

ASX ANNOUNCEMENT

March 2020 Appendix 4C and Quarterly Report

HIGHLIGHTS

- Exopharm is now a clinical stage company and the first company in the world to test a proprietary exosome product in human clinical trials for regenerative medicine, with first dosing of Plexaris™ occurring in Exopharm's PLEXOVAL Study during the quarter
- Planning for the first-in-human allogeneic Plexaris safety study – is progressing, however the PLEXOVAL I study has been affected by the COVID-19 situation
- BioMAP external testing validates possible safety and mechanism of action
- Independent testing by PELVIPHARM shows potency of Cevaris in models of erectile dysfunction and provides a basis for further testing and future potential clinical trials in post-operative erectile dysfunction
- Positive PELVIPHARM testing provides a basis for further testing and future potential clinical trials in urinary bladder control
- Exopharm consolidates main laboratory and manufacturing facility at the Baker Institute in Melbourne

24 April 2020

Melbourne, Australia: Regenerative medicine company Exopharm Limited (ASX:EX1) today releases its Appendix 4C and Quarterly Report for the quarter ended 31 March 2020.

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.

Exopharm has recently refined its strategy and focus, as detailed in the updated investor presentation during the quarter. The aim is to maximise shareholder value over the long term and capitalise upon the power of the LEAP purification technology owned by Exopharm.

The LEAP technology triggered a burst of innovation in exosome manufacture that has in turn propelled Exopharm to the front-runner position in clinical trials and the potential use of exosomes in many clinical applications. But exosomes have so many potential applications and Exopharm is a new company with limited resources.

To focus our attention and use of capital, Exopharm has decided on a clear development and partnership strategy :-

Core programs [partnering after Phase II human trials] –fund our own clinical trials through to the end of Phase IIb only in mobility and sensory deficit areas (e.g. treatments for osteoarthritis, tendinopathy, bone repair, muscle, dry age-related macular degeneration, hearing and erectile dysfunction)

Non-core programs [partnering early with non-clinical in vitro or in vivo data] – fund early proof of concept tests in areas outside of mobility and sensory (e.g. cardiac repair, neurodegeneration, autoimmune disease, transplant rejection, cancer and autosomal dominant conditions)

‘Engineered exosomes’ are also part of our non-core programs and are intended to be spun out or partnered early.

PLEXOVAL Study

The PLEXOVAL study achieved a major milestone of first dosing during the quarter. The PLEXOVAL Phase I study uses 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. First dosing is a key milestone for Exopharm as a clinical stage company developing exosome-based medicines.

The timing of the PLEXOVAL I wound healing study has not been met, with progress affected by COVID-19 factors. These factors are outside of the control of Exopharm and its research partners.

At this stage it is not clear when or if the PLEXOVAL study will be completed. Exopharm now expects that the numbers of participants will be reduced, neither Cohorts 1 and 2 will fully recruit and the study report will be delayed. The Company continues to monitor the situation.

As previously announced, dosing of Cohort 2 in the PLEXOVAL I Study commenced first. Cohort 2 testing is planned to include histology of biopsied post treatment wound tissue for assessment of biological activity within the healed wound. Results from the limited Cohort 2 testing may be available in the coming months.

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

Allogeneic Plexaris study

Exopharm’s commercial objective is to develop off-the-shelf exosome medicines, so a Phase 1 allogeneic Plexaris safety study is the next major clinical step to demonstrate product safety and tolerability and an off-the-shelf logistics chain.

Exopharm is planning the first-in-human allogeneic (off-the-shelf) Plexaris safety study, with planning activities for this study progressing during the quarter.

Exopharm has secured a supply chain of blood platelets. A larger source of blood platelets has allowed us to scale up manufacturing operations and build the capacity of the LEAP process.

BioMAP testing

During the quarter, BioMAP testing of two Exopharm exosome products has explored safety and mechanism of action (MOA). The testing found that the two products have different and distinct activities compared to 4,500 other drugs and between the products.

Exopharm submitted its exosome products for testing under the BioMAP testing program operated by Eurofins, a European-based group of laboratories.

The headline results of the BioMAP® Diversity Plus® screen testing are:

Exopharm’s Plexaris product (exosomes from platelets) was compared with 4,500 experimental and sold medicines across a panel of 12 human primary cell-based systems. Plexaris was found to be nontoxic (by comparison and absolute measures) and had notable biological activity in (i) tissue remodeling (ii) immunomodulatory and (iii) inflammatory-related activities.

Exopharm's Cevaris product (exosomes from adult stem cells) was compared with 4,500 experimental and sold medicines across a panel of 12 human primary cell-based systems. Cevaris was found to be nontoxic (by comparison and absolute measures) and had notable biological activity in (i) tissue remodeling, (ii) inflammatory and (iii) immune-modulatory-related activities.

Plevipharm tests for bladder control dysfunction

During the quarter testing of Cevaris has shown that the exosome product could be a potential treatment for bladder control dysfunction, which affects more than five million Australians.

Exopharm outsourced the testing of Cevaris and Xevaris to independent French group, PELVIPHARM. The testing in ex vivo models of bladder control demonstrated that treatment with Cevaris could improve bladder control by improving contractile performance and strength.

This provides a basis for further non-clinical testing of Exopharm's products in bladder control. After that, human clinical trials involving patients with bladder control problems would be the next step.

Bladder control dysfunction, also known as urinary incontinence, affects both males and females and involves leaking urine or urgent urges to urinate. Urinary incontinence (UI) affects around 37% of Australian women and around 13% of Australian men. The incidence increases with age. Urinary and faecal incontinence are reported to affect more than 50% of nursing home residents.

Cevaris treatment increased the contractile effect of carbachol on bladder strips compared to control substance (Vehicle i.e. phosphate-buffer saline (PBS)) with high statistical significance ($p < 0.001$). Carbachol is a non-selective muscarinic agonist that mediates the parasympathetic nervous system controlling bladder contractions. This means that treatment with Cevaris could enhance bladder control by improving contractile performance. See figure 1 below.

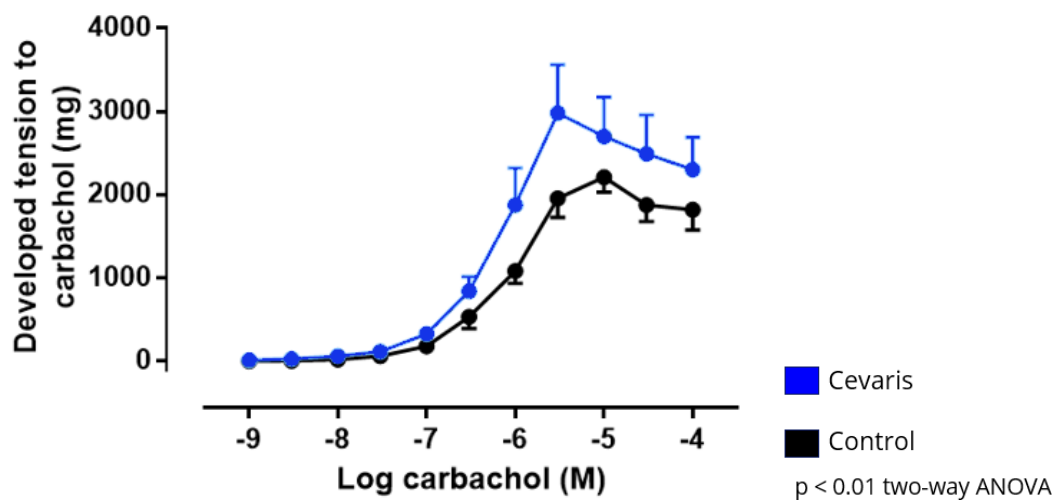


Figure 1: Contractile effect of carpabachol on bladder strips

Note: Data in BLUE is for treatment with Cevaris exosomes and BLACK for control samples.

In a second functional test Cevaris increased the strength of electrical field stimulation (EFS) induced contraction on bladder strips compared to control substance as a trend ($p < 0.066$). This means that treatment with Cevaris could improve bladder control by improving contractile strength.

Conclusion: Cevaris product (exosomes from adult stem cells) warrants further investigation as a new treatment for bladder control. Cevaris increased the contractile effect in both models, one significantly and one as a trend. Therefore, Cevaris could be considered for the potential treatment of underactive bladder. Underactive bladder is associated with diabetes, ageing, or injury to spinal cord.

Plevipharm tests for erectile dysfunction (ED)

Independent testing of Exopharm's exosome Cevaris product in ex vivo models of erectile dysfunction (ED) has demonstrated that a Cevaris treatment provided statistically significant improvement in muscle contraction and release.

ED is common among middle-aged and older men, and increases in prevalence with age. The condition affects a majority of men over 50, and current treatments provide considerable benefit to many. However, ED can also be the result of prostatectomy and rectal surgery, where localised tissue damage can prevent any benefit from existing treatments.

Unlike current treatments, Cevaris enhanced the nitrenergic relaxations of isolated corpus cavernosum strips compared to control substance with high statistical significance ($p < 0.01$). The cavernous smooth musculature is contracted when in the flaccid (non-erect) state, and smooth muscle relaxation is essential for an erectile response. This means Cevaris could restore erectile function. See figure 2. below.

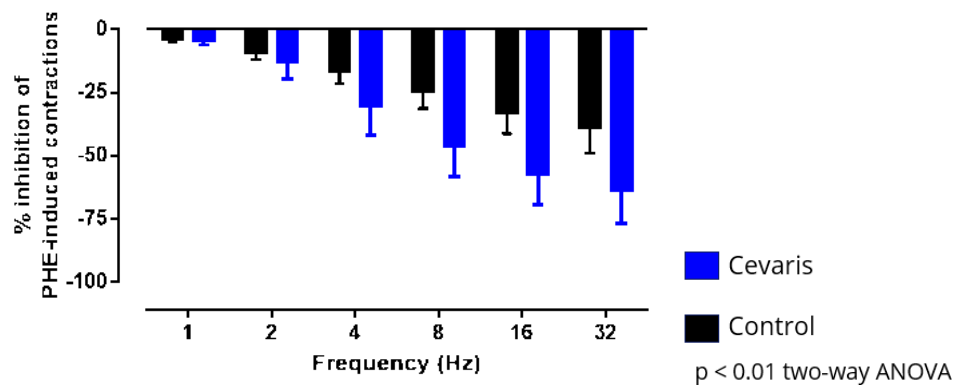


Figure 2. Enhancement of nitrenergic relaxations of isolated corpus cavernosum strips.

Note: The test result is BLUE for treatment with Cevaris exosomes and BLACK is the control.

This testing provides a basis for further non-clinical testing of Exopharm's products in erectile dysfunction. After that, human clinical trials involving patients with this problem are the next step.

Other Non-clinical testing in 2020

Two ocular animal studies are underway and are expected to be reported in coming months. These studies fit with our interest in sensory disability and the treatment of dry age-related macular degeneration (AMD). Testing has the primary purpose of generating data to support approvals for planned clinical programs across our core indications.

Other non-core non-clinical studies have been planned and scheduled, but recent events have led to postponement of the start times.

Other in vitro testing and development work is being progressed by the team and will be conducted subject to further workplace restrictions due to COVID-19 requirements.

Work on engineered exosomes continues.

Baker Institute facilities

Exopharm has consolidated its main laboratory and manufacturing facilities under one roof at the Baker Institute in Commercial Road Melbourne. Having employees centralised at a main laboratory will enable more efficient development activities.

Appendix 4C Commentary

The Company completed the quarter with \$4.264m 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 received 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, for circa \$500,000. Work has commenced on the FY 2019/20 grant which is expected to be lodged shortly after the end of the financial year.

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

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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 MARCH 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(545)	(2,083)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(59)	(105)
(d) leased assets	(31)	(89)
(e) staff costs	(771)	(2,014)
(f) administration and corporate costs	(441)	(1,098)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	17	57
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	505	505
1.8 Other (GST received)	149	212
1.9 Net cash from / (used in) operating activities	(1,176)	(4,615)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(112)	(402)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(278)	(278)

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)	-	-
2.6	Net cash from / (used in) investing activities	(390)	(680)

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	-	(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 (repayment of lease liability)	(69)	(69)
3.10	Net cash from / (used in) financing activities	(69)	5,122

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,881	4,419
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,176)	(4,615)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(390)	(680)

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)	(69)	5,122
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	4,246	4,246

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	1,746	865
5.2	Call deposits	2,500	5,016
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)	4,246	5,881

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
174
-

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.

	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)	(1,185)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,246
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	4,246
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	3.58x

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 This statement gives a true and fair view of the matters disclosed.

Date: 24 April 2020

Authorised by: The Board of Exopharm Ltd
(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.