



ASX ANNOUNCEMENT

QUARTERLY REPORT & APPENDIX 4C – DECEMBER QUARTER 2019

HIGHLIGHTS

- First human dosing of Plexaris™ has occurred in Exopharm's PLEXOVAL Study post the end of the quarter
- Acceleration of pre-clinical testing and other R&D activities
- Executive Management appointments

29 January 2020

Melbourne, Australia: Regenerative medicine company Exopharm Limited (ASX:EX1) today releases its Appendix 4C and Quarterly Report for the quarter ended 31 December 2019.

The Development Program

The Company has a well-defined Development Program which includes pre-clinical testing, clinical research and other development activities. Exopharm continues to make solid progress across all parts of its business and has a clear strategy to build value from its leadership position in the promising new field of exosome therapeutics.

PLEXOVAL Study

The Company has continued to progress the PLEXOVAL Study during the quarter and since the end of the quarter announced that first dosing occurred in the PLEXOVAL Phase I study using exosomes isolated from human platelets for wound healing, Exopharm's first human clinical trial.

The PLEXOVAL study placed Exopharm in a worldwide leadership position in the exosome field, and first dosing is a key milestone for Exopharm as a clinical stage company developing exosome-based medicines. Exopharm has been granted Human Research Ethics Committee approval to commence the PLEXOVAL wound healing study with its Plexaris™ (exosomes from platelets) autologous product under the Australian Clinical Trials Notification (CTN) scheme.

During the quarter, the PLEXOVAL study program was modified to prioritise Cohort 2 over Cohort 1. Cohort 2 involves up to 5 participants. Recruitment for Cohort 2 is planned to be conducted on a rolling basis. The recruitment process has been initiated and is ongoing. Selection of the first participant and first dosing would be the next step in the study.

Exopharm is manufacturing the Plexaris product at its Fitzroy manufacturing facility. The main readouts of the PLEXOVAL study will be safety, wound closure and scarring. Subject to

successful rolling recruitment and throughput, a study report will be provided to Exopharm, at this stage expected after mid CY '20.

For additional information on the PLEXOVAL Study, see the ASX announcement dated 26 August 2019 which provides full study details.

Pre-clinical testing and other development activities

Exopharm's development team continues to test Exopharm's exosome products (derived from human platelets and adult stem cells) in a number of ways – including in vitro testing and in vivo testing.

This testing is aimed at selecting key indications for later human studies.

The Company has continued to build manufacturing and analytics capabilities during the quarter.

Increased investment in engineered exosome field

Over the past few years there has been a significant amount of corporate activity in this field and Exopharm seeks to leverage its exosome manufacturing and analytical capabilities towards the engineered exosome field.

During the quarter the Company increased its activity within the engineered exosome field and in a number of distinct areas.

More information is expected in CY '2020 as these research and development activities are further advanced by the Company.

Number of scientific publications on exosomes continues to accelerate

The number of scientific publications focused on exosomes continues to increase and continue to point to exosomes as an important field in regenerative medicine and other medical areas.

Exopharm articles

Understanding exosomes can be challenging. Exopharm writes and publishes articles regularly to provide shareholders and investors a better understanding of the scientific and commercial developments in the exosome field.

A recent article explains that a growing number of stem cell companies are seeing the light and shifting their focus to exosome products. This article provides commentary on an interesting group of companies that are soon to begin human clinical trials of experimental

therapeutic exosome products including naïve (unmodified) exosomes and engineered exosomes.

Commercialisation and Collaborative Partnerships

Exopharm has extended its activities in commercialisation over the quarter and has attended international biotechnology conferences for partnering discussions.

To build value in the engineered exosome field, Exopharm also continued to assess and progress a number of collaborations and intellectual property transactions.

Corporate & Executive Appointments

Managing Director and CEO

During the quarter, Dr Ian Dixon renewed his commitment to the Company, signing a new permanent employment contract as Managing Director and CEO.

Dr Dixon is the founder of the Company and a highly experienced developer of therapeutic technologies. The Company is pleased to have secured the services of Dr Dixon on an ongoing basis to provide continuity of service and deliver on the commercial vision of the Company.

Chief Commercial Officer

During the quarter the Company secured the services of Dr Chris Baldwin as Chief Commercial Officer. Dr Baldwin has extensive international experience, most recently with Haemontics Corporation, a world leader in the plasma and blood supply chains with sales of approximately \$US1B and over 3,000 employees.

Dr Baldwin has begun using his expertise and networks across strategy, marketing and communications towards strategically positioning the Company within the broad international regenerative medicine industry.

Quality & Regulatory Affairs Manager

During the quarter the Company secured the services of Mr Ivan Jasenko as Quality & Regulatory Affairs Manager. Mr Jasenko has extensive international experience bringing therapeutic products and medical devices through international regulatory requirements including TGA (Australia), FDA (USA) and EMA (EU).

Ivan has worked for companies such as CSL, Bayer Healthcare, PolyNovo Limited and Schering-Plough Animal Health.

Mr Jasenko works at our Melbourne headquarters to ensure our operations are compliant with present and future regulations and that our commercial objectives are met in this critical area of compliance and quality.

Dr Dixon said 'The development of new medicines is a complex and demanding area. Ivan works within our team to ensure that we either meet or exceed the compliance requirements

to bring our products forward. He also helps us manage risk and understand what regulators such as the FDA want to see before they issue an IND to permit a clinical trial in the USA.'

Appendix 4C Commentary

The Company completed the quarter with \$5,881,000 in cash as detailed in the Appendix 4C report that accompanies this announcement.

The Company continues to conservatively manage its cash assets and will consider augmenting its cash position in consideration of commercial requirements and market conditions.

The Company also plans to lodge its R&D claim as part of the Company's 2019 Annual Tax Return in the March 2020 quarter, following receiving its R&D grant registration from AusIndustry for the 2019 FY.

By the Board - this announcement has been authorised for release by the board.

Company and Media Enquiries

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ABOUT EXOPHARM

Exopharm Limited (ASX:EX1) is a clinical-stage Australian regenerative medicine company developing therapeutic exosome products as alternatives to stem-cell therapies.

Exosomes are small particles naturally produced by cells, which deliver therapeutic 'cargoes' to other cells to reduce inflammation and promote regeneration. Exosomes are plentiful in our youth but decline with age. Recent research points to exosomes as a way to extend the number of healthy, functional years (extending health span).

Exosomes secreted by stem cells could be used instead of stem-cell therapy with equal or greater benefit – and without the problems of stem-cell therapies. They could be used to deliver targeted 'novel' drugs and have potential as diagnostics.

While trillions of exosomes are produced by stem cells, the real challenge is to 'purify' them as drug products. Exopharm owns a purification technology called Ligand-based Exosome Affinity Purification (LEAP). LEAP technology and associated know-how places Exopharm at the forefront of this emerging field worldwide. Exopharm is at clinical stage with pending and current trials for wound healing, dry aged-related macular degeneration and osteoporosis.

Exopharm was founded in 2013 by Dr Ian Dixon, co-founder of the ASX-listed stem-cell therapy developer Cynata Therapeutics. He was also a director of Cell Therapies, which produced adult stem cells for ASX-listed stem cell company Mesoblast. Exopharm listed on the ASX in December 2018.

FORWARD LOOKING STATEMENTS

This announcement contains forward-looking statements which incorporate an element of uncertainty or risk, such as 'intends', 'may', 'could', 'believes', 'estimates', 'targets', 'aims', 'plans' or 'expects'. These statements are based on an evaluation of current corporate estimates, economic and operating conditions, as well as assumptions regarding future events. These events are, as at the date of this announcement, expected to take place, but there cannot be any guarantee that such events will occur as anticipated or at all given that many of the events are outside of Exopharm's control or subject to the success of the Development Program. Furthermore, the Company is subject to several risks as disclosed in the Prospectus dated 6 November 2018.

INHERENT RISKS OF INVESTMENT IN BIOTECHNOLOGY COMPANIES

There are a number of inherent risks associated with the development of biopharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Exopharm are dependent on the success of their research and development projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore, investment in companies specialising in drug development must be regarded as highly speculative. Exopharm strongly recommends that professional investment advice be sought prior to such investments.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

EXOPHARM LIMITED

ABN

78 163 765 991

Quarter ended ("current quarter")

31 DECEMBER 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(672)	(1,539)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(29)	(46)
(d) leased assets	(58)	(58)
(e) staff costs	(630)	(1,242)
(f) administration and corporate costs	(389)	(656)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	25	39
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	63	64
1.9 Net cash from / (used in) operating activities	(1,690)	(3,438)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(163)	(290)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(1)	(1)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(164)	(291)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,540
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(349)
3.5	Proceeds from borrowings	-	
3.6	Repayment of borrowings	-	
3.7	Transaction costs related to loans and borrowings	-	
3.8	Dividends paid	-	
3.9	Other (provide details if material)	-	
3.10	Net cash from / (used in) financing activities	(4)	5,191

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,739	4,419
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,690)	(3,438)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(164)	(291)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(4)	5,191
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,881	5,881

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	865	1,239
5.2	Call deposits	5,016	6,500
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,881	7,739

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$A'000
150
-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

The payments to directors or their associates in 6.1 include gross salaries, superannuation, fees and benefits to executive and non-executive directors, company secretarial/consulting fees and reimbursements paid.

Quarterly cash flow report for entities subject to Listing Rule 4.7B

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 **Unused financing facilities available at quarter end** -

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Not applicable.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,690)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	5,881
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	5,881
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.48x

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 The September quarter Appendix 4C included \$181,910 of Property Plant and Equipment (2.1c) which was made up of several items each being of less than \$25,000 for each item. This expenditure should have been expensed and accounted for as 1.2 Payments for (a) research and development, i.e operating expenditure; accordingly the "Year to Date" columns for 1.2a and 2.1c have been adjusted to reflect the accurate cash movement of these payments.
- 3 This statement gives a true and fair view of the matters disclosed.

Date: 29 January 2020

Authorised by: By the Baord.....
(The Appendix 4C has been authorised for release by the Board.)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.