ASX Announcement

CORPORATE DIRECTORY

Chairman
MR JASON WATSON

Founder, Managing Director
DR IAN DIXON

Non-Executive Director
and Company Secretary
MR DAVID PARKER

CORPORATE INFORMATION

Issued Capital: 80.5m FPO

Share Price: $0.415

Market Cap: $33.4m

CONTACT DETAILS

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ASX CODE: EX1
ACN: 163 765 991

EXTENDING HEALTH SPAN THROUGH CELL FREE REGENERATIVE MEDICINE

30 APRIL 2019

March 2019 Quarterly Activities Report and Appendix 4C

- **Positive outcomes in first animal study involving Plexaris and Exomeres**
    - **Manufacturing of both Plexaris and Exomeres in house using the LEAP Technology was achieved and the exosome products demonstrated safety with no adverse events; and**
    - **Wound tissue tensile strength showed signs of a positive dose-response with Plexaris treatment, being the explorative primary efficacy outcome of the study.**
- **Progression in preparations for first in human use of autologous Plexaris in wound healing.**
    - **Advancements in manufacturing of Plexaris, including that the Exopharm product manufacturing facility is now operational in Melbourne for future manufacture of autologous Plexaris (platelet derived) product for our 'PLEXOVAL' study; and**
    - **Documentation seeking approval to run the PLEXOVAL study has been completed.**
- **Recent publications (including Liu et al 2019 from Johns Hopkins University) highlight the potential benefits of exosomes - with new data showing that stem cell derived exosomes (also known as extracellular vesicles or EVs) can reverse cellular aging (senescence) in vitro (i.e. in cells tested in a laboratory)**
- **Exopharm expanded its manufacturing and analytics team together with the purchase of specialised equipment**
- **Exopharm released the LEAP Explainer intended to detail the critical bottleneck of exosome isolation and the power of Exopharm's LEAP technology**

Positive outcomes in first animal study involving Plexaris and Exomeres

During the quarter the Company reported on its early-stage proof of concept (POC) animal study that investigated the safety, efficacy and biochemistry of treating rodents with either Plexaris or Exomeres in a model of wound healing.

The main purpose of this study was to test manufacturing using Exopharm's LEAP Technology and test the exosome products for safety and possible adverse events.

The key outcomes from this study are positive - i.e. manufacturing using LEAP Technology was achieved and the exosome products demonstrated safety with no adverse events.

This study was conducted for Exopharm by a Contract Research Organisation (CRO) as a paid study under Animal Ethics Committee oversight and in conformance with the Australian Code for the care and use of animals for scientific purposes. Plexaris and Exomeres were manufactured by Exopharm's manufacturing group in-house and were tested for sterility by an external party before release.

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Positive outcomes in first animal study involving Plexaris and Exomeres (continued)

The pre-clinical study reports the first time that our Plexaris and Exomere products have been made in sufficient quantity and quality (including sterility) for animal testing. Making these materials has demonstrated the LEAP Technology and the upstream and downstream process equipment and protocols used by the Exopharm team to make the Plexaris and Exomeres products.

This study has allowed us to look at the potential similarities and differences between the Plexaris (from platelets) and Exomeres (from adult stem cells). In the future Exopharm intends to consider which medical problems better suit Plexaris and which medical problems better suit treatment with Exomeres.

The report also highlights the safety and tolerability of the Plexaris and Exomeres products at all three concentrations tested – albeit that the total number of animals treated was only 18 in this study.

Further information about the study is available in the ASX release dated 5th February 2019.

Manufacturing and Clinical Programs

Exopharm is undertaking a Development Program with the ultimate aim to establish both Plexaris and Exomeres as leading regenerative medicines to treat health span related medical conditions.

The manufacturing and clinical activities within the Development Program includes:

- manufacturing clinical grade Plexaris and then later Exomeres suitable for Exopharm's planned non-clinical and clinical programs; and
- conduct non-clinical and clinical programs to potentially demonstrate safety and efficacy of Plexaris and then later Exomeres as treatments for human use.

PLEXOVAL study

The development of Exopharm's manufacturing capabilities progressed throughout the quarter.

Good progress has been made on the downstream process (DSP) development for Plexaris product by the Exopharm Manufacturing team based in Melbourne.

The Exopharm Manufacturing Team has been expanded with extra staff and new manufacturing equipment to support manufacture of product for clinical trials and other experimentation.

Exosomes require sophisticated analytical approaches and the Exopharm Analytics Team is addressing this challenge with extra expert staff and new analytic instruments.

Together, the Exopharm Manufacturing Team and the Exopharm Analytics Team have provided extensive information for inclusion in the PLEXOVAL study proposal.

PLEXOVAL stands for **P**rospective open-**L**abel, single dose proof of concept study to Evaluate the safety, tolerability and biological activity of Platelet-derived **EX**tracellular Vesicles, on the augmentation of w**O**und healing rate and effect on scar formation following skin punch biopsy in healthy **V**olunteer **A**du**L**ts.

Exopharm is sponsoring the PLEXOVAL study which is being managed by a Contract Research Organisation (CRO) on behalf of Exopharm and will be run in Melbourne. Subject to approvals, the study is expected to involve up to 20 participants – up to 15 in cohort 1 and up to 5 in cohort 2.

PLEXOVAL is a First-in-Human (FIH) study primarily looking at the safety of Plexaris but also looking at the secondary exploratory signs of autologous PLEXARIS (exosomes from platelets) treatment on wound healing and scar formation.

Autologous Plexaris will be sourced from platelets collected from the participant at an apheresis unit in Melbourne. Platelets from the donor will be processed at Exopharm's manufacturing facility in Melbourne. Participants will have autologous Plexaris administered by injection at a Melbourne public hospital under Human Research Ethics (HREC) approvals and oversight by a Principal Investigator.

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Manufacturing and Clinical Programs (continued)

The PLEXOVAL study is scheduled to commence by around mid CY '19 with 2 cohorts to be recruited into the study. Cohort 1 participants will be monitored after recruitment and before treatment and out to around 42 days from the treatment date. The results of the study are anticipated to be provided to Exopharm as a formal Report after a period of assessment, analysis and checking.

At this stage it is not possible to estimate when the PLEXOVAL Report will be received by the Company, although it is not expected until CY '20. At this stage it is not possible to estimate when (or if) approvals will be granted to commence the PLEXOVAL study, however documentation seeking approval to run the PLEXOVAL study has been completed and is currently being assessed.

Other clinical and non-clinical studies

Exopharm also has plans for further human clinical studies in two other medical indications – dry age-related macular degeneration (dry-AMD) and osteoarthritis (OA) and is also investigating other non-clinical studies to support the planned clinical studies and ongoing internal research and development activities.

Recent expert publications highlight Exopharm's potential

During the quarter the Company highlighted to the market recent expert publications.

The paper from exosome experts at Johns Hopkins University highlights two important points:-

- "the delivery of human iPSC-EVs attenuated cell aging and promoted cell proliferation, suggesting that highly purified EVs from human iPSCs may represent a cell-free approach for treating aging"; and
- "a major bottleneck of MSC derived EV (MSC-EV)-based applications in clinics is the inefficient production and purification of clinical-grade EVs"

Note. iPSC is induced pluripotent stem cell, MSC is mesenchymal stem cell, EV is extracellular vesicle (another name for exosomes).

The first of these quotes highlights how stem cell derived exosomes have been shown to reverse cell senescence and the potential for stem cell derived exosomes to treat aging or age related conditions.

The second quote highlights the problem (the 'purification bottleneck') that Exopharm's LEAP Technology addresses. The purification bottleneck issue (that still exists in 2019 aside from Exopharm's LEAP Technology) is holding back the treating of humans with stem cell derived exosomes.

Exopharm sees LEAP as the key to solving the bottleneck problem that is delaying the production and purification of clinical-grade exosomes/EVs. The LEAP Technology is referred to as a 'platform technology' – because the one technology can be used to make a range of products. Platform technologies can be especially important and valuable once a few example products have derisked the performance and safety of the platform technology itself.

Additional non-core Research and Development Activities

The Company has also initiated additional research and development activities that utilise the LEAP Technology and which are outside the core Plexaris and Exomere product development programs.

These additional Research and Development activities are in line with the allocation of funding disclosed in the Prospectus and have the intention of adding to the development program in due course. Initial activities consist of early stage research and development activities, further information will be available in due course if and when these activities get to an advanced stage.

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Corporate

As at 31 March 2019, cash at bank was $5.144 million.

The Company has 80,500,000 fully paid ordinary shares on issue (no other securities on issue) and a current market capitalisation of $33.4 million at $0.415.

Please refer to the Appendix 4C quarterly cash flow report for the period ended 31 March 2019 for more information.

During April, the Chief Operating Officer, Gregor Lichtfuss, had an annual review of his employment and was subsequently awarded an increase of his salary by $11,000 to $155,000 per annum (including Statutory Super).

ENDS.

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ABOUT EXOPHARM

Exopharm Limited ("Exopharm" or the "Company") (ASX:EX1) is an Australian regenerative medicine biopharmaceutical company seeking to develop and commercialise exosomes as therapeutic agents – initially a product called Plexaris™ and later as a product called Exomeres™.

These products are exosomes that are derived from human platelets in relation to Plexaris, and adult stem cells in relation to Exomeres, and purified using the LEAP Technology and referred to as biologic products.

As its primary focus, Exopharm aims to be a leader in the field of clinical human therapeutics using exosomes as regenerative medicine products for heath span related conditions.

The Initial Development Program: The Company's main objectives for the next 12 months are to complete the following stages of its Development Program using the funds raised from the Prospectus Offer:

1. manufacturing - make and supply clinical grade autologous Plexaris product and development of the Exomere manufacturing process;
2. clinical use - completing animal studies, pre-clinical testing and initial small-scale human clinical studies of autologous Plexaris in wound healing;
3. supporting research and development activities - conducting research activities to support the ongoing Development Program and the development of related intellectual property; and
4. to also investigate other LEAP Technology Opportunities.

Exopharm Limited is listed on the Australian Securities Exchange (ASX:EX1).

For more information please visit: https://exopharm.com/ or contact Dr Ian Dixon on (03) 9111 0026 or via email, info@exopharm.com.

FORWARD LOOKING STATEMENTS

Exopharm Limited ("Exopharm" or the "Company This announcement contain 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.

+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

EXOPHARM LIMITED

ABN	**Quarter ended ("current quarter")**
78 163 765 991	31 MARCH 2019

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*	(124)	(330)
	(b) product manufacturing and operating costs	-	-
	(c) inventory	-	-
	(d) advertising and marketing	(10)	(43)
	(e) leased assets	-	-
	(f) staff costs	(201)	(514)
	(g) administration and corporate costs	(167)	(608)
1.3	Dividends received	-	-
1.4	Interest received	1	2
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (GST Payment)	-	-
1.9	**Net cash used in operating activities**	**(501)**	**(1,493)**

*1.2(a) Research and Development is not inclusive of allocation for staff, administration and corporate costs.

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(394)	(487)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
	(d) intellectual property	-	(325)
	(e) rental equipment	-	-
	(f) product development & patents	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash used in investing activities**	**(394)**	**(812)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares & options	-	8,200
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	(803)
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 (Monies for shares to be allotted)	-	-
3.10	**Net cash (used in)/from financing activities**	**-**	**7,397**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	6,039	52
4.2	Net cash from used in operating activities (item 1.9 above)	(501)	(1,493)
4.3	Net cash used in investing activities (item 2.6 above)	(394)	(812)
4.4	Net cash (used in)/from financing activities (item 3.10 above)	-	7,397

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**5,144**	**5,144**

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	1,144	6,039
5.2	Call deposits	4,000	-
5.3	Bank overdrafts	-	-
5.4	Other (monies for shares to be allotted)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**5,144**	**6,039**

6.	Payments to directors of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	123
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

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 and reimbursements paid.

7.	Payments to related entities of the entity and their associates	Current quarter $A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (na)	-	-

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

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	(500)
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	(15)
9.4	Leased assets	-
9.5	Staff costs [Note A]	(400)
9.6	Administration and corporate costs	(200)
9.7	Other (R&D equipment purchases)	(200)
9.8	**Total estimated cash outflows**	**(1,315)**

Note A: Includes research and development staff costs.

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.

Sign here:  Date: 30 April 2019

(Director and Company Secretary)

Print name: David R Parker

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.