

## **ASX ANNOUNCEMENT**

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

- Work in our laboratory is generating important data to support partnering discussions and the growing value of our intellectual property
- Interest in using exosomes as a delivery method for medicines is building worldwide as part of a US\$170 billion pa drug delivery systems and services market<sup>1</sup>
- Exosomes are an ideal delivery technology for nucleic acid medicines (e.g. mRNA and gene-editing), exciting new medicines growing at CAGR of 33.3% (global US\$7.23 Bn in 2024)<sup>2</sup>
- Exopharm is concentrating its investment in exosome medicines and LEAP technology, whilst enabling blood product companies to commercialise bloodderived exosome products
- Patents for Exopharm's LEAP technology are making progress granted in Russia

27 July 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 30 June 2021.

#### Important data and test results to support partnering discussions

Exopharm is one of a handful of exosome technology companies in the world. The Company continues to build its 'tool box' of exosome-related technologies knowing that Pharma companies are bringing exosomes into their development programs.

Partnering to derive income from deals that allow Pharma companies to use our tools and intellectual property is a key focus of Exopharm and our team. Partnering is a process built upon (i) establishing relationships and confidence and (ii) having data to share that demonstrates the value of our technology.

We now have a list of data and test results that Partners want answers to – and our people are working in the laboratory to deliver these results to support our partnering discussions.

<sup>&</sup>lt;sup>1</sup> https://formulations.pharmaceuticalconferences.com

<sup>&</sup>lt;sup>2</sup> www.globenewswire.com/news-release/2020/10/20/2110809/0/en/Global-7-23-Bn-Nucleic-Acid-Therapeutics-Oligonucleotide-Markets-2020-2024-Insights-Forecast-with-Potential-Impact-of-COVID-19.html

Recently, some of this data about Exopharm's LEAP purification technology was included in the June edition of industry publication BioProcess International – showing the power and importance of the LEAP technology and our manufacturing knowhow.

In our Laboratory, we have many activities underway and are producing results potential partners want to see. Examples include:

- LEAP Exopharm's exosome isolation technology continues to be a leader in the industry, with no apparent comparable technology for delivering clinical-grade exosomes economically at scale. The first LEAP patent was granted in June 2021 (Russia), and it continues to progress through the national phases in eleven other jurisdictions. In addition to its core role in the manufacture of Exopharm's pipeline of exosome products, LEAP is also of significant interest to potential partners; discussions with companies in the bioprocessing industry are underway, with a Heads of Agreement with the Finnish Red Cross Blood Service providing an early outcome from this engagement in Q3 of the financial year.
- LOAD The success of the RNA vaccines developed for SARS-CoV-2 has
  demonstrated that nucleic acid medicines offer a promising avenue for preventing
  and treating disease. With its LOAD technology, Exopharm is creating novel and
  powerful medicines for a range of diseases using exosome nanoparticles loaded up
  with nucleic acid cargo. The Company holds an exclusive licence for LOAD, with the
  patent progressing through national phases in six jurisdictions.
- EVPS Exopharm holds an exclusive licence for the EVPS technology, which can turn
  exosomes into targeted drug delivery vehicles, with the patent granted in the United
  States. Exosomes made with EVPS can be directed to specified cell types and deliver
  the cargo into cells of a certain type (e.g. neurons). Targeted delivery is important for
  nucleic acid medicines.

Together, LOAD and EVPS enable exosomes to become powerful delivery vehicles for a wide range of medicines.

As one of only a handful of companies with the capabilities to modify exosomes, Exopharm is well placed to make these types of deals.

These technologies are attracting interest from Pharma companies seeking to use exosomes to successfully deliver their drug candidates.

Over the past quarter further progress has been made with our extra technologies – Exoria, Fortrexo and Formulation H.

Exoria – Exoria is a novel dye developed by Exopharm that stains otherwise 'invisible'
extracellular vesicles (EVs) to enable improved EV tracking in both lab experiments
and animal studies. Exopharm lodged a provisional patent application for Exoria in
December of 2020 and the product could provide Exopharm with an early source of
revenue.

• Fortrexo – Fortrexo CoV is Exopharm's exosome therapeutic being developed to treat infection with SARS-CoV-2. Good progress has been made in early preclinical work with the product, and it is progressing towards animal studies later in CY2021.

The Fortrexo design serves as a proof-of-concept for Exopharm's exosome modification technologies and provides data for partnering discussions. The Company filed a provisional patent for the Fortrexo invention in May 2021.

 Formulation H – Exopharm's scientists have developed an advanced formulation to maintain the stability and activity of exosome medicines during storage. The Company has filed a provisional patent for Formulation H. Our formulation technology can be used to generate revenue and support our own exosome medicine products.

Earlier in the year we shifted from using adult stem cells as the source of exosomes to using HEK293 cells. HEK293 cells are widely used within the biomanufacturing industry and a familiar and safe cell type known to Regulators (such as the FDA and EMA). Exopharm now has a full commercial license to use HEK293 cells.

#### **Exosomes and nucleic acid medicines**

Products made using Exopharm's exosomes are called exosome medicines.

Exopharm's exosome medicines are well suited to delivering nucleic acid medicines – using our LOAD technology to load nucleic acids into the exosomes and using EVPS to target the exosomes and their nucleic acid cargo into the cells where they will do the most good and least harm.

The global nucleic acid therapeutics market is expected to record a value of US\$7.23 billion in 2024, increasing at a CAGR of 33.3%, for the duration spanning 2020-2024.<sup>3</sup>

Over the past 18 months, we have seen biotechnology harness versions of these nucleic acid medicines to deliver new and remarkable messenger ribonucleic acid (mRNA) vaccines against SARS-CoV-2 at unprecedented speed and scale.

Exopharm believes that other nucleic acid medicinal products can be brought forward with the same speed and success as the combination of artificial lipid nanoparticles and mRNA have been for SARS-CoV-2 vaccines.

- Exosomes are another sort of nanoparticle, similar to but superior in specific ways to lipid nanoparticles.
- The medicines contained within the exosomes can be any nucleic acids including mRNA, DNA, micro RNA (miRNA) and other active cargos.

<sup>&</sup>lt;sup>3</sup> www.globenewswire.com/news-release/2020/10/20/2110809/0/en/Global-7-23-Bn-Nucleic-Acid-Therapeutics-Oligonucleotide-Markets-2020-2024-Insights-Forecast-with-Potential-Impact-of-COVID-19.html

The combination of exosomes as the delivery vehicle and nucleic acids as the medical cargo can be designed in hundreds of variations to treat many medical problems including cancer, neurological diseases, infectious diseases and rare inherited medical conditions.

#### Exosomes:

- are natural and well accepted by the body;
- can deliver the cargo into the cell and even into the nucleus of the cell with high efficiency;
- can be loaded with a variety of cargos;
- can be targeted to certain cell types to improve the safety and efficacy of the treatment; and
- can replace the use of viral vectors and lipid nanoparticles.

Despite these advantages, it has not been possible to purify exosomes in large scale and as a cost-effective drug delivery ingredient. Invented in 2016, the LEAP technology owned by Exopharm has solved this manufacturing bottleneck. With LEAP purification technology, Exopharm is a leader in exosome medicines.

The combination of our three technologies (LEAP, LOAD and EVPS) enables Exopharm's exosomes to be powerful delivery vehicles for a wide range of nucleic acid medicines for rare diseases, gene therapies and antivirals.

Exopharm's Fortrexo antiviral product is an example product – using LEAP, LOAD and EVPS to deliver siRNA into cells infected by the SARS-CoV-2 virus.

#### **Investment focus**

Exopharm is investing 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.

#### 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.

#### Revenue streams identified - partnering discussions progressing

We see that near-term revenue will start to come from two streams:

- **Licensing**: multiple non-exclusive deals from out-licensing our LEAP technology (and Exoria and Formulation H technology) to allow others to make and use exosomes themselves; and
- **Partnering**: multiple deals allowing our partners to use our exosome medicines (incorporating LOAD and EVPS) to make transformative exosome therapeutic products e.g. gene therapies, mRNA medicines.

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.

#### **Patent for LEAP granted**

In June 2021, Exopharm was granted its first patent for its LEAP technology by the Russian Patent Office with an expiry date of 22 December 2037.

The patent underpins a core Exopharm technology, with the grant designation providing a constructive signal to the prosecution of the related patent family in the other eleven jurisdictions where the patent applications are progressing through national phases. This includes the United States wherein a successful Fast Track application has been approved by the US Patent and Trademark Office.

#### Corporate activities - progress, peers and partnering

Over the past quarter Exopharm has continued to increase its discussions with potential partners and building visibility in the biopharmaceutical industry.

#### **Appendix 4C commentary**

Exopharm ended the quarter with cash of \$12.7 million (\$5.1 million at 31 March 2021). Quarterly operating cash outflows for the period was \$2.9 million (\$2.9 million in the prior quarter).

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

Exopharm also undertook a successful \$12 million capital raise, which was well supported by institutions, as well as new and existing sophisticated and professional investors.

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: \$120,600 (including superannuation)
- Total consulting fees for company secretarial services paid to related parties: \$28,600 (Automic Pty Ltd)
- Total payments to related parties and their associates included in items 6.1: \$149,200

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

### Company and Media Enquiries:

Join our mailing list to receive updates:

http://exo.ph/ExoMails www.exopharm.com

P: +61 (0)3 9111 0026

Rudi Michelson Monsoon Communications Tel: +61 (0)3 9620 3333

#### **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	Quarter ended ("current quarter")
78 163 765 991	30 June 2021

Consolidated statement of cash flows		solidated statement of cash flows \$A'000	
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(736)	(2,983)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(94)	(386)
	(d) leased assets	-	-
	(e) staff costs	(1,369)	(4,712)
	(f) administration and corporate costs	(704)	(2,528)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	6
1.5	Interest and other costs of finance paid	(18)	(45)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	61	2,383
1.8	Other (provide details if material)	84	284
1.9	Net cash from / (used in) operating activities	(2,775)	(7,981)

2.	Cas	sh flows from investing activities		
2.1	Payments to acquire:			
	(a)	entities	-	-
	(b)	businesses	-	-
	(c)	property, plant and equipment	(544)	(1,627)
	(d)	investments	-	-
	(e)	intellectual property	-	-
	(f)	other non-current assets	-	-

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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	(544)	(1,627)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,000	22,000
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	(720)	(842)
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)	(154)	(394)
	Other (bank guarantee)	(176)	(176)
3.10	Net cash from / (used in) financing activities	10,950	20,588

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,091	1,743
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,775)	(7,981)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(544)	(1,627)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10,950	20,588
4.5	Effect of movement in exchange rates on cash held	1	-
4.6	Cash and cash equivalents at end of period	12,723	12,723

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	8,023	5,091
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (term desposit)	4,700	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	12,723	5,091

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	149
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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 and company secretarial fees.

7.	Note: to arrange Add no	ncing facilities  the term "facility' includes all forms of financing tements available to the entity.  The same recessary for an understanding of the same recessary for the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000	
7.1	Loan	facilities	-	-	
7.2	Credi	t standby arrangements	-	-	
7.3	Other	(please specify)	-	-	
7.4	Total	financing facilities	-	-	
7.5	Unus	ed financing facilities available at qu	arter end	-	
7.6	rate, r faciliti	de in the box below a description of eacl maturity date and whether it is secured of es have been entered into or are propo de a note providing details of those facili	or unsecured. If any addi sed to be entered into af	tional financing	
8.	Estin	nated cash available for future op	erating activities	\$A'000	
8.1	Net c	Net cash from / (used in) operating activities (Item 1.9)		(2,775)	
8.2	Cash	ash and cash equivalents at quarter end (Item 4.6)		12,723	
8.3	Unus	ed finance facilities available at quarter	end (Item 7.5)	-	
8.4	Total	,		12,723	
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)  4.6				
8.6	If Iten	n 8.5 is less than 2 quarters, please pro	vide answers to the follow	wing questions:	
	1.	Does the entity expect that it will contast flows for the time being and, if r		level of net operating	
	Answ	Answer:			
	2.	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?			
	Answ	Answer:			
	3.	Does the entity expect to be able to objectives and, if so, on what basis?	continue its operations ar	nd to meet its business	
	Answ	er:			

#### **Compliance statement**

- 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:	27 July 2021
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.
- 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".
- 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.