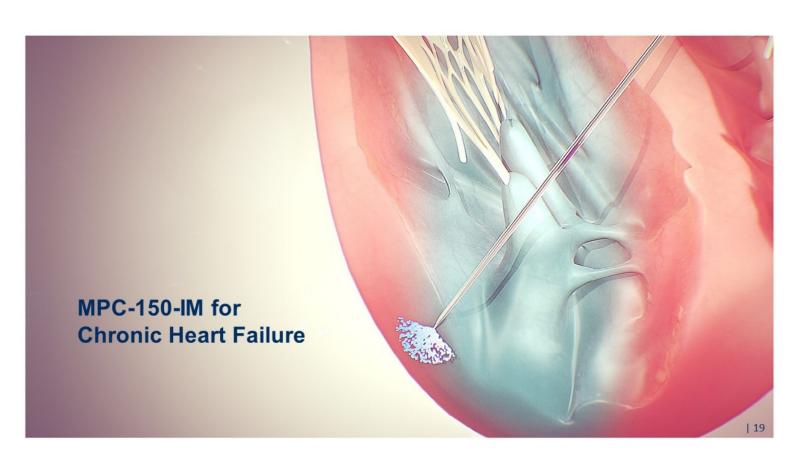
## Regulatory

- Final preparations for Biologics License Application (BLA) filing underway
- Expected pre-BLA meeting Q4 CY2018
- Fast Track designation allows eligibility for priority review and rolling BLA review process

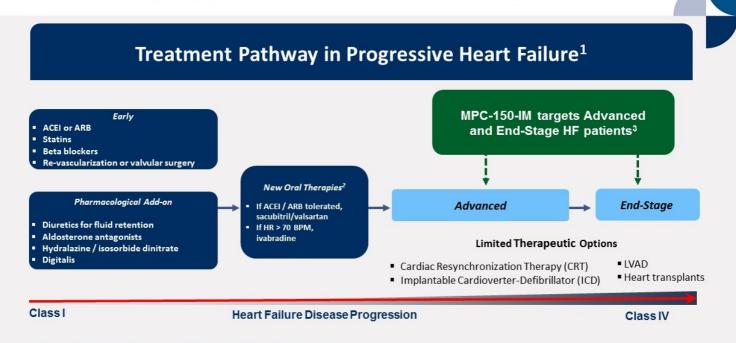
#### Commercial

- Parallel track commercial planning for pricing, reimbursement and product launch
- Using real-world sales data of TEMCELL® in Japan to inform commercial strategy for the US

152% increase in annual royalty income on TEMCELL® sales in Japan Rapid penetration of addressable market within two years of launch



## MPC-150-IM: Targeting patients with advanced and end-stage heart failure



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

## MPC-150-IM: End-stage heart failure market opportunity

#### Burden of Illness/Limited Options

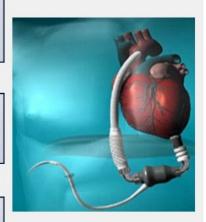
- 50k patients/year in the United States alone have end-stage heart failure<sup>1</sup>
- 1-year mortality exceeds 50% in these patients
- Only ~2K heart transplants are performed in U.S. annually due to limited donors<sup>2</sup>
- LVADs have improved survival, but has high morbidity and 1-year mortality 20-30%<sup>1</sup>

#### **Unmet Need**

- Reduce morbidity of LVAD therapy (e.g. reduce GI bleeding)
- Strengthen native heart muscle sufficiently to explant LVAD
- Increase the number of LVADs implanted/year (currently <5K due to high morbidity and no option to explant temporary LVAD)



- US LVAD market growing double-digit CAGR<sup>4</sup>
- US targeted commercial footprint (top 40 centers represent 75% of volume) provides low cost market entry<sup>3</sup>
- USD >\$500m US market opportunity



1. Gustafsson G, Rogers J. (2017) Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. European Journal of Heart Failure 19, 595-602, 2. Agency for Healthcare Research and Quality: HCUPnet: ICD-9 principal procedure code 27.51 2014., 3. Medicare provider charge inpatient-DRGALL-FY2014., 4. St. Jude Medical-2016-analyst and investor day.

## MPC-150-IM: End-stage heart failure clinical strategy

- 159-patient, double-blind, placebo-controlled 2:1 randomized Phase 2b trial, evaluating safety and efficacy of a single injection of MPC-150-IM into the native myocardium of LVAD recipients
- Study funded by the US National Institutes of Health (NIH) and Canadian Health of Research Institute, and conducted by the NIH-funded Cardiothoracic Surgical Trials Network (CTSN)
- Study Endpoints:
  - Safety, including GI bleeding
  - Number of temporary weans from LVAD tolerated through 6 months
  - Time to re-hospitalization (through 12 months)
  - Patient survival (through 12 months)
- Enrollment completed in Q3 CY2017
- 12 month database lock in Q3 CY2018
- Full trial results to be presented at upcoming major cardiovascular conference

Mesoblast is in active discussions with the FDA on the regulatory pathway under the Regenerative Medicine Advanced Therapies (RMAT) designation granted in December 2017

## MPC-150-IM: Advanced heart failure market opportunity

Burden of Illness/Limited Options

- Est. >8 million patients with chronic heart failure by 2030 in US alone
- 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 failure<sup>2</sup>

**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



Less blood Weakened he pumped out muscle can't of ventricles squeeze as we

Market Opportunity

- US healthcare costs for NYHA class II-IV patients \$115bn/year
- Hospitalizations account for ~69% of expenditure<sup>3-5</sup>
- Multi-billion dollar annual market opportunity in US for a new treatment that reduces hospitalizations in advanced heart failure

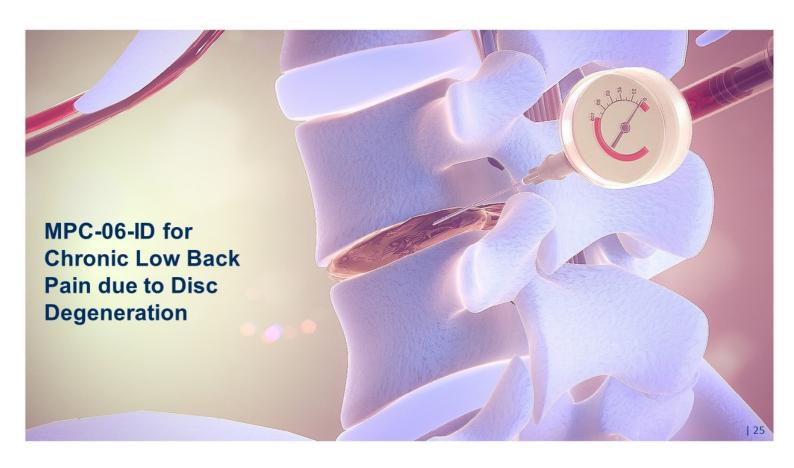
Heart Failure: Preventing disease and death worldwide — European Society of Cardiology. 2014., 2. ACC/AHAHFSA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013. ACC/FAHA Guideline for the Management of Heart Failure. 3. Gurwitz JH, Magid DJ, Smith DH, et al. Contemporary 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. Clini. 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.ijard.2015.10.112.

## MPC-150-IM: Phase 3 trial in patients with advanced heart failure



- 85% of patients enrolled in this events-driven Phase 3 trial
- Enrollment completion targeted by end CY18
- Pre-specified interim futility analysis of the efficacy endpoint in the first 270 patients successfully achieved in April 2017
- Data Monitoring Committee recommended continuation of the trial without modification after a scheduled review of available data from 465 randomized patients, including the primary and secondary endpoints of HF-MACE, terminal cardiac events, and all safety data in April 2018

Plan to leverage results with additional clinical data from global trials performed by strategic partners



## MPC-06-ID: Chronic low back pain due to degenerative disc disease

#### Burden of Illness

- Back pain causes more disability than any other condition<sup>1</sup>
- Inflicts substantial direct and indirect costs on the healthcare system,<sup>1</sup> including excessive use of opioids in this patient population

#### 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)

#### **Unmet Need**

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

#### Market Opportunity

- MPC-06-ID targets over ~3.2m patients CLBP due to degenerative disc disease (DDD) in US alone<sup>2,3,4</sup>
- Annual US market opportunity > USD 1 billion



1. Williams, J., NG, Nawi, Pelzter, 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(8): e0127880., 2. Decision Resources: Chronic Pain December 2015., 3. LEK & NCI opinion leader interviews, and secondary analysis., 4. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

## MPC-06-ID: Phase 3 trial in patients with chronic low back pain



- Phase 3 study completed enrollment in March 2018
- Over 400 patients were enrolled at 48 sites across the US and Australia
- Patients randomized 1:1:1 to receive saline, 6-million MPCs with hyaluronic acid and 6-million MPCs without hyaluronic acid
- Primary efficacy composite endpoint requires a patient to achieve:
  - Reduction in pain (50% decrease in Visual Analog Score) and improvement in function (15 point improvement in as measured by the Oswestry Disability Index)
  - No additional intervention at the treated level through 24 months
  - Primary endpoint at 12 and 24 months



## CY 2018 corporate milestones



#### MSC-100-IV for Acute Graft versus Host Disease

- Successfully met Day 28 primary end point pediatric Phase 3 trial (Q1 CY18) √
- Day 100 survival/safety data pediatric Phase 3 trial (Q2 CY18) √
- Day 180 survival/safety data pediatric Phase 3 trial (Q3 CY18)
- Pre-BLA meeting (Q4 CY18)

#### MPC-150-IM for Advanced and End-Stage Heart Failure

- Phase 2b trial full 12 month database lock in end-stage heart failure patients with LVADs (Q3 CY18)
- Phase 2b results presentation expected at major cardiovascular conference (Q4 CY18)
- Phase 3 trial in advanced heart failure enrollment completion (H2 CY18)

#### MPC-06-ID for Chronic Low Back Pain

■ Phase 3 trial completed enrollment (Q1 CY18)

Completed non-dilutive transactions for commercialization of MSC-100-IV (remestemcel-L) ✓

Establish regional commercial partnerships ✓

Establish global commercial partnerships







#### MESOBLAST PROVIDES UPDATE ON TRANSACTION WITH TASLY PHARMACEUTICAL GROUP

New York, USA, and Melbourne, Australia; August 29, 2018: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that Tasly Pharmaceutical Group has received People's Republic of China governmental approvals of Overseas Direct Investment from Tianjin Commission of Commerce and Tianjin Development and Reform Commission to enter into an investment agreement as well as a development and collaboration agreement with Mesoblast to commercialize cell therapies for cardiovascular diseases in China

Under the terms of the agreements with Tasly, on closing Mesoblast will receive US\$40 million, comprising a US\$20 million upfront technology access fee and US\$20 million for equity in Mesoblast purchased by Tasly at AUD\$1.86 per share. The transaction is subject to filing with the State Administration of Foreign Exchange.

About Tasly Pharmaceutical Group
Tasly Pharmaceutical Group (SHA: 600535) is one of the largest pharmaceutical companies in China with more than 20 years of operational history. Its business focuses on R&D, manufacturing and commercialization of innovative modern traditional Chinese medicine, biologics and chemical drugs in the therapeutic areas of cardiology, metabolism and oncology. Tasly has the only marketed biological product for cardiovascular diseases approved in China. It has one of the largest pharmaceutical sales and marketing teams, including 809 offices established in 29 regions covering all the main therapeutic areas, and a vast distribution network across approximately 20,000 hospitals in China. At 2017, its total annual revenues exceeded US\$2.5 billion.

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

#### 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 applicable federal securities laws. Forward-looking statements include, but are not limited to, statements about: the potential benefits of this alliance and the parties' ability to maintain the alliance; whether the conditions to the transaction will be satisfied in a timely manner, if at all; the parties' ability to advance product candidates into, enroll and successfully complete, clinical studies, advance their manufacturing capabilities, and obtain regulatory fillings and approvals. There are many uncertainties and risks that may cause our 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.

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