

# ASX ANNOUNCEMENT

# **Exopharm Quarterly Activities Report and Appendix 4C**

- The Company raised \$10 million in a well-supported placement
- Alison Mew appointed as Interim Director of Manufacturing and Development to lead product and process development operations
- Plexoval II study underway with first human dosing complete. This world-first Phase I study uses a cell-free, allogeneic (unmatched) platelet-derived exosome product for wound healing
- World-wide interest in EVs is accelerating rapidly
- Operations continue despite restrictions, with an increased focus on EEVs

#### 27 October 2020

**Melbourne, Australia**: Exopharm Limited (ASX:EX1) is a clinical-stage Australian extracellular vesicle (EV) medicine company with investment into development programs across manufacturing, Naïve EVs and Engineered EVs.

Exopharm provides an update on our activities and the Appendix 4C for the quarter ended 30 September 2020.

#### **Development activities**

Over the past quarter, Exopharm has made numerous advances across the business to strengthen its pioneering position in the EV field world-wide. The Company continues to make steady progress across its main activity areas:

- Commercial ongoing discussions with potential partners regarding future transactions
- Technology including the exclusive LEAP, LOAD and EVPS platforms
- Developing NEVs (naïve EVs) from stem cells and platelets as a new class of regenerative medicine
- EEVs (engineered EVs) designed as precision medicines to treat conditions such as viral infections, cancer and neurological conditions

#### Engineered EVs (EEVs)

Exopharm has increased emphasis on its EEV program. The Company's in-licensed exclusive technologies, LOAD and EVPS, have enabled the design and manufacture of a range of EEVs. The program holds a pipeline of EEV products including Plexodox (platelet derived) and Fortrexo (MSC derived) and offers a high-value, medium-term pathway to revenue.

#### Fortrexo CoV – Exopharm's response to COVID-19

Exopharm has been working over the past months to build its Fortrexo platform – EEVs for fast response to viral infections. Specifically, with Fortrexo CoV, the Company joined the battle against SARS-CoV-2. This prototype product is designed to stop the virus from replicating within infected cells. This could potentially reduce the duration and severity of SARS-CoV-2 infection in the early phase of a patient's exposure. A patent application for Fortrexo CoV has been lodged, and the product is now moving through step-wise development in Melbourne.

The Fortrexo CoV product serves as a prototype for precision medicines for other applications such as genetic diseases, neurodegeneration and cancer. The Company is working towards advancing more novel EEV products through into clinical development and partnering.

#### Naïve EVs (NEVs)

#### Plexoval II Study is underway

Exopharm is leading the world in human clinical trials for EVs. In September 2020, Exopharm was granted Human Research Ethics Committee approval to commence the Plexoval II Phase I study under the Australian Clinical Trials Notification (CTN) scheme. The study assesses the safety and biological activity and benefits of allogeneic (off-the-shelf) Plexaris for wound healing and sources clinical-grade platelets from a pool of donor patients. The study has achieved major milestones of first dosing and full enrolment and is on track to complete in CY 2020. These advancements underscore Exopharm's technology capabilities, as the only company to initiate two separate human trials.

The autologous Plexoval I study was suspended in April 2020 due to COVID-19 restrictions and the Company decided to terminate further recruitment of the study.

#### <u>Technology</u>

Exopharm has been making further manufacture scale-up and improvements using its LEAP technology.

Exopharm has announced the external expert testing of its proprietary Exoria EV tagging product. Presently, dyes used by researchers work poorly with EVs and are expensive. Exopharm recently developed a proprietary fluorescent dye for EVs called Exoria, which is the first dye in the world specifically designed to allow researchers to track how EVs migrate and deliver their pay load into cells. This invention is being tested in nine internationally recognised EV institutions. Feedback has been promising, signifying the potential for Exoria as a powerful research tool.

#### Global interest in EVs continues to grow rapidly

Interest in the emerging EV field is accelerating globally, with announcements of partnerships and large deals for EV therapeutic products. On 15 July 2020, Evox Therapeutics announced the grant of a key patent to cover exosomes for RNA therapeutics. Codiak Biosciences announced its first human dosing in a Phase 1 clinical trial of its novel exosome therapeutic candidate, exoIL-12 on 15 September 2020. These developments highlight that the EV medicine field is advancing rapidly and the growing importance of using EVs as a new form of medicine.

#### **Corporate activities**

The Company continues its ongoing partnering discussions to accelerate EV therapeutic development. Exopharm has continued to progress non-exclusive outlicensing discussions to technology partners, including involvement at recent Meeting on the Mesa and Bio Investor forum. Exopharm will attend numerous partnership events and conferences in the next quarter, including AusBiotech, Exosome Based Therapeutic Development Summit, where Dr Chris Baldwin, Chief Commercial Officer, will provide insights into Exopharm's manufacturing focus and process to industry peers.

On 27 August 2020, Exopharm announced a placement of 41,666,667 shares to raise \$10 million in a well-supported placement. Canary Capital, the manager of the placement, and its directors elected to take the majority of their fees in shares, which demonstrates the conviction Canary has in the future of the Company. The funds are being used to fast-track the commercialisation of technology platforms, advance clinical trials and further develop IP. Following the success of the capital raise, Exopharm announced a 12-month corporate advisory mandate with Canary Capital starting on 1 September 2020.

Exopharm announced the appointment of Alison Mew to join the senior management team as Interim Director of Manufacturing and Development to lead product and process development operations on 15 September 2020. Ms Mew has more than 30 years of management and leadership experience across the biopharmaceutical, diagnostic and health service sectors. During her 13 years with CSL, she worked across several divisions in senior operations management and general management positions. Ms Mew continues her role as Director at Centre for Biopharmaceutical Excellence Pty Ltd and Non-Executive Director at McPherson Ltd.

Exopharm held a 'Behind the Scenes' science webinar for shareholders and interested people on 2 September 2020. This booked-out event saw over 90 attendees and was received positively. The Company plans to present more webinars in this series. Exopharm also held a shareholder update webinar hosted by Monsoon Communications in July and presented at the ShareCafe Hidden Gems Webinar in September.

## **Appendix 4C Commentary**

Exopharm ended the quarter with cash of \$5.8 million (\$1.7 million at 30 June 2020), a further \$4.3 million (before costs) due upon completion of the EGM and a further \$2.2 million due from the R&D Rebate (\$2.1 million has been received, as announced to the market on 22 October 2020, and a further rebate from previous periods is also expected). Quarterly operating cash outflows for the period was \$1.8 million (\$2.1 million in the prior quarter).

The increase in total cash inflow for the quarter relative to the prior period was a result of a successful \$10 million capital raise (\$5.9 million of which relates to Tranche 1 and has been received), which was well-supported by Institutions, as well as new and existing sophisticated and professional investors.

Operating cash outflows for the period was predominately R&D costs – made up of R&D salary costs, manufacture and testing programs and equipment purchases – all aimed at the continued development of Exopharm's preclinical and clinical assets. Management of spending remains a key priority for the business, with the allocation of spend being carefully managed to build a sustainable business beyond the current milestones and funding.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes gross salaries, superannuation and fees and benefits to executive and non-executive directors, company secretarial fees, reimbursements paid and corporate fees, as follows:

- Total Gross salaries to directors: \$101,500
- Total consulting fees for corporate, secretarial and accounting services paid to related parties: \$26,250
- Total payments to related parties and their associates included in items 6.1: \$127,750

### Company and Media Enquiries:

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## **ABOUT EXOPHARM**

Exopharm Limited (ASX:EX1) is a clinical-stage Australian extracellular vesicle (EV) medicine company with investment into development programs across manufacturing, Naïve EVs and Engineered EVs .

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.

EVs can also be used to deliver targeted 'novel' drugs as potential precision medicines.

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 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	Quarter ended ("current quarter")
78 163 765 991	30 September 2020

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(569)	(569)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(84)	(84)
	(d) leased assets	-	-
	(e) staff costs	(839)	(839)
	(f) administration and corporate costs	(344)	(344)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	2
1.5	Interest and other costs of finance paid	(11)	(11)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	25	25
1.8	Other (provide details if material)	43	43
1.9	Net cash from / (used in) operating activities	(1,777)	(1,777)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(50)	(50)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	(50)	(50

3.10	Net cash from / (used in) financing activities	5,839	5,839
3.9	Other (repayment of lease liability)	(82)	(82)
3.8	Dividends paid	-	-
3.7	Transaction costs related to loans and borrowings		-
3.6	Repayment of borrowings	-	-
3.5	Proceeds from borrowings	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,921	5,921
3.	Cash flows from financing activities		

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,743	1,743
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,777)	(1,777)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(50)	(50)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,839	5,839
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,755	5,755

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	5,755	1,243
5.2	Call deposits	-	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)	5,755	1,743

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

Aggregate amount of payments to related parties and their

Current quarter \$A'000	
	128
	-

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

associates included in item 1

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 and fees and benefits to executive and non-executive directors, company secretarial fees, reimbursements paid and corporate fees.

6.1

#### 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.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-

#### 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.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(1,777)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	5,755
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	5,755
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.1

- 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:

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:

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:

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#### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

#### The Board of Directors

Authorised by:	
	(Name of body or officer authorising release – see note 4)

#### 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.