BELL POTTER

27 August 2019

Speculative

See Key risks on Page 4 & Biotechnology Risk Warning on Page 6
Speculative securities may not be suitable for Retail clients

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Mesoblast (MSB)

FDA clarifies path forward for approval of Revascor in LVAD patients

Recommendation
Buy (unchanged)
Price
$1.44
Valuation
$4.13 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**186.8%**
Dividend yield	**0.0%**
Total expected return	**186.8%**
Company Data & Ratios	
Enterprise value	**$761.2m**
Market cap	**$718.1m**
Issued capital	**498.66m**
Free float	**70.5%**
Avg. daily val. (52wk)	**$1.87m**
12 month price range	**$1.015- $2.47**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.49	1.48	1.54
Absolute (%)	-5.39	-4.75	-8.77
Rel market (%)	-1.23	-3.99	-11.39

FDA agreement on Phase 3 de-risks Revascor

MSB met with the FDA in late July'19 to discuss a definitive pathway for approval for Revascor for reduction of GI bleeding in LVAD patients with end stage heart failure. The meeting was positive and MSB has provided the key outcomes from it today.

FDA has advised that MSB can conduct a single Phase 3 trial to confirm the benefits of Revascor in reducing mucosal bleeding events in LVAD patients (as demonstrated in the recently completed Phase 2b trial), to support marketing approval of the product. FDA has also confirmed MSB's assertion that ***'reduction in major mucosal bleeding events'*** **is an approvable end point,** allowing it to be the **primary endpoint for this trial.** *'Improvement in various parameters of cardiovascular function'* will be key **secondary endpoints**.

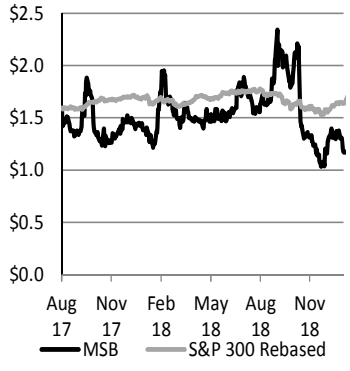
In our view, FDA has provided MSB with a clear path to full approval, which also allows MSB time to scale up manufacturing in parallel to the Phase 3 program. Importantly, MSB has FDA agreement on the primary endpoint of reduction in bleeding, on which the Phase 2b trial demonstrated strong benefit and MSB can conduct a single pivotal trial to meet approval requirements (in line with other orphan indications).

We also note that MSB already has funding arranged for this trial. Recall, MSB has signed a MoU with InCHOIR, to run and fund this confirmatory trial. InCHOIR served as the central co-ordinating and data management arm (effectively like a CRO) for the NIH run and funded Phase 2b LVAD trial with Revascor. We expect the Phase 3 trial to be only slightly larger than the 159 patient Phase 2b trial and it could start by end of CY19, depending on how fast MSB signs the formal agreement with InCHOIR.

We note MSB is in partnering discussions on Revascor and the clarification of path forward for the LVAD program and the upcoming results from the ongoing Phase 3 trial in advanced heart failure patients due to report in 1HCY20, will be key drivers of an outcome to these discussions.

No change to earnings pending MSB's FY19 results (due on 30th Aug'19). **We retain Buy (spec) and valuation of A$4.13/sh.**

Absolute Price



SOURCE: IRESS

Earnings Forecast

Year end 30th June	2017A	2018A	2019E	2020E	2021E
Sales (US$m)	3.5	18.8	16.0	70.1	51.0
EBITDA (US$m)	-87.5	-71.9	-84.9	-41.8	-68.5
NPAT (reported) (US$m)	-76.8	-35.3	-95.2	-53.8	-84.1
NPAT (adjusted) (US$m)	-90.2	-66.0	-101.0	-53.8	-84.1
EPS (reported) (cps)	-19.2	-7.6	-19.4	-10.8	-16.2
EPS (adjusted) (cps)	-22.6	-14.2	-20.6	-10.8	-16.2
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
PER (x)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA (x)	-5.9	-7.1	-6.1	-12.3	-7.5
Dividend (¢ps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-17.5%	-12.1%	-21.2%	-12.5%	-18.1%

Note: Revenue includes R&D tax incentive, commercial milestone and royalty revenue from launch of TEMCELL GvHD product in Japan, revenue from launch of GvHD and CHF in US and potential upfront and milestone from CLBP deal.SOURCE: BELL POTTER SECURITIES ESTIMATES

Revascor approval path clarified

MSB met with the FDA in late July'19 to discuss a definitive pathway for approval for MPC-150-IM (Revascor/ rexlemestrocel-L) for reduction of GI bleeding in LVAD patients with end stage CHF. The meeting was positive and the company has provided the key outcomes from it today (following receipt of formal minutes of the meeting).

Key outcomes from the FDA meeting

- **FDA reiterated that 'reduction in major mucosal bleeding events (collectively termed gastrointestinal bleeding and/or epistaxis i.e. nose bleeds)' is an important clinical outcome** in end stage heart failure patients implanted with an LVAD (left ventricular assist device).
- **FDA advised that a single Phase 3 clinical trial** to confirm the significant benefit of treatment with Revascor in reducing mucosal bleeding post-LVAD implantation, as seen in the recently completed Phase 2b trial, **will be sufficient to support a BLA filing for approval in the US market.**
- FDA has also confirmed MSB's assertion that ***'reduction in major mucosal bleeding events'*** **is an approvable end point**, and has allowed MSB to have that as **the primary endpoint for its confirmatory Phase 3 trial.** *'Improvement in various parameters of cardiovascular function'* will be key **secondary endpoints** of this trial.

Our comments

In our view, FDA has provided MSB with a clear path to full approval, which also allows MSB time to scale up manufacturing in parallel to the Phase 3 program.

Importantly, MSB has FDA agreement on the primary endpoint of reduction in bleeding, on which the Phase 2b trial demonstrated strong benefit **and MSB can conduct a single pivotal trial** to satisfy approval requirements (in line with other orphan indications).

We also note that MSB already has funding arranged for this trial, which is important as we believe that if MSB was to conduct such a trial itself, it could have cost as per our estimates ~US$40m-$50m. Recall, MSB has already signed a MoU with the International Center for Health Outcomes and Innovation Research (InCHOIR), to run and fund this trial.

InCHOIR served as the central co-ordinating and data management arm for the NIH run and funded Phase 2b LVAD trial with Revascor. It gets its funding from NIH and federal and industry grants. They are experienced in running cardiovascular trials. They have conducted the key trial (called REMATCH) which established LVADs as destination therapy for advanced heart failure patients. They also have conducted other trials which they believe have helped to shape treatment paradigms for heart failure.

This is an ultra-orphan indication and we expect the Phase 3 trial to be only slightly larger than the Phase 2b trial (BPe ~200 patients) and it could potentially start by end of CY19. We expect further details on the Phase 3 trial design and timelines will be provided by MSB once it signs a formal agreement with InCHOIR.

We note MSB is in partnering discussions on Revascor and the clarification of path forward for the LVAD program and the upcoming results from the ongoing Phase 3 trial in advanced heart failure patients due to report in 1HCY20, will be key drivers of an outcome to these discussions.

Key Near-term Catalysts

- **Completion of BLA filing for paediatric GvHD for MSC-100-IV in 2HCY19-** In June'19 MSB initiated its rolling BLA submission for use of MSC-100-IV to treat children with steroid refractory aGvHD. MSB will be submitting clinical data from its Phase 3 trial and the Expanded Access program under which the product has been available for compassionate use. Recall, MSC-100-IV successfully met its Day 28 primary endpoint showing improved overall response (69% vs. 45% historical controls, p=0.0003) and continued to show safety and improved overall survival at both Day 100 (75%, with 87% survival in Day 28 responders) and Day 180 (Overall Survival 69%, with 79% survival in Day 28 responders) in the Phase 3 paediatric GvHD trial in the US. It has Fast Track designation which should make it eligible for priority review. MSB expects to complete filing in 2HCY19, with potential approval and launch in 1HCY20. MSB will be launching this product in the US by establishing a small sales force (~6-12 sales reps).
- **Initiation of Phase 3 trial for Revascor (MPC-150-IM) in end stage Heart Failure patients requiring LVAD:** MSB met with the FDA in late July'19 (having full study data from recently completed Phase 2B trial) to discuss definitive pathway for approval for Revascor in LVAD patients with end stage HF. FDA has agreed for MSB to run a single Phase 3 confirmatory trial with reduction in mucosal bleeding as primary end point and improvement in various parameters of cardiovascular function as secondary endpoints. MSB has agreement with InCHOIR to run and fund this Phase 3 trial. We expect the Phase 3 trial to start by end CY19, following MSB signing a formal agreement with InCHOIR. The Phase 2b trial successfully achieved the clinically meaningful and approvable endpoint of reduction in incidence of GI bleeding, a serious and common complication of LVAD with high morbidity associated with it. The product has an RMAT (Regenerative Medicine Advanced Therapy) and an orphan drug designation.
- **Potential global partnering deal for MSB's congestive heart failure product in FY20:** Enrollment has now been completed in MSB's Phase 3 congestive heart failure (CHF) trial with Revascor (MPC-150-IM) and 90% of events for the primary endpoint have accrued. The double-blind, placebo controlled trial has enrolled 566 moderate to advanced CHF patients (class II/III), across 55 sites in North America. Although Top-line results from this events driven trial (with 12 months follow up) are not expected till early CY20, we believe the completion of enrollment will now assist MSB in its ongoing partnering negotiations for the product. A partnering deal over the next 10 months could act as a significant re-rating catalyst for the stock.
- **Increase in royalties from TEMCELL in Japan:** JCR Pharmaceuticals launched its GvHD product TEMCELL on 24th Feb' 16. MSB has received in 4QCY15 US$3.5m in pre-commercial milestones triggered by the approval of TEMCELL. Under the deal sales milestones (BPe ~US$3m) as well as royalties in the mid 20% range are also payable by JCR. MSB has received the entire US$3m in sales milestones and to date has recorded ~US$10.4m in royalty revenues. Royalty in FY19 grew 37% over pcp, with 4QFY19 the strongest quarter for sales to date. We assume that at peak sales of US$52m; MSB will receive ~US$13m in annual royalty revenues from TEMCELL from GvHD indication alone.
- **Potential global or regional partnering deal for MSB's chronic discogenic lower back pain (CLBP) product in FY20:** MSB is in active discussions with several potential strategic partners for its CLBP product. The company finished enrolment in the first Phase 3 trial for this product in 1QCY18. All patients have finished their 12 month assessment for safety and efficacy, however the trial will remain blinded until the 24 months assessment are complete. We assume that a deal for CLBP is inked in FY20 and model a US$60m upfront in our forecasts.

Mesoblast (ASX: MSB, NASDAQ:MESO)

MSB has 3 late stage Tier 1 products

COMPANY DESCRIPTION

The Melbourne-based Mesoblast (MSB) is a biotechnology company commercialising the therapeutic use of mesenchymal lineage cells (MPCs and MSCs) – a kind of adult stem cell. MSB's MPC technology allows these cells to be extracted from the bone marrow of donors, grown into therapeutic quantities and administered 'allogeneically' – ie, to patients that are not related to the donor. It has one of the most diversified pipelines, with 3 Tier 1 products in late stage. The first commercial for GvHD launched in Japan in 1QCY16. Substantial shareholders include CEO Silviu Itescu, M&G, Thorney and Capital Group.

INVESTMENT STRATEGY

MSB is the leading allogeneic stem cell player with several late-stage clinical assets in multiple therapeutic indications. We expect progress of the Tier 1 products towards commercial launch and monetisation to be the key value driver for MSB. In recent months MSB has organised non-dilutive financing both through debt facility agreements and its strategic licensing agreement with Tasly for China. It has completed enrolment in 2 phase 3 trials (back pain and CHF) and reported clinically meaningful results from a Phase 2b trial in end stage CHF patients with LVAD. The company has cash runway into 1QCY20. MSB's strengthened balance sheet allows it to focus on its BLA submission for its GvHD product which is in progress and could become the first allogeneic stem cell product to be approved in the US (BPe 1HCY20). MSB's meeting with the FDA has clarified path to approval for Revascor in LVAD patients with end stage CHF and MSB will now run through InCHOIR a Phase 3 confirmatory trial. The company's first marketed product Temcell for GvHD in Japan is doing well, with both royalties and sales milestones increasing in FY19. A partnership deal in FY20 for the back pain or CHF products could result in substantial cash injection, extend MSB's cash runway and trigger a re-rating.

KEY RISKS

We see the following key stock specific risks to our investment thesis on Mesoblast:

- **Clinical risk:** There is a risk that MSB's clinical trials fail to reach their endpoints. Failure of a Phase III trial may significantly impact markets confidence on Mesoblast's technology and in case of an un-partnered product will reduce its partnering prospects.
- **Commercialisation risk:** MSB needs a partner to undertake commercialization for its pipeline products. The ability of MSB's products to finally reach the market will depend on them doing a partnering deal. We currently assume the back pain asset is partnered in FY20. Delays or failure in attracting a suitable partner at terms as we have postulated will negatively impact our forecasts.
- **Manufacturing risk:** The key success of Mesoblast's business model is dependent on its ability to manufacture its stem cells on commercial scale as well as at a cost-effective price. Mesoblast has partnered with Lonza to manufacture its stem cells. Our underlying assumption is that together the companies will be able to drive down the COGS by driving efficiencies in the manufacturing process. Failure to cost-effectively manufacture would impact our valuation.
- **Regulatory risk:** Successful commercialisation of MSB's products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. Failure to satisfy regulatory requirements could mean that the product will fail to reach the market.
- **Funding risk:** MSB has cash runway into 2QCY20, with further extension expected through additional drawdown on its existing debt facilities, new debt facilities and partnering deals. Failure to attract a partner is likely to impact MSB's ability to service its debt and would require MSB to raise additional capital. There is no guarantee that such funds will be available or at suitable terms.

Mesoblast
as at 27 August 2019

Recommendation	Buy, Speculative
Price	$1.44
Valuation	$4.13

Table 1 - Financial summary

Mesoblast (MSB) — **Share price (A$)** **$1.440**
As at 27 August 2019 — **Market cap (A$m)** **718.1**

Profit and Loss

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Revenue	3.5	18.8	16.0	70.1	51.0
Gross profit (loss)	3.5	18.8	16.0	68.1	43.4
Total Operating costs	-90.9	-90.7	-100.9	-109.9	-111.9
EBITDA	**-87.5**	**-71.9**	**-84.9**	**-41.8**	**-68.5**
Depreciation & Amortisation	-3.1	-2.7	-2.4	-2.4	-2.5
EBIT	**-90.5**	**-74.6**	**-87.3**	**-44.2**	**-71.0**
Net interest & Other Income/(expense)	0.3	8.6	-13.7	-9.5	-13.2
Pre-tax profit (loss)	-90.2	-66.0	-101.0	-53.8	-84.1
Tax	0.0	0.0	0.0	0.0	0.0
Adjusted Net Profit (Loss)	-90.2	-66.0	-101.0	-53.8	-84.1
Less minority interests	0.0	0.0	0.0	0.0	0.0
Net profit (loss) to shareholders	**-90.2**	**-66.0**	**-101.0**	**-53.8**	**-84.1**
Reported net profit (loss) to shareholders	-76.8	-35.3	-95.2	-53.8	-84.1

Cashflow

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Reported NPAT	-76.8	-35.3	-95.2	-53.8	-84.1
Non-cash items	-4.9	-30.8	19.1	8.4	8.4
Working capital	-13.8	-8.9	18.3	-4.5	-5.8
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**-95.5**	**-75.0**	**-57.8**	**-49.8**	**-81.5**
Capex	-0.3	-0.2	-0.3	-0.4	-0.4
Investments	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.3**	**-0.2**	**-0.3**	**-0.4**	**-0.4**
Change in borrowings	0.0	31.3	42.0	35.0	-36.2
Equity issued	60.0	37.3	29.7	0.2	114.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Financing cashflow	**60.0**	**68.6**	**71.6**	**35.2**	**77.8**
Net change in cash	**-35.8**	**-6.6**	**13.5**	**-15.1**	**-4.1**
Cash at end of period*	45.8	37.8	50.4	35.4	31.3
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow	**-95.8**	**-75.2**	**-58.1**	**-50.2**	**-81.9**

Balance sheet

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Cash	45.8	37.8	50.4	35.4	31.3
Current receivables	3.7	50.4	3.7	5.6	6.6
Inventories	0.0	0.0	0.0	0.6	2.4
Other current assets	14.1	12.9	11.6	11.6	11.6
Current assets	**63.6**	**101.1**	**65.8**	**53.2**	**51.9**
PPE	1.8	1.1	0.7	0.4	0.0
Non-current receivables	0.0	0.0	0.0	0.0	0.0
Intangible assets	586.4	584.6	582.8	581.1	579.4
Other non-current assets	3.9	5.7	5.9	5.9	5.9
Non-current assets	**592.1**	**591.4**	**589.5**	**587.4**	**585.3**
Total assets	**655.7**	**692.4**	**655.2**	**640.6**	**637.2**
Payables	21.8	18.9	23.6	21.6	18.6
Debt	0.0	59.4	79.6	114.6	78.4
Provisions	67.8	48.0	51.6	51.6	51.6
Other liabilities	49.3	20.1	24.3	24.3	24.3
Total liabilities	**138.9**	**146.4**	**179.0**	**212.0**	**172.8**
Shareholders' equity	516.8	546.0	476.2	428.6	464.4
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	**516.8**	**546.0**	**476.2**	**428.6**	**464.4**
Total funds employed	**655.7**	**692.4**	**655.2**	**640.6**	**637.2**
W/A shares on issue	399.0	465.7	490.6	498.8	519.0

Valuation data

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Net profit (US$m)	-90.2	-66.0	-101.0	-53.8	-84.1
adjusted EPS (c)	-22.6	-14.2	-20.6	-10.8	-16.2
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	N/A	N/A	N/A	N/A	N/A
CFPS (c)	-23.9	-16.1	-11.8	-10.0	-15.7
Price/CF (x)	-6.0	-8.9	-12.2	-14.4	-9.2
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-5.9	-7.1	-6.1	-12.3	-7.5
EV/EBIT	-5.7	-6.9	-5.9	-11.6	-7.2

Share price now (A$)	$1.44
Valuation: (A$)	$4.13
Premium (discount) to price	186.8%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2017A	2018A	2019E	2020E	2021E
EBITDA/revenue (%)	N/A	N/A	N/A	N/A	N/A
EBIT/revenue (%)	N/A	N/A	N/A	N/A	N/A
Return on assets (%)	-13.8%	-9.5%	-15.4%	-8.4%	-13.2%
Return on equity (%)	-17.5%	-12.1%	-21.2%	-12.5%	-18.1%
Return on funds empl'd (%)	-17.5%	-10.9%	-18.2%	-9.9%	-15.5%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Net cash (debt) (US$m)	45.8	-21.6	-29.2	-79.2	-47.1
Net debt/equity (%)	N/A	-4.0%	-6.1%	-18.5%	-10.2%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	1.7	4.2	1.3	0.7	0.7

Interims

Y/e June 30 (US$m)	2H17A	1H18A	2H18A	1H19A	2H19E
Revenue	2.0	15.3	3.5	13.2	2.8
EBITDA	-44.0	-27.4	-44.5	-40.1	-44.8
Depreciation & Amortisation	-1.5	-1.2	-1.4	-1.1	-1.3
EBIT	-45.5	-28.6	-45.9	-41.2	-46.1
Net interest & Other Income/(expense)	1.4	9.1	-0.5	-6.5	-7.2
Pre-tax profit (loss)	-44.1	-19.6	-46.4	-47.7	-53.3
Tax	0.0	0.0	0.0	0.0	0.0
Adjusted Net Profit (loss)	-44.1	-19.6	-46.4	-47.7	-53.3
Less minority interests	0.0	0.0	0.0	0.0	0.0
Net profit (loss) to shareholders	-44.1	-19.6	-46.4	-47.7	-53.3
Reported net profit (loss) to shareholders	-37.0	6.7	-42.0	-44.1	-51.1

Revenue Summary

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Temcell Royalties (Japan)	1.4	3.6	5.0	6.7	8.8
Temcell Milestones (Japan)	0.5	1.5	1.0	0.0	0.0
MSC-100-IV GvHD risk adjusted revenue (US)	0.0	0.0	0.0	3.4	21.4
Revascor risk adjusted (LVAD/CHF) Royalties	0.0	0.0	0.0	0.0	3.2
Tigenix License Payment	0.0	11.8	0.0	0.0	0.0
Upfront from Tasly deal in China	0.0	0.0	10.0	0.0	0.0
Potential CLBP deal (upfront/milestones)	0.0	0.0	0.0	60.0	17.6
R&D Tax incentive	1.5	1.8	0.0	0.0	0.0
Total Revenues	**3.5**	**18.8**	**16.0**	**70.1**	**51.0**

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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Biotechnology Risk Warning:

The stocks of biotechnology companies without strong revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock including **Mesoblast. For a list of risks specific to Mesoblast please refer to Page 4 of this note.**

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