

## ASX ANNOUNCEMENT

### Quarterly Activities Report and Appendix 4C

- Interest in exosome medicines is building worldwide as part of a US\$170 billion p.a. drug delivery systems and services market<sup>1</sup>
- The importance and value of Exopharm's LEAP technology is becoming increasingly clear
- Recent studies demonstrated the safety of our manufacturing process and products
- Exopharm is concentrating its investment in exosome medicines and LEAP technology

16 April 2021

**Melbourne, Australia:** Exopharm Limited (ASX:EX1) is a clinical-stage company at the forefront of developing transformative exosome medicines.

Exopharm provides this update on activities and the Appendix 4C for the quarter ended 31 March 2021.

#### Achievements and recognition

In 2021 exosomes are seen as a unique drug delivery platform with the potential to enhance tissue delivery for a variety of payloads like mRNA and proteins – part of the global market for drug delivery systems that is growing at a compound annual growth rate (CAGR) of 5% and valued at around US\$170 billion in 2021.

Exopharm is one of only two exosome medicine companies listed on public exchanges worldwide and one of a handful of companies creating exosome medicines through partnership deals, clinical trials and eventually commercialisation.

In the past quarter the promise of exosome medicines has had further support from human clinical use in the USA and Israel.

Exopharm continues to invest in important advances that strengthen its pioneering position in the international exosome medicines field.

We released information about our studies just after the close of the quarter, consistently showing product safety.

#### Investment focus to generate revenue

Exopharm is investing in two interrelated technologies to support partnering transactions with exosomes:

##### 1. Exosome Technologies

Licensing the LEAP technology and Exoria exosome labelling technology, alongside Exopharm's expert bioprocessing know-how to:

- Empower contract manufacturing organisations to serve exosome companies
- Integrate LEAP into the GMP processes of biotechnology companies including blood plasma fractionators, blood services and emerging exosome companies.

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<sup>1</sup> Source: <https://formulations.pharmaceuticalconferences.com>

## 2. Exosome Medicines

Leveraging our LOAD and EVPS technologies, using exosomes to deliver transformative medicines:

- Enabling biopharma companies to deliver new and existing drug candidates in novel ways
- Designing and evaluating new exosome medicines that we own and invest in.

### **The importance and value of Exopharm's LEAP technology is becoming increasingly clear**

Increased manufacturing scale will be required as the demand for exosome medicines increases over coming years. A lack of manufacturing scale has been holding back the whole field.

Exopharm's LEAP purification technology has been demonstrated to be the most scalable exosome therapeutics purification technology available, pointing to the potential for multiple partnership deals to enable exosome product development by others.

Discussions are underway for licensing LEAP to companies already active in the bioprocessing industry. The collaboration with the Finnish Red Cross Blood Service is an early example.

### **Engineered EVs (EEVs) – *proving the performance***

Over the past 36 months there have been six deals each in the billion-dollar range executed by a few exosome therapeutics companies, each deal delivering cash upfront payments of around \$70m, and each based upon only preclinical exosome therapeutic candidates.

For some medicines exosomes are an alternative and superior means for delivery inside the body – alongside technologies such as lipid nanoparticles (LNP), cell penetrating peptides, viral vectors and liposomes.

Potential pharma partners are seeking exosome therapeutics that have 'tropism' ie. exosomes that preferentially target selected tissue types (e.g. glial cells in the brain). Such targeting would allow selective delivery of medicines, improving the safety profile and efficacy of the treatment.

Exopharm's EVPS technology (US patent issued) provides targeting and can be adapted to hundreds or thousands of variations, so multiple partnering deals are possible. Partners are also looking for enhanced loading of nucleic acids (e.g. mRNA, siRNA or miRNA) into exosome therapeutics. Exopharm's LOAD technology also provides that.

### **Naïve EVs (NEVs) – *our work is complete***

Exopharm has been leading the world in human clinical trials for NEVs.

The PLEXOVAL II results have been released and demonstrated safety of the off-the-shelf Plexaris product from blood platelets.

The CellVax OA animal study results were released showing safety of both Cevaris and Plexaris products.

These studies consistently showed safety of the products and provide data for partnering discussions.

### **NEV products into the future – enabling partners and licensees**

Given the focus on LEAP and exosome medicine transactions, we will not invest further into animal studies or clinical trials of our blood or stem cell derived exosome programs (Plexaris and Cevaris).

Instead the aim is to partner these products out and leave investment in the development and commercialisation of these NEV products with partners.

Exopharm does not intend to run future clinical trials using Plexaris or Cevaris in wound healing or osteoarthritis.

Potential partners for the Plexaris product include the blood products companies.

A non-binding Heads of Agreement was signed with the Finnish Red Cross Blood Service on the use of Exopharm's LEAP technology for NEV purification from blood components such as platelet derived Plexaris™.

### **Business model and revenue streams identified**

As a platform technology company and one of the few exosome therapeutics companies worldwide, Exopharm now has exosome-related technologies with the potential to make hundreds of exosome medicine variants using LOAD and EVPS, and later purified at high scale and low cost using LEAP. Exopharm is positioned as a viable and credible partner as the field booms.

In April 2021 we see that near-term revenue will start to come from two streams:

- Licensing: multiple non-exclusive deals from out-licensing our LEAP technology to allow others to purify exosomes; and
- Partnering: multiple deals allowing our partners to use our exosome medicines (incorporating LOAD and EVPS) to make transformative exosome therapeutic products.

### **Corporate activities – *progress, peers and partnering***

Over the past quarter Exopharm has continued to increase its visibility in the biopharmaceutical industry with ongoing participation in events aimed at increasing our profile.

The number of shareholders is growing and liquidity in the stock is improving. There have been numerous announcements over the quarter.

In Q4 FY21, Exopharm will receive an additional \$61,197 from the Export Market Development Grant scheme (as confirmed by Austrade).

### **Appendix 4C commentary**

Exopharm ended the quarter with cash of \$5.1 million (\$7.9 million at 31 December 2020). Quarterly operating cash outflows for the period was \$2.9 million (\$3.0 million in the prior quarter).

The increase in total net operating cash outflow for the quarter relative to the prior period was a result of increased R&D related staff costs and the receipt in the prior quarter of \$2.1 million from the FY2020 R&D tax incentive rebate.

Cash outflow for the period was predominantly R&D costs – clinical trial costs, product manufacture and testing programs and R&D related salary costs – all aimed at supporting Exopharm's development and commercialisation activities.

Exopharm also received an additional \$160,697 from the R&D Tax Incentive program for FY 2020 following an overseas finding.

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, fees to executive and non-executive directors, company secretarial and share registry fees, as follows:

- Total Gross salaries to directors: \$111,817 (including superannuation)
- Total consulting fees for corporate, secretarial and share registry services paid to related parties: \$34,812 (Automic Pty Ltd)
- Total payments to related parties and their associates included in items 6.1: \$146,629

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

**Company and Media Enquiries:**

*Join our mailing list to receive updates:*

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**ABOUT EXOPHARM**

Exopharm (ASX:EX1) is a clinical-stage biopharmaceutical company using exosomes to deliver a new class of transformative medicines and generate revenue from multiple partnership deals.

Exosomes are seen by the Biopharma industry as a highly differentiated platform with the potential to enhance tissue delivery for a variety of payloads like mRNA and proteins – part of the global market for drug delivery systems which is growing at a compound annual growth rate (CAGR) of 5% and valued at around US\$170 billion in 2021.

For some medicines, exosomes are an alternative and superior means for delivery inside the body, alongside technologies such as lipid nanoparticles (LNP), cell penetrating peptides, viral vectors and liposomes.

Exopharm's LEAP technology solves the challenge of purifying clinical-grade exosomes at large scale and low cost.

Exopharm also has two exclusive proprietary technologies that allow advanced customisation of exosomes – the LOAD technology improves loading of nucleic medicines into exosomes and the EVPS technology allows exosomes to be directed towards selected cell types.

Exopharm uses variations and combinations of LOAD and EVPS to enable its biopharma partners to improve delivery of their drug candidates and help them design and test new exosome medicines aimed at treating a wide scope of medical problems including neurological disease, infectious disease, cancer, and fibrosis.

**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.

## 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 March 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(724)	(2,247)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(134)	(292)
(d) leased assets	-	-
(e) staff costs	(1,307)	(3,343)
(f) administration and corporate costs	(746)	(1,824)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	5
1.5 Interest and other costs of finance paid	(6)	(27)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	161	2,322
1.8 Other (provide details if material)	174	200
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,580)</b>	<b>(5,206)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(87)	(1,083)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(87)</b>	<b>(1,083)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	10,000
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	-	(122)
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 (repayment of lease liability)	(95)	(240)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(95)</b>	<b>9,638</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	7,854	1,743
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,580)	(5,206)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(87)	(1,083)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(95)	9,638
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,091</b>	<b>5,091</b>

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	5,091	7,854
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,091</b>	<b>7,854</b>

**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**

147

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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.

## 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.*

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

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.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(2,580)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	5,091
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	5,091
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>2.0</b>

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:



## 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.

Date: 16.04.2021  
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Authorised by: Board of Directors  
.....  
(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.