

# ASX Announcement

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## CORPORATE DIRECTORY

Chairman  
MR JASON WATSON

Founder, Managing Director  
DR IAN DIXON

Non-Executive Director  
and Company Secretary  
MR DAVID PARKER

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## CORPORATE INFORMATION

Issued Capital: 80.5m FPO  
Share Price: \$0.52  
Market Cap: \$41.86m

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## CONTACT DETAILS

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**ASX CODE: EX1**  
**ACN: 163 765 991**

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**EXTENDING HEALTH SPAN  
THROUGH CELL FREE  
REGENERATIVE MEDICINE**

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31 JANUARY 2019

## December 2018 Quarterly Activities Report

- **Exopharm raised \$7m through a fully subscribed Initial Public Offering (IPO) and listed on the ASX.**
- **Exopharm aims to be a leader in the field of clinical human therapeutics using exosomes as regenerative medicine products to treat health span related conditions.**
- **Funding from the IPO is being used to fund a Development Program and accordingly the development and commercialisation of the LEAP technology, Plexaris and Exomere products.**
- **The Company has initiated the Development Program with testing of Plexaris and Exomere product in animal models of wound healing underway at a contract research organisation (CRO).**

### ASX Initial Public Offering

Exopharm Limited ('Exopharm' or the 'Company') successfully listed on the Australian Securities Exchange (ASX) in December via an Initial Public Offer, raising \$7,000,000 through the issue of 35,000,000 shares at \$0.20. The Company was admitted to the Official List of the ASX on 14 December 2018 and trading commenced on Tuesday, 18 December 2018 at 1:30 EST.

### Primary Focus

As its primary focus, Exopharm aims to be a leader in the field of clinical human therapeutics using exosomes as regenerative medicine products. Exopharm 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. Exopharm's Development Program has the ultimate aim to establish both Plexaris and Exomeres as leading regenerative medicines to treat health span related medical conditions.

### The Development Program

The Company has a well-defined Development Program which is detailed in the IPO Prospectus. The Company's initial focus in CY 2019 is to complete the following stages of its Development Program:

1. manufacturing - make and supply clinical grade autologous Plexaris product and development of the Exomere manufacturing process;
2. clinical use - completing animal studies, non-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.

Further information is included in the manufacturing and clinical programs update.

# ASX Announcement

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## Manufacturing and Clinical Programs – Quarterly Update

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.

The development of Exopharm's manufacturing capabilities progressed throughout the quarter and has further advanced since the ASX listing in December.

The manufacture of sterile Plexaris and Exomere product supports Exopharm's activities in non-clinical (animal) studies and the planned clinical programs scheduled to start mid CY 2019.

The present experimental (i.e. not approved for sale) products have been manufactured using the LEAP Technology from both human platelets (Plexaris) and an experimental human adult stem cell line (Exomeres).

In parallel, analytical capability has been built up and biochemical test assays have been developed and underwent preliminary qualifications.

Exopharm took the strategic decision in 2018 to undertake its biologics manufacturing and analytics programs in-house – and has built a small team of experts around this activity. Exopharm has also contracted to have access to an existing biologics manufacturing facility and plans to use that facility to manufacture clinical-grade Plexaris and Exomeres products.

An important milestone was achieved in the December Quarter 2018 in collaboration with an animal testing Contract Research Organisation (CRO). Under this CRO program, animals were dosed for the first time with prototype Plexaris and Exomere drug products in a preliminary tolerability study focusing on safety and efficacy. Progress in both manufacturing and analytics enabled Exopharm to formulate first batches of experimental drug substances as a sterile drug product that was released for these initial animal studies.

The Company anticipates results from the initial non-clinical animal study to be released in February 2019.

Exopharm's manufacturing and analytical development work leading up to the initial non-clinical study is forming Exopharm's research and development priorities for 2019 and driving the company's development program for 2019 and beyond.

The present experience with the LEAP Technology indicates that exosome-based biologic products should be capable of being manufactured as sterile clinical grade materials that can be characterized and released as a biologic product for human use.

The type of manufacturing equipment presently being used has the potential to scale up to support further and expanded clinical trials. Off-the-shelf components of the downstream process (DSP) can be purchased in sizes that are suited to commercial scale and cost-effective production of a biologic product.

The Company plans to reach a refined manufacturing and analytics development stage and transfer of its in-house manufacturing operations into a certified clinical manufacturing facility in the first half of CY 2019.

Overall, this work supports the plan to release the first clinical grade Plexaris drug product to a study site managing Exopharm's first-in-human small-scale clinical study of autologous Plexaris product for wound healing. This is currently planned for commencement in mid CY 2019.

Exopharm also has plans for further human clinical studies in two other medical indications – dry age-related macular degeneration (dry-AMD) and osteoarthritis (OA).

# ASX Announcement

## Corporate

As at 31 December 2018, cash at bank was 6.04 million.

Exopharm Limited raised \$7,000,000 (less costs) through the issue of 35,000,000 shares at \$0.20 in December 2018.

The Company has 80,500,000 fully paid ordinary shares on issue (no other securities on issue) and a current market capitalisation of \$41.86 million at \$0.52.

Please refer to the Appendix 4C quarterly cash flow report for the period ended 31 December 2018 for more information.

## Question and Answer

The Company has received various queries from investors regarding exosomes and the regenerative medicine products, as such a brief Q&A is provided below for general information purposes.

*What is regenerative medicine?*

Regenerative medicine is a term used to cover different ways scientists can harness the body's own regenerative capabilities.

*What are some examples of regenerative medicines?*

A well-known example is blood. Blood (or blood plasma) from donors is used routinely in hospitals if the patient needs more blood urgently. Another example would be cell therapy, where cells are injected or infused into the patient to trigger regeneration or replace lost cells.

*What problems does regenerative medicine seek to solve?*

Examples would be osteoporosis (bone density reduction), sarcopenia (muscle loss), arthritis, neurodegeneration, diabetes, heart degeneration, macular degeneration, tendonitis (degeneration of tendons), autoimmune disease (e.g. multiple sclerosis). Many of these are age-related conditions.

*Why are there no exosome products on the market for regenerative medicine yet?*

Before a new drug can be sold (registered for sales), it needs to progress through clinical trials to demonstrate safety and efficacy. Running clinical trials through to registration typically requires treating hundreds (or even thousands) of patients. Whilst exosomes are naturally occurring and plentiful, the technology to harvest and purify exosomes as a proper biologic product has been missing until recently. Only when the "purification technology" problem is solved can sufficient exosomes be available to run proper clinical trials.

*What is the "purification technology" problem?*

Exosomes are invisible nano-sized natural lipid particles produced by stem cells and other cells in our bodies. Whilst exosomes are described as "cell juice", the limitation has been a proprietary commercial-scale purification process that produces a biologic product. The process needs to be proprietary (i.e. patentable) to protect the investment to run clinical trials and commercialise. The process needs to be commercial-scale, as bench-scale production is unsuited to treating millions of patients. The process needs to produce a biologic product – not some heterogeneous variable "soup" of molecules and contaminants.

*Why is Exopharm seen as an innovator in this field?*

Exopharm has acquired the LEAP Technology from Dr Ian Dixon. The LEAP Technology potentially solves the "purification technology" problem and is a proprietary purification process that produces a biologic product. Other companies and researchers are using purification technologies that are different from the LEAP Technology, and in many cases clearly inferior (e.g. ultracentrifuge or tangential flow filtration).

Having a developing solution to the "purification technology" problem, Exopharm is positioned to manufacture its exosome products (Plexaris and Exomeres) and run clinical trials to test safety and efficacy of these biologic products.

# ASX Announcement

## **Question and Answer Continued...**

*What is Plexaris?*

Plexaris is our trade mark name for the exosome product from blood platelets purified with our LEAP Technology.

*What is Exomeres?*

Exomere is our trade mark name for the exosome product from stem cells (not embryonic stem cells) purified with our LEAP Technology.

*How do Plexaris and Exomeres compare? Why have both?*

We expect that Plexaris may suit treating some conditions better than Exomeres, and may also be less expensive to produce. The strategy is to partner Plexaris and Exomeres separately, leaving room for two transactions instead of one.

*Why does Exopharm believe its products will be safe?*

Previous testing of platelet derived and adult stem cell derived exosomes/extracellular vesicles in animal studies have not demonstrated safety problems or toxicity to date. Exopharm is presently conducting testing of its own. There have also been some recent small-scale human studies involving adult stem cell derived exosomes/extracellular vesicles and no serious adverse events were recorded in publications.

*Why does Exopharm believe its products will work?*

Previous testing of platelet derived and adult stem cell derived exosomes/extracellular vesicles in animal studies have demonstrated signals of efficacy in a range of models. There have also been some recent small-scale human studies involving adult stem cell derived exosomes/extracellular vesicles and these studies have demonstrated signals of efficacy in a range of medical conditions including chronic kidney disease and graft versus host disease.

*Is there interest from bigger companies?*

Yes, some of the bigger companies are following the field and there has been some notable corporate transactions in the exosome field.

*Will Exopharm sell exosomes to others?*

Our present strategy is not to supply clinical grade exosome product(s) to potential competitors. However, there may be ways to support companies we see as outside of our own focus areas.

*What is the difference between autologous and allogeneic?*

Autologous means the donor and the recipient are the same person (i.e. matched). Allogeneic means the donor and the recipient are different people.

*What is a biologic product?*

Biologic products come from living things e.g. proteins from cells. A synthesised peptide is not a biologic. Exosomes are biologics because they are secreted by cells naturally.

## **Shareholder Correspondence**

Pursuant to ASX Listing Rule 3.17.1, please see Appendix A for a copy of correspondence that is being mailed to shareholders over the next week.

**ENDS.**

# ASX Announcement

## 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 health 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.

An investment in Exopharm includes several risks, not limited to Technology Risk; Clinical Trial risks; Future Capital Requirements; Access to stem cells, blood and blood platelets; Patents and trade secrets; Third party infringement; Reliance on key personnel; Partnership and service provider risks; Changes in legislation and government regulation; Liquidity and volatility; Competition; No profit to date and limited operating history; and the Emerging exosomes market, as described in the Prospectus dated 6 November 2018.

**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](mailto:info@exopharm.com).**

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## FORWARD LOOKING STATEMENTS

Exopharm Limited (“Exopharm” or the “Company”) 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.

# ASX Announcement

**APPENDIX A: SHAREHOLDER CORRESPONDANCE – COPY OF POSTCARD (FRONT AND BACK) BEING SENT TO SHAREHOLDERS**

