



MESOBLAST REPORTS SUBSTANTIAL OPERATIONAL PROGRESS AND FINANCIAL RESULTS FOR THE YEAR ENDED JUNE 30, 2020

Mesoblast Well Prepared Ahead of First Potential US Product Launch

Melbourne, Australia, August 27, 2020 and New York, USA, August 26, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today reported operational highlights and financial results for the fourth quarter and full-year ended June 30, 2020 (FY2020).

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are very pleased to report the significant corporate progress made by the Company over the last financial year. The most notable achievement was the successful FDA Advisory Committee meeting held this month which resulted in an overwhelmingly positive vote in favor of the efficacy of our lead product candidate remestemcel-L (RYONCIL[™]) for children with steroid-refractory acute graft versus host disease (aGVHD). We are working closely with the FDA ahead of next month's approval action date and are well prepared for a potential US launch during Q4 2020, with inventory build and a commercial organization in place.

"In parallel, based on its anti-inflammatory effects in aGVHD, we have positioned remestemcel-L to address the most significant inflammatory complications in children and adults infected with COVID-19. Our randomized controlled Phase 3 trial continues to enroll adults in the US with acute respiratory distress syndrome, aiming to reduce the primary cause of mortality due to COVID-19 infection. We have also made remestemcel-L available to physicians for treatment of COVID-19 infected children with multisystem inflammatory syndrome (MIS-C) involving the heart under our Expanded Access Program.

"We look forward to the upcoming results of our COVID-19 studies and the Phase 3 trials for chronic advanced heart failure and discogenic low back pain."

Financial Highlights

- 92% increase in revenues to US\$32.2 million for FY2020, compared with US\$16.7 million for FY2019.
 - O 127% increase in milestone revenue from strategic partnerships, to US\$25.0 million for FY2020.
 - 32% increase in royalty revenue on TEMCELL® HS. Inj.¹ sales in Japan by licensee JCR Pharmaceuticals (JCR), to US\$6.6 million for FY2020.
- 13% reduction in loss after tax (US\$77.9 million for FY2020 compared with US\$89.8 million for FY2019), even after US\$13.8 million increased investment in commercial readiness for the potential US launch of RYONCIL (US\$8.8 million for commercial manufacturing activities and US\$5.0 million for sales/marketing).
- US\$129.3 million (A\$188.4 million)² cash on hand at June 30, 2020, after US\$90 million (A\$138 million)³ capital raise from global institutional investors in May 2020.
- May have access to up to an additional US\$67.5 million over the next 12 months through existing financing facilities and strategic partnerships.

US Market Opportunity for RYONCIL[™]

• The market adoption and sales of TEMCELL in Japan for SR-aGVHD by JCR provides insight into potential market adoption and sales of RYONCIL in the US.

- As announced by JCR on July 31, production capacity for TEMCELL is being increased as JCR has received orders far in excess of its initial forecasts since the product's 2016 launch.
- Mesoblast estimates that the US addressable market opportunity for remestemcel-L in SR-aGVHD in children and adults is approximately eight times larger than Japan given differences in population size, incidence of aGVHD, and relative pharmacoeconomics.⁴⁻⁷ This represents a significant commercial opportunity for Mesoblast's first potential product launch in the US.
- The Company's commercial and strategic execution capabilities have been further strengthened with the appointment of Chief Operating Officer, Dagmar Rosa-Bjorkeson, who has more than 25 years of global experience in the pharmaceutical industry, including executive leadership in operational execution, market development, and corporate strategy.

Operational Highlights for Phase 3 Product Candidates

Mesoblast is developing culture expanded allogeneic cellular medicines based on its proprietary remestemcel-L and rexlemestrocel mesenchymal lineage cell technology platforms. The product candidates derived from these cell platforms share mechanisms of action that counteract the cytokine storms implicated in various inflammatory conditions by reducing pro-inflammatory cytokines, increasing anti-inflammatory cytokines, and recruiting anti-inflammatory cells to involved tissues.

Remestemcel-L (RYONCIL) for Pediatric SR-aGVHD

On August 13, 2020, the Oncologic Drugs Advisory Committee (ODAC) of the United States Food and Drug Administration (FDA) voted 9-1⁸ in favor that the available data support the efficacy of remestemcel-L (RYONCIL) in pediatric patients with steroid-refractory acute graft versus host disease (SR-aGVHD), a life-threatening complication of a bone marrow transplant. The ODAC is an independent panel of experts that evaluates efficacy and safety of data and makes appropriate recommendations to the FDA. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

The Biologics License Application (BLA) for RYONCIL is under Priority Review by the FDA with an action date of September 30, 2020, under the Prescription Drug User Fee Act (PDUFA). If approved by the PDUFA date, Mesoblast plans to launch RYONCIL in the US in Q4 CY2020 in children and adolescents up to 18 years old. There are currently no FDA-approved treatments in the US for children under 12 with SR-aGVHD.

Remestemcel-L for Adults With SR-aGVHD

Beyond pediatric SR-aGVHD, Mesoblast will seek to obtain approval for RYONCIL in adults with the most severe forms of SR-aGVHD. In an earlier randomized placebo-controlled Phase 3 trial, a post-hoc analysis showed that remestemcel-L was associated with an increased Day 28 overall response in steroid-refractory patients with Grade C/D disease. This patient population continues to represent a high-risk population with poor overall survival, and in August 2020 Mesoblast convened an advisory meeting with key opinion leaders to develop a clinical trial design for a post-market study evaluating remestemcel-L in this patient population.

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Remestemcel-L for Adults with COVID-19 Acute Respiratory Distress Syndrome (ARDS)

Despite improvements in the treatment of COVID-19, mortality remains high, particularly in patients with cytokine storm and ARDS who require mechanical ventilation. A pilot study in 12 COVID-19 patients with moderate to severe ARDS treated with remestemcel-L under emergency compassionate use at Mt Sinai Hospital in New York demonstrated promising results, with 75% of patients successfully taken off a ventilator and discharged from hospital within a median of 10 days. In order to definitively determine the safety and efficacy of these data, a Phase 3 randomized controlled trial is being conducted in 300 ventilator-dependent patients with moderate to severe COVID-19 ARDS.⁹ Up to 30 leading medical centers across the US are taking part in the trial, which is expected to complete recruitment during Q4 CY2020.

Patients in the Phase 3 trial are randomized 1:1 to receive either two intravenous infusions of remestemcel-L within five days or placebo on top of maximal care. The primary endpoint is all-cause mortality within 30 days of randomization, with the key secondary endpoint being the number of days off mechanical ventilator support.

An independent Data Safety Monitoring Board (DSMB) has set a review date of early September for its first interim analysis of the Phase 3 trial of remestemcel-L in ventilator-dependent COVID-19 patients with moderate to severe ARDS. The DSMB will review safety and efficacy data from the first 90 patients after they have all completed 30 days of follow up and will inform Mesoblast on whether to proceed as planned to full enrollment of 300 patients or to stop the trial early.

Remestemcel-L Expanded Access Program (EAP) for Children With COVID-19 Multisystem Inflammatory Syndrome (MIS-C)

Children hospitalized with COVID-19 infection are at risk of both ARDS, seen in 22% of children,¹⁰ and a life-threatening inflammation called MIS-C which in approximately 50% of cases is associated with significant cardiovascular complications resulting in decreased heart function and dilation of coronary arteries.^{11-13.}

Mesoblast has established an EAP which provides physicians with access to use remestemcel-L in COVID-19 infected children aged between two months and 17 years with cardiovascular and other complications of MIS-C under the Company's existing Investigational New Drug (IND) application with the FDA. ¹⁴ The first patient has received treatment under the EAP and has been discharged from the hospital. Mesoblast will continue to monitor the outcome in all MIS-C patients treated under the EAP to establish the safety and effectiveness of the protocol in children with this potentially life-threatening complication of COVID-19.

Rexlemestrocel (REVASCOR®) for Advanced Chronic Heart Failure

In the United States alone, of more than 6.5 million patients with chronic heart failure, there are more than 1.3 million patients with advanced stage of the disease who have high rates of morbidity and mortality despite maximal existing therapies.¹⁵ The objective of treatment with Mesoblast's allogeneic cell therapy REVASCOR is to reduce or reverse the severe inflammatory process in the damaged heart of these patients, and thereby prevent or delay further progression of heart failure or death.

Mesoblast's 566-patient Phase 3 randomized controlled trial of REVASCOR for advanced heart failure has completed patient follow-up and all events have been independently adjudicated. While the COVID-19 pandemic has delayed completion of data quality review at the study sites, the Phase 3 trial data readout is expected during Q4 CY2020.

In parallel, Mesoblast's partner in China, Tasly Pharmaceuticals, is leveraging the results of this trial in its discussions with the Chinese regulatory authority.

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In an earlier randomized placebo-controlled 60-patient Phase 2 trial, a single intra-myocardial injection of REVASCOR at the dose administered in the subsequent Phase 3 trial prevented any hospitalizations or deaths over three years of follow-up in patients with advanced chronic heart failure.

Additionally, in results presented at the 2020 American College of Cardiology Virtual Scientific Sessions from 70 patients with end-stage ischemic heart failure and a Left Ventricular Assist Device (LVAD), a sub-study of 159 patients randomized to either REVASCOR or saline, a single intramyocardial injection of REVASCOR at the dose administered in the Phase 3 trial resulted in a beneficial effect on LVAD weaning, hospital readmissions for heart failure, and major mucosal bleeding events. These end-stage ischemic heart failure patients closely resemble the majority of patients enrolled in the Phase 3 randomized controlled trial of REVASCOR for advanced chronic heart failure.

Rexlemestrocel (MPC-06-ID) for Chronic Low Back Pain

Mesoblast's MPC-06-ID development program targets over 3.2 million patients in the United States and 4 million in the E.U.5 with chronic low back pain due to moderate to severe inflammatory disc degeneration.¹⁶ Back pain causes more disability than any other condition and inflicts substantial direct and indirect costs on the healthcare system, including excessive use of opioids in this patient population. There is a significant need for a safe, efficacious and durable treatment in patients with chronic low back pain due to severely inflamed degenerative disc disease.

While the COVID-19 pandemic has delayed completion of data quality review at the study sites, data readout for the 2:1 randomized placebo-controlled US Phase 3 trial in 404 patients is expected during Q4 CY2020. Mesoblast continues to collaborate closely with Grünenthal on the clinical protocol for a confirmatory Phase 3 trial in Europe for MPC-06-ID in chronic low back pain due to degenerative disc disease, with the results of this and the US Phase 3 trial expected to support both FDA and European Medicines Agency regulatory approvals.

Manufacturing

During fiscal 2020, Mesoblast established a commercial supply agreement with Lonza ahead of the potential FDA approval and commercial launch of RYONCIL. This agreement has facilitated inventory build in preparation for the potential product launch. Manufacturing is also being scaled-up to meet projected increase in capacity requirements for potential label extensions of RYONCIL such as COVID-19 ARDS.

Mesoblast has proprietary technology that facilitates the increase in yields necessary for the long-term commercial supply of its product candidates, and next generation manufacturing processes using xeno-free technologies and three-dimensional bioreactors to reduce labor, drive down cost of goods and improve manufacturing efficiencies.

Intellectual Property

Mesoblast has an extensive patent portfolio with over 1,100 patents and patent applications across 82 patent families, and patent terms extending through 2040. These patents cover composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells, and provide strong commercial protection for our products in all major markets, including the United States, Europe, Japan and China.

Licensing agreements with JCR, Grünenthal, Tasly and Takeda highlight the strength of Mesoblast's extensive intellectual property portfolio covering mesenchymal lineage cells. Mesoblast will continue to use its patents to prosecute its commercial rights as they relate to its core strategic product portfolio. When consistent with the Company's strategic objectives, it may consider providing third parties with commercial access to its patent portfolio.

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Financial Results for the Year Ended June 30, 2020 (FY2020):

Loss after tax reduced by US\$11.9 million to US\$77.9 million for FY2020 compared to US\$89.8 million for FY2019 as detailed below:

Revenues increased US\$15.4 million to US\$32.2 million for FY2020, compared to US\$16.7 million for FY2019.

- O Milestone revenue increased by US\$14.0 million due to the upfront milestone payment of US\$15.0 million received for the strategic partnership with Grünenthal GmbH in FY2020. In FY2019 we recognized US\$1.0 million of cumulative sales milestones for sales of TEMCELL in Japan. Additionally, we recognized US\$10.0 million of milestone revenue in FY2020 and FY2019 in relation to our partnership with Tasly in China.
- Royalty revenue on sales of TEMCELL in Japan increased US\$1.6 million (32%) to US\$6.6 million for FY2020 compared with US\$5.0 million for FY2019.

Research and Development expenses decreased by US\$3.6 million to US\$56.2 million for FY2020, compared to US\$59.8 million for FY2019. The total reduction in overall R & D costs due to savings on Phase 3 clinical trials was US\$8.6 million, offset by our investment in pre-commercial activities as we prepare for the potential launch of RYONCIL in the United States.

Manufacturing expenses increased by US\$9.9 million to US\$25.3 million for FY2020, compared to US\$15.4 million for FY2019 due to increased expenditure on pre-launch inventory for the potential launch of RYONCIL and clinical supply for the COVID-19 ARDS phase 3 trial offset by a reduction in manufacturing activities related to filing the Biologics License Application (BLA) for this product.

Management and Administration expenses increased US\$4.0 million to US\$25.6 million for FY2020, compared with US\$21.6 million for FY2019, primarily due to non-cash share-based payments to employees and consultants.

Finance Costs for borrowing arrangements with Hercules and NovaQuest were US\$13.3 million for FY2020, compared to US\$11.3 million for FY2019, an increase of US\$2.0 million.

Income tax benefit increased by US\$0.5 million to US\$9.4 million for FY2020, compared with US\$8.9 million for FY2019 in relation to deferred tax liabilities recognized on the balance sheet during the period.

The net loss attributable to ordinary shareholders was 14.74 US cents per share for FY2020, compared with 18.16 US cents per share for FY2019.

Conference Call Details

There will be a webcast today on the financial results beginning at 8am AEST (Thursday, August 27, 2020); 6pm EDT (Wednesday, August 26, 2020). It can be accessed via https://webcast.boardroom.media/mesoblast-limited/20200826/NaN5f2ba898ed347b00198de987

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

References

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

2.Cash on hand at June 30, 2020 has been translated from US\$ to A\$ at a spot rate of 1.457.

3.Proceeds from the May 13, 2020 placement have been translated from A\$ to US\$ at a spot rate of 0.651.

4. Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT) - Activities and Outcomes of Hematopoietic Cell Transplantation in Japan 2018.

5.Westin, J., Saliba, RM., Lima, M. (2011) Steroid-refractory acute GVHD: predictors and outcomes. Advances in Hematology.

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6.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.

7.Risk factors for acute GVHD and survival after hematopoietic cell transplantation - Blood 2012 119:296-307; Madan Jagasia et al.

8. This vote includes a change to the original vote by one of the ODAC panel members after electronic voting closed.

9. https://clinicaltrials.gov/ct2/show/NCT04371393

10.Chao JY et al. J Pediatr 2020; 223: 14-9

11.Lancet2020; May 7. DOI: <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31094-1</u>

12.Lancet2020; May 13 DOI: https://doi.org/10.1016/S0140-6736(20)31103-X

13.<u>https://www.nejm.org/doi/full/10.1056/NEJMoa2021756</u>

14.https://clinicaltrials.gov/ct2/show/NCT04456439

15.AHA's 2017 Heart Disease and Stroke Statistics

16.Decision Resources: Chronic Pain December 2015.

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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast's Biologics License Application to seek approval of its product candidate RYONCIL[™] (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease has been accepted for priority review by the United States Food and Drug Administration (FDA), and if approved, product launch in the United States is expected in 2020. Remestemcel-L is also being developed for other inflammatory diseases in children and adults including moderate to severe acute respiratory distress syndrome (ARDS). Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore 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 forwardlooking 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. Forwardlooking 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

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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.

Release authorized by the Chief Executive, as approved by the Board of Directors.

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Consolidated Income Statement

	Year Ended June 30,	
(in U.S. dollars, in thousands, except per share amount)	2020	2019
Revenue	32,156	16,722
Research & development	(56,188)	(59,815)
Manufacturing commercialization	(25,309)	(15,358)
Management and administration	(25,609)	(21,625)
Fair value remeasurement of contingent consideration	1,380	(6,264)
Other operating income and expenses	(455)	(1,086)
Finance costs	(13,330)	(11,328)
Loss before income tax	(87,355)	(98,754)
Income tax benefit	9,415	8,955
Loss attributable to the owners of Mesoblast Limited	(77,940)	(89,799)

Losses per share from continuing operations attributable

to the ordinary equity holders of the Group:	Cents	Cents
Basic - losses per share	(14.74)	(18.16)
Diluted - losses per share	(14.74)	(18.16)

Consolidated Statement of Comprehensive Income

	Year Ended June 30,	
(in U.S. dollars, in thousands)	2020	2019
Loss for the period	(77,940)	(89,799)
Other comprehensive (loss)/income		
Items that may be reclassified to profit and loss		
Financial assets at fair value through other comprehensive income	(446)	(4)
Exchange differences on translation of foreign operations	1,146	(137)
Other comprehensive (loss)/income for the period,		
net of tax	700	(141)
Total comprehensive losses attributable to the		
owners of Mesoblast Limited	(77,240)	(89,940)

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Consolidated Balance Sheet

	As of Ju	As of June 30,	
(in U.S. dollars, in thousands)	2020	2019	
Assets			
Current Assets			
Cash & cash equivalents	129,328	50,426	
Trade & other receivables	1,574	4,060	
Prepayments	5,646	8,036	
Total Current Assets	136,548	62,522	
Non-Current Assets			
Property, plant and equipment	2,293	826	
Right-of-use assets	7,978	_	
Financial assets at fair value through other comprehensive income	1,871	2,317	
Other non-current assets	3,311	3,324	
Intangible assets	581,601	583,126	
Total Non-Current Assets	597,054	589,593	
Total Assets	733,602	652,115	
Liabilities			
Current Liabilities			
Trade and other payables	24,972	13,060	
Provisions	29,197	7,264	
Borrowings	32,455	14,007	
Lease liabilities	3,519	_	
Deferred consideration	-	10,000	
Total Current Liabilities	90,143	44,331	
Non-Current Liabilities	720	11 104	
Deferred tax liability	730	11,124	
Provisions	27,563	48,329	
Borrowings	57,023	67,279	
Lease liabilities	6,317	_	
Deferred consideration	2,500		
Total Non-Current Liabilities	94,133	126,732	
Total Liabilities	184,276	171,063	
Net Assets	549,326	481,052	
Equity			
Issued Capital	1,051,450	910,405	
Reserves	46,634	40,638	
(Accumulated losses)/retained earnings	(548,758)	(469,991)	
Total Equity	549,326	481,052	
i otai Equity	349,320	401,032	

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Consolidated Statement of Cash Flows

	Year ended June 30,	
(in U.S. dollars, in thousands)	2020	2019
Cash flows from operating activities		
Commercialization revenue received	7,676	4,359
Upfront and milestone payments received	17,500	26,409
Government grants and tax incentives received	1,577	1,654
Payments to suppliers and employees (inclusive of goods and services tax)	(77,711)	(86,294)
Interest received	546	726
Interest and other costs of finance paid	(5,947)	(4,641)
Income taxes (paid)	(7)	(3)
Net cash (outflows) in operating activities	(56,365)	(57,790)
Cash flows from investing activities		
Investment in fixed assets	(2,096)	(279)
Payments for contingent consideration	(1,027)	(721)
Payments for licenses	(150)	_
Net cash (outflows) in investing activities	(3,273)	(1,000)
Cash flows from financing activities		
Proceeds from borrowings	512	43,572
Repayment of borrowings	(512)	-
Payments of transaction costs from borrowings	(312)	(1,614)
Proceeds from issue of shares	144,946	30,258
Payments for share issue costs	(6,277)	(608)
Payments for lease liabilities	(1,625)	(000)
Net cash inflows by financing activities	137,044	71,608
Act cash hillows by infancing activities	137,044	71,000
Net increase/(decrease) in cash and cash equivalents	77,406	12,818
Cash and cash equivalents at beginning of period	50,426	37,763
FX gain/(losses) on the translation of foreign bank accounts	1,496	(155)
Cash and cash equivalents at end of period	129,328	50,426

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