# 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 July 2022

Commission File Number 001-37626

# **Mesoblast Limited**

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

Silviu Itescu Chief Executive Officer and Executive Director Level 38 55 Collins Street Melbourne 3000 Australia

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:
Form 20-F ☑ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
Yes □ No ☑
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):
Yes □ No ☑

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

On July 14, 2022, Mesoblast Limited filed with the Australian Securities Exchange a new issue announcement, notification of cessation of securities (Appendix 3H) & a new issue announcement, change of director's interest notice (Appendix 3Y) which are attached hereto as <a href="Exhibit 99.1"><u>Exhibit 99.1</u></a>, and are incorporated herein by reference.

On July 19, 2022, Mesoblast Limited filed with the Australian Securities Exchange a new release announcement which is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

### SIGNATURES

Pursuant to the requirements of the Sec	curities Exchange Act of 1934	the registrant ha	is duly caused t	his report to be s	signed on its beh	alf by the undersigned	<ol> <li>thereunto duly organized</li> </ol>

MESOBLAST LIMITED

/s/ Niva Sivakumar

Niva Sivakumar Company Secretary

Dated: July 20, 2022

## INDEX TO EXHIBITS

Item

Appendix 3H & 3Y of Mesoblast Ltd, dated July 14, 2022. Press release of Mesoblast Ltd, dated July 19, 2022. 99.1 99.2

## **Appendix 3H**

## Notification of cessation of +securities

Information and documents given to ASX become ASX's property and may be made public. \*Denotes minimum information required for first lodgement of this form.

### Part 1 – Entity and announcement details

Question no	Question	Answer
1.1	*Name of entity We (the entity named above) provide the following information about our issued capital.1	MESOBLAST LTD
1.2	*Registration type and number  Please supply your ABN, ARSN, ARBN, ACN or another registration type and number (if you supply another registration type, please specify both the type of registration and the registration number).	
1.3	*ASX issuer code	MSB
1.4	*The announcement is Select whichever is applicable.	<ul> <li>☑New announcement</li> <li>☐Update/amendment</li> <li>to previous</li> <li>announcement</li> <li>☐Cancellation of previous</li> <li>announcement</li> </ul>
1.4a	*Reason for update Answer this question if your response to Q 1.4 is "Update/amendment to previous announcement".	N/A
1.4b	*Date of previous announcement to this update  Answer this question if your response to Q 1.4 is "Update/amendment to previous announcement".	N/A
1.4c	*Reason for cancellation  Answer this question if your response to Q 1.4 is "Cancellation of previous announcement".	N/A
1.4d	*Date of previous announcement to this cancellation  Answer this question if your response to Q 1.4 is "Cancellation".	N/A

- Listing rule 3.10.3E requires an entity to notify ASX of details of the cessation of:
  - (a) any securities issued under an employee incentive scheme:
    - (i) to key management personnel or an associate, within 5 business days of their cessation;
    - (ii) to someone who is not key management personnel or an associate, within 10 business days of the end of the quarter in which the cessation occurred;
  - (b) any other equity securities not otherwise notifiable to ASX under rule 3.8A, within 5 business days of their cessation; or
  - (c) any quoted debt securities, within 5 business days of their cessation.

The notification must be in the form of, or accompanied by, an Appendix 3H.

Listing rule 3.8A requires an entity to notify ASX of the cessation of securities pursuant to a buy-back by giving ASX an Appendix 3H:

- in the case of a minimum holding buy-back, within 5 business days of the completion of the buyback; or
- in all other cases, within 5 business days of giving ASX the final notice for the buy-back
- + See chapter 19 for defined terms
- 5 June 2021Page 1

This appendix is available as an online formAppendix 3H Notification of cessation of +securities 14 July 2022 \*Date of this announcement

+ See chapter 19 for defined terms 5 June 2021 Page 2

### Details of +equity securities or quoted +debt securities that have ceased Part 2 -

Question No.	Question	Answer
2.1	*ASX +security code and description	MSBAI - Options expiring various dates ex various prices
2.2	*Number of securities that have ceased	1,553,334 options expired and 313,333 options lapsed.
2.3	Note: the conversion of a convertible security (which is notifiable to ASX under Listing Rule 3.10.3B) is not regarded as the "cessation" of the convertible security for the purposes of this rule. Likewise, the payment up of a partly paid security resulting in it becoming a fully paid security (which is notifiable to ASX under Listing Rule 3.10.3D) is not regarded as the "cessation" of the partly paid security for the	XExpiry of option or other convertible security without exercise or conversion
	purposes of this rule.	■Lapse of conditional right to securities because the conditions have not been, or have become incapable of being, satisfied
		□Cancellation pursuant to a minimum holding buy-back
		□Cancellation pursuant to an employee share scheme buy- back
		□Cancellation pursuant to an on-market buy- back
		□Cancellation pursuant to an equal access scheme buy-back
		□Cancellation pursuant to a selective buy- back
		□Cancellation pursuant to another form of buy back
		□Cancellation pursuant to a reduction of capital
		□Cancellation pursuant to a scheme of arrangement or othe reconstruction
		□Cancellation by agreement between the entity and the holder
		Repayment or redemption of +convertible debt security without conversion
		□Repayment or redemption of quoted +debt security
		□Redemption of redeemable preference securities
		☐Redemption of units
		Cancellation of partly paid +securities upon which a call or instalment has not been paid
		Other  If you have selected 'other' please provide additional details regarding the reason for cessation here:

<sup>+</sup> See chapter 19 for defined terms 5 June 2021Page 3

# This appendix is available as an online formAppendix 3H

Notification	of	cessation	of	+securities

2.4	*Date of cessation	113,334 on 30 April 2022
		1,753,333 on 30 June 2022
2.5	*Is the entity paying any consideration for the cessation?	No
	Example: the payment of an amount to the holder of an option or right as consideration for the holder to agree to a cancellation of the option or right.	
	The repayment of the principal amount of a convertible debt security or quoted debt security in accordance with its terms is not regarded as consideration paid for the cessation of that security.	
2.6	*In what currency is the consideration being paid?	N/A
	Answer this question if your response to Q 2.5 is "Yes"	
2.6a	*Consideration amount per +security paid by the entity for the cessation	N/A
	Answer this question if your response to Q 2.5 is "Yes"	
	The consideration amount per security should be provided per the currency specified in Q2.6.	
	Note: This question is <u>not</u> applicable for buy-back events (i.e. Minimum Holding, Employee, On-Market, Equal Access, Selective),	
2.6b	*Total consideration paid or payable for the securities	N/A
	The total consideration amount should be provided per the currency specified in Q2.6.	
	Note: This question <u>is</u> applicable to buy-back events only (i.e. minimum holding, employee share scheme, on-market, equal access scheme, selective or other),	
2.7	Any other information the entity wishes to notify to ASX about the cessation?	N/A

Repeat the above questions if you are advising the cessation of more than one security class.

<sup>+</sup> See chapter 19 for defined terms 5 June 2021 Page 4

Notification of cessation of +securities

## Part 3 – Issued capital following changes

3.1	*Quoted +equity securities and +debt s +securities quoted on ASX)	ecurities (total number of each +class of
	ASX +security code and description	Total number of +securities on issue
	Ordinary shares	650,454,551
3.2	*Unquoted +equity securities (total num but not quoted on ASX):	ber of each +class of +equity securities iss
3.2		ber of each +class of +equity securities iss  Total number of +securities on issue
3.2	but not quoted on ASX):	
3.2	but not quoted on ASX):  ASX +security code and description	Total number of +securities on issue
3.2	but not quoted on ASX):  ASX +security code and description  Unquoted options	Total number of +securities on issue 42,150,468

Note: the figures provided in the tables in sections 3.1 and 3.2 above are used to calculate the total market capitalisation of the entity published by ASX from time to time. Please make sure you include in the relevant table each class of securities issued by the entity.

If you have quoted CHESS Depository Interests (CDIs) issued over your securities, include them in the table in section 3.1.
Restricted securities should only be included in the table in section 3.1 if you are applying to have them quoted because the escrow period for the securities has expired or is about to expire. Otherwise include them in the table in section 3.2.

Introduced 05/06/21

5 June 2021

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<sup>+</sup> See chapter 19 for defined terms

Rule 3.19A.2

# **Appendix 3Y**

# **Change of Director's Interest Notice**

Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public. Introduced 30/09/01 Amended 01/01/11

Name of entity	Mesoblast Limited	
ABN	68 109 431 870	

We (the entity) give ASX the following information under listing rule 3.19A.2 and as agent for the director for the purposes of section 205G of the Corporations Act.

Name of Director	Philip Facchina
Date of last notice	17 January 2022

### Part 1 - Change of director's relevant interests in securities

In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

Direct or indirect interest	Indirect
Nature of indirect interest (including registered holder) Note: Provide details of the circumstances giving rise to the relevant interest.	HNP, LLC (Philip Facchina, is a member of HNP, LLC and is deemed to be the beneficial owner of these securities)
Date of change	8 July 2022
No. of securities held prior to change	273,224 Ordinary Shares, held indirectly 68,306 Warrants, held indirectly 200,000 Options, held directly.
Class	Ordinary Shares
Number acquired	1 Ordinary Share
Number disposed	Not applicable

+	See	chapter	19	for	defined	terms.

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Value/Consideration  Note: If consideration is non-cash, provide details and estimated valuation	\$0.84
	54,645 American Depositary Shares, held indirectly, which represents 273,225 Ordinary Shares 68,306 Warrants, held indirectly 200,000 Options, held directly
Example: on-market trade, off-market trade, exercise of options, issue of securities under dividend reinvestment plan participation in buy-back	On market purchase of an additional share for rounding purposes to facilitate the conversion of Mesoblast Ordinary Shares into Mesoblast American Depositary Shares.

## Part 2 – Change of director's interests in contracts

Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

Detail of contract	Not Applicable
Nature of interest	Not Applicable
Name of registered holder (if issued securities)	Not Applicable
Date of change	Not Applicable
No. and class of securities to which interest related prior change  Note: Details are only required for a contract in relation to which the interest has changed	to Not Applicable
Interest acquired	Not Applicable
Interest disposed	Not Applicable
Value/Consideration Note: If consideration is non-cash, provide details and an estimated valuation	Not Applicable

<sup>+</sup> See chapter 19 for defined terms.

01/01/2011 Appendix 3Y Page 7

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Ap	pend	IX	3

Change of Director's Interest Notice

	_	
Interest after change	Not Applicable	

# Part 3 – +Closed period

Were the interests in the securities or contracts detailed above traded during a +closed period where prior written clearance was required?	No
· · · · · · · · · · · · · · · · · · ·	Not Applicable
If prior written clearance was provided, on what date was this provided?	Not Applicable

01/01/2011 Appendix 3Y Page 8

<sup>+</sup> See chapter 19 for defined terms.

### asx announcement



### SINGLE INTERVENTION WITH REXLEMESTROCEL-L IMPROVES LEFT VENTRICULAR EJECTION FRACTION AT 12 MONTHS, PRECEDING LONG-TERM REDUCTION IN MAJOR ADVERSE CARDIOVASCULAR EVENTS

### Key points:

- Improvement in left ventricular ejection fraction (LVEF) at 12 months was shown after a single intervention with rexlemestrocel-L in the 565-patient randomized controlled trial in New York Heart Association (NYHA) class II/III chronic heart failure (CHF) with reduced ejection fraction (HFrEF)
- Increased LVEF preceded long-term reduction in major adverse cardiovascular events (MACE) and associated recurrent hospitalizations for non-fatal heart attack or stroke
- LVEF improvement at 12 months may be an appropriate early surrogate endpoint for long-term reduction in MACE
- Effects on LVEF and MACE outcomes were even more pronounced in 301 HFrEF patients with high baseline levels of inflammation as measured by
- Results from three randomized controlled trials in class II/III HFrEF and in end-stage HFrEF with left ventricular assist devices (LVADs) support the idea of a common mechanism of action (MOA) by which rexlemestrocel-L reverses inflammation-related endothelial dysfunction and reduces adverse clinical outcomes across the spectrum of HFrEF patients
- Rexlemestrocel-L has regenerative medicine advanced therapy (RMAT) designation from the US Food and Drug Administration (FDA) for treatment of chronic heart failure with left ventricular systolic dysfunction in patients with an LVAD. Mesoblast now intends to meet with FDA under the RMAT framework to discuss the totality of the data and the evidence of a common rexlemestrocel-L MOA across the broader HFrEF spectrum.

Melbourne, Australia; July 19, and New York, USA; July 18, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that treatment of HFrEF patients with rexlemestrocel-L, its allogeneic "off-the-shelf" product candidate for the treatment of chronic heart failure with reduced ejection fraction, resulted in greater improvement in the pre-specified analysis of left ventricular ejection fraction at 12 months relative to controls in the DREAM-HF Phase 3 trial. Improvement in LVEF was most pronounced in the setting of inflammation and preceded long-term reduction in the 3-point MACE of cardiovascular death, non-fatal heart attack or stroke. These results were recently highlighted in a heart failure panel discussion titled "Late-Stage Advancements in Heart Failure Therapeutics and Management."

Rexlemestrocel-L is an immunomodulatory therapy developed to target the high degree of inflammation and resultant endothelial dysfunction present across the spectrum of HFrEF, from NYHA class II through end-stage CHF on LVADs. This MOA is postulated to improve systolic function and LVEF in HFrEF patients and reduce the high rate of major cardiovascular events and complications, notably 3-point MACE in NYHA class II/III patients and gastrointestinal (GI) tract ischemia, abnormal GI blood vessels, and life-threatening GI bleeding events in LVAD patients. Rexlemestrocel-L has already been granted FDA RMAT and Orphan Drug designations for treatment of chronic heart failure with left ventricular systolic dysfunction in patients with an LVAD.

Results from two large placebo-controlled randomized studies in patients with HFrEF, a disease associated with inflammation, a 565-patient trial in NYHA class II/III patients (DREAM-HF) and a 159-patient trial in end-stage heart failure patients implanted with an LVAD, as well as in an earlier 30-patient trial in LVAD patients, provide support for a common MOA for rexlemestrocel-L across the spectrum of HFrEF. New data from the DREAM-HF trial shows that a single intervention with rexiemestrocel-L resulted in improvement from baseline to 12 months in LVEF, which preceded and correlated with long-term reduction in MACE across a mean follow up of 30 months. This suggests that early improvement in LV systolic function, as measured by LVEF change from baseline to 12 months, could be an appropriate surrogate endpoint predictive of adverse long-term clinical outcomes in this patient population.

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In the DREAM-HF study, among the 537 patients who were randomized and received either treatment or sham, a single injection of rexlemestrocel-L resulted in the following:1

- 52% greater increase in LVEF from baseline to 12 months compared with controls. While both groups had similar LVEF at baseline (28.7% and 28.6%), at 12 months least squared mean change from baseline was 5.0 for the rexlemestrocel-L group and 3.3 for controls (p=0.021)
- 65% reduction in 2-point MACE (non-fatal heart attack or stroke) compared to controls, 4.6% vs 13.0%, p=0.001, across a mean follow-up of 30 months
- 33% reduction in 3-point MACE compared to controls, 20.3% vs 30.1%, p=0.021, across a mean follow-up of 30 months
- · 68% reduction in the rate of recurrent hospitalizations from non-fatal heart attacks or strokes compared with controls (p=0.0002)

Outcomes were even more pronounced in the pre-specified subgroup of 301 NYHA class II/III HFrEF patients with detectable circulating evidence of inflammation as measured by elevated baseline hsCRP, where a single injection of rexlemestrocel-L resulted in the following:

- 86% greater increase in LVEF from baseline to 12 months compared with controls: while both groups had similar LVEF at baseline (29.1% and 28.2%), at 12 months least squared mean change from baseline was 5.6 for the rexlemestrocel-L group and 2.9 for controls (p=0.005)
- 79% reduction in 2-point MACE compared to controls, 2.6% vs 12.2%, p=0.004, across a mean follow-up of 30 months
- 45% reduction in 3-point MACE compared to controls, 19.0% vs 32.4%, p=0.012, across a mean follow-up of 30 months

Outcomes in a second HFrEF population with high levels of inflammation, 159 patients with end-stage heart failure and LVAD implantation, showed that a single intervention with rexlemestrocel-L reduced life-threatening mucosal bleeding events requiring hospitalization through 6 months (GI or epistaxis) compared with controls, 17% vs 33%, p=0.02. These results confirmed the observed reduction in major GI bleeding events seen in an earlier 30-patient randomized study. The FDA has indicated that a reduction in life-threatening mucosal bleeding events is an important clinical outcome in patients implanted with an LVAD.

These results are consistent with a postulated mechanism of action by which rexlemestrocel-L targets inflammation and endothelial dysfunction across the spectrum of HFrEF with the potential to reduce major adverse clinical events in HFrEF patients from NYHA class II/III through to end-stage disease and LVADs. Mesoblast now intends to meet with FDA under the RMAT framework to discuss the totality of the data, the evidence of a common MOA across the broad HFrEF spectrum, and how the outcomes from each trial may support the regulatory approval pathway for rexlemestrocel-L.

#### About Heart Failure

Heart failure affects approximately 6.5 million people in the United States and 26 million people globally, with increasing prevalence and incidence. The mortality rate approaches 50% at 5 years as patients progress beyond NYHA class II disease in parallel with increasing inflammation in the heart and in the circulation.<sup>2,3</sup> Despite recent approvals of new therapies for HFrEF, including SGLT2 inhibitors, that have reduced hospitalizations due to reversible volume-related events, NYHA class II/III HFrEF patients with inflammation remain at high risk for cardiac death, heart attacks and strokes. Over 60,000 patients annually in the US progress to end-stage heart failure (NYHA class IV) and these patients have a one-year mortality exceeding 50%.<sup>4</sup> Use of LVADs in end-stage heart failure patients to improve survival is gaining momentum, with approximately 5,500 LVADs implanted annually in the US.<sup>5-7</sup> However, systemic inflammation associated with major life-threatening gastrointestinal bleeding high rates of rehospitalization remain a major obstacle to greater LVADsuse.<sup>8,9</sup>

#### About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 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 is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic 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 <a href="https://www.mesoblast.com">www.mesoblast.com</a>, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

#### **Footnotes**

- 1. LVEF, 2-point MACE, and recurrent hospitalizations due to heart attack or stroke were pre-specified endpoints and the 3-point MACE was a post-hoc analysis of pre-specified endpoint components
- 2. AHA's 2017 Heart Disease and Stroke Statistics
- 3. Ponikowski P., et al. Heart Failure: Preventing disease and death worldwide. European Society of Cardiology. 2014; 1: 4-25
- 4. Gustafsson F, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. European Journal of Heart Failure 2017;19:595-602.
- United Network for Organ Sharing
- 6. Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project Claims Analysis ICD- 37.6.
- 7. Data on file
- 8. Chatterjee A, Feldmann C, Hanke JS (2018) The momentum of HeartMate 3: a novel active magnetically levitated centrifugal left ventricular assist device (LVAD). J Thorac Dis 10 (Suppl 15): S1790-S1793.
- 9. Mehra, MR Salerno C, Clèveland JĆ (2018) Health care resources use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure.

### **Forward-Looking Statements**

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including BLA resubmission), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forwardlooking 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.

For more information, please contact:

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