



## ASX ANNOUNCEMENT

### INVESTOR DECK – TO BE PRESENTED AT THE TWILIGHT INVESTOR BRIEFING

05 February 2020

**Melbourne, Australia:** Regenerative medicine company Exopharm Limited (ASX:EX1) advises that it will be presenting the attached Investor Deck to the Twilight Investor Briefing in Melbourne which is hosted by Monsoon Communications, Wednesday 5<sup>th</sup> February 4:30 EST.

The PLEXOVAL first dosing event marks an important milestone for the Company and paves the way for increased activity from clinical and non-clinical studies in 2020, as detailed in the Investor Deck.

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

#### ***Company and Media Enquiries***

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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.



# Introduction to Exopharm Ltd.

Refreshing Medicine, Today

February 2020

# IMPORTANT INFORMATION



- **Purpose of presentation:** This presentation (including this document, any related video or oral presentation, any question and answer session and any written or oral material discussed or distributed in relation to this presentation) has been prepared by Exopharm Limited (ACN 163 765 991) (**Exopharm** or **Company**). This presentation is intended for sophisticated or professional investors (as those terms are defined in the *Corporations Act 2001* (Cth)), and their professional investment advisors and has been prepared for the sole purpose of providing general high-level information on Exopharm and its operations.
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## Overview

- Exopharm is an Australian clinical stage biotechnology company with a rapidly-developing technology platform for turning exosomes into medicines
- 24 staff (currently) based in Melbourne, Victoria
- Publicly-traded on the ASX (ASX:EX1) (listed Dec 2018)

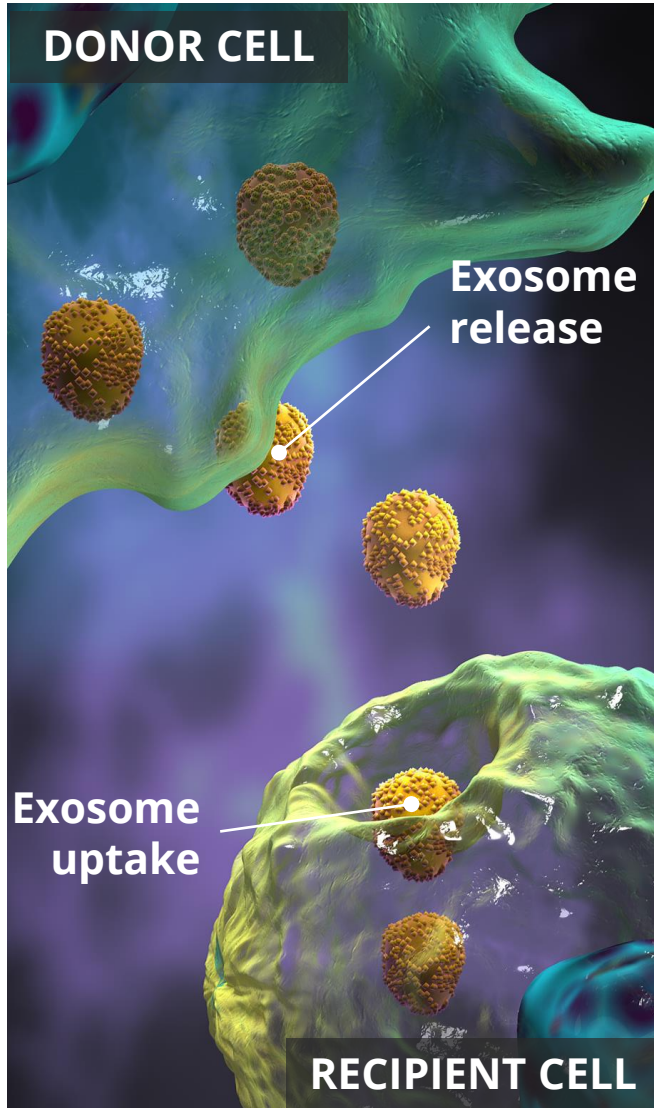
## Financials (as of 01/01/2020)

- 95.47 million shares outstanding with a market capitalisation of \$24.8 million
- Cash balance of \$5.88 million
- Quarterly burn rate (per Dec 4C) of \$1.85 million

## Priorities

- Accelerate the development of our exosome generation, manufacturing and characterization technologies
- Advance early products through clinical trials
- Leverage our unique access to exosomes to partner with established biopharmaceutical and cell therapy companies
- Add institutional investors/strategic partners to the share register

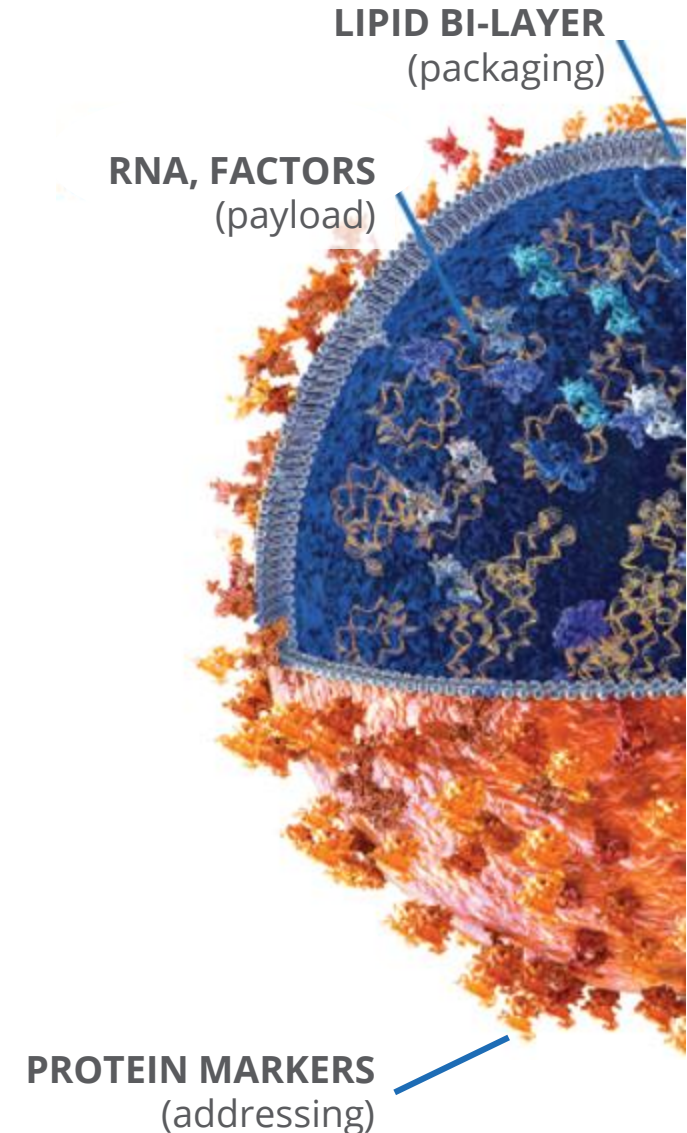
# EVs: the Body's Delivery Packets



**Extra-corporeal Vesicles (or EVs, also referred to as exosomes) are the key intracellular delivery mechanism**

## **EV's consist of three parts:**

1. **Address:** External protein markers that provide identifying information about the donor and recipient cells
2. **Package:** Lipid bi-layer that holds the EV in tact
3. **Payload:** The contents of the EV, comprised of RNA fragments (often miRNA), growth factors, and free proteins





# EV Therapies May Replace Cell Therapies



EVs from stem cells deliver their payloads to existing cells, reducing inflammation and promoting regeneration and healing by **multiple mechanisms**

Stem cells appear to work by orchestrating and guiding existing cells to heal and grow, rather than by replacing them

"In the cases where cells and their respective exosomes were studied in parallel, exosome treatment has demonstrated a similar or even superior therapeutic capacity to MSC treatment"

doi: 10.3389/fcvm2017.00063 2017

"In comparison to cell-based therapies, this cell-free regenerative strategy offers a lower risk and potentially higher scalability"

doi: 10.3390/cells7080110 2018



news feature

## Exosome redux

Adult stem cell companies are pivoting their businesses to commercialize exosomes as therapeutics.

NATURE BIOTECHNOLOGY | VOL 37 | DECEMBER 2019 | 1395-1400 | [www.nature.com/naturebiotechnology](http://www.nature.com/naturebiotechnology)

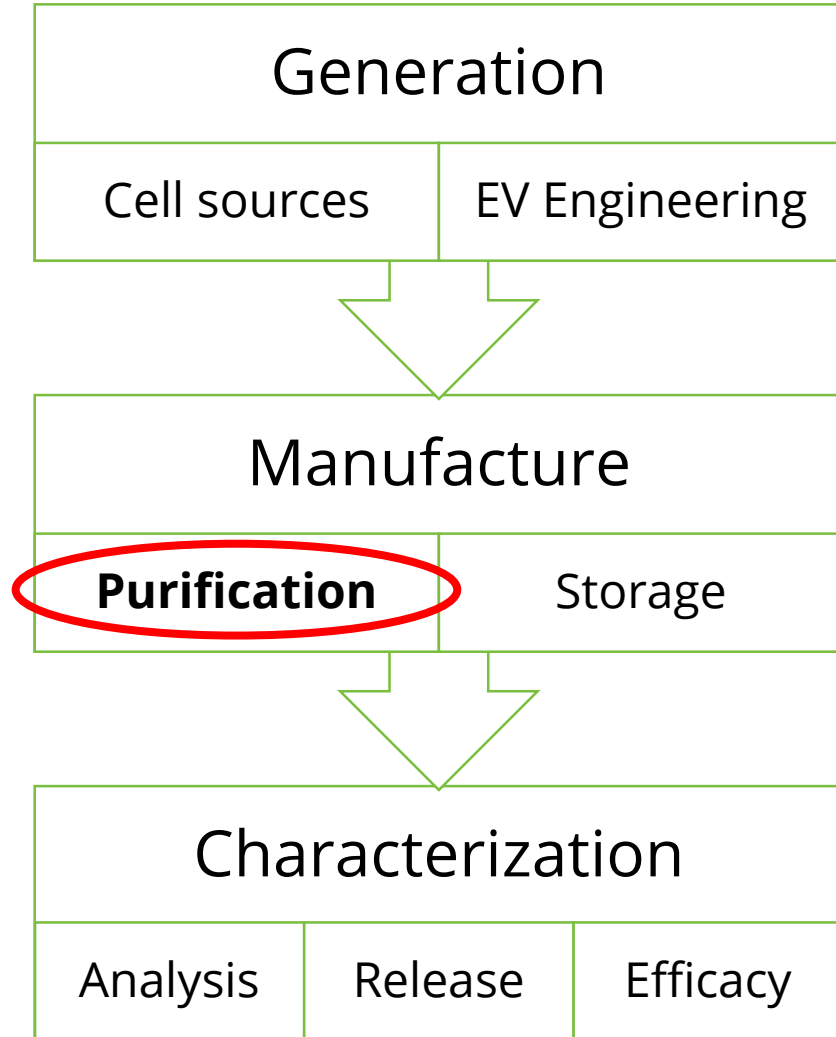
# EVs are Capturing the Attention of the Therapies Markets – Recent Developments



Established Company	EV Partner	Interaction
Jazz Pharmaceuticals (NASDAQ: JAZZ) US\$8.6 billion	Codiak Biosciences Private US	Access to Codiak's exosome platform for cancer through therapies <b>Undisclosed upfront with milestones exceeding \$1 billion</b>
Roche (SWX: ROG) CHF 271 billion	Puretech Health PLC (LON: PRTC) GBP 860 million	Milk-derived exosome technology <b>US\$36 million upfront with milestones exceeding \$1 billion</b>
Bio-Techne Corp (NASDAQ: TECH) US\$8.3 billion	Exosome Diagnostics, Inc. Acquired	Acquisition of diagnostic technology <b>US\$250 million upfront with additional US\$325 million in milestones</b>



# Challenge: The Bottleneck Problem



Trillions of exosomes are naturally produced in the human body, yet the purification of these natural nano-scale particles as a proper drug product is a major challenge.

- “Despite these advances, a major **bottleneck** of MSC (Mesenchymal stem cell) derived EV (MSC-EV) - based applications in clinics **is the inefficient production and purification** of clinical-grade EVs”\*
- “Currently, there is **no state-of-the-art technology to isolate EVs**, for either therapeutic application or basic research.”\*\*

## References

\* Liu *et al* Stem Cells, 2019, doi.org/10.1002/stem.2996

\*\* Lener *et al* Journal of Extracellular Vesicles, 2015, 4: 30087

## Ligand-based Exosome Affinity Purification

Exopharm invented and owns all LEAP™ IP, patent applications and associated know-how

The LEAP technology is:

- Gentle and selective;
- Based on inexpensive materials;
- Highly scalable;
- Easily combinable with other manufacturing operations

## LEAP Provides Exopharm a Substantial Competitive Advantage by:

1. Providing early access to EVs, allowing Exopharm to build **additional know-how and IP** in the areas of EV generation and characterization
2. Supplying sufficient clinical grade material for **multiple pre-clinical studies**
3. Positioning Exopharm as an ideal **partner for incumbents interested in investing** in EV therapies

# Leading into Clinical Trials



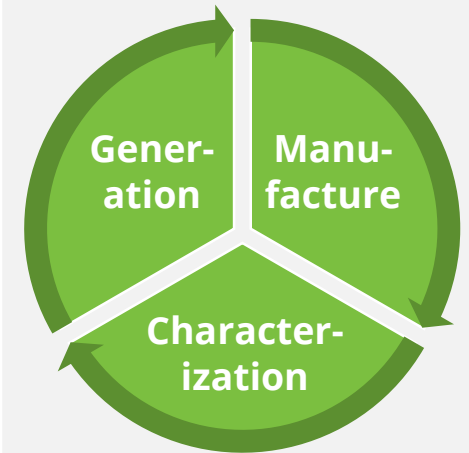
news feature

## Exosome redux

Adult stem cell companies are pivoting their businesses to commercialize exosomes as therapeutics.

NATURE BIOTECHNOLOGY | VOL 37 | DECEMBER 2019 | 1395-1400 | [www.nature.com/naturebiotechnology](http://www.nature.com/naturebiotechnology)

Companies Reviewed: 14	Planning Clinical Trials: 5	Clinical Trials Running: 1
Aegle Therapeutics Alxerion Biotech Anjarium Biosciences Aruna Biomedical Capricor Therapeutics Codiak Biosciences Evox Therapeutics ExoCoBio Exopharm Ltd NeurExo Sciences PureTech Health ReNeuron Tavec Pharma Versatope Therapeutics	Aegle Therapeutics Codiak Biosciences Capricor Therapeutics Evox Therapeutics Exopharm Ltd	<b>Exopharm Ltd</b> (first dosing Jan 2020)



LEAP has set off a virtuous circle of innovation that is accelerating Exopharm toward clinical applications of EVs



# Age-related EV Applications

Review Article

## Extracellular vesicles and aging

Paul D. Robbins

Department of Molecular Medicine and the Center on Aging, the Scripps Research Institute, Jupiter, Florida, USA  
doi: 10.21037/sci.2017.12.03



**Highly purified human extracellular vesicles produced by stem cells alleviate aging cellular phenotypes of senescent human cells**

Johns Hopkins University  
School of Medicine, Baltimore,  
Maryland;

2019

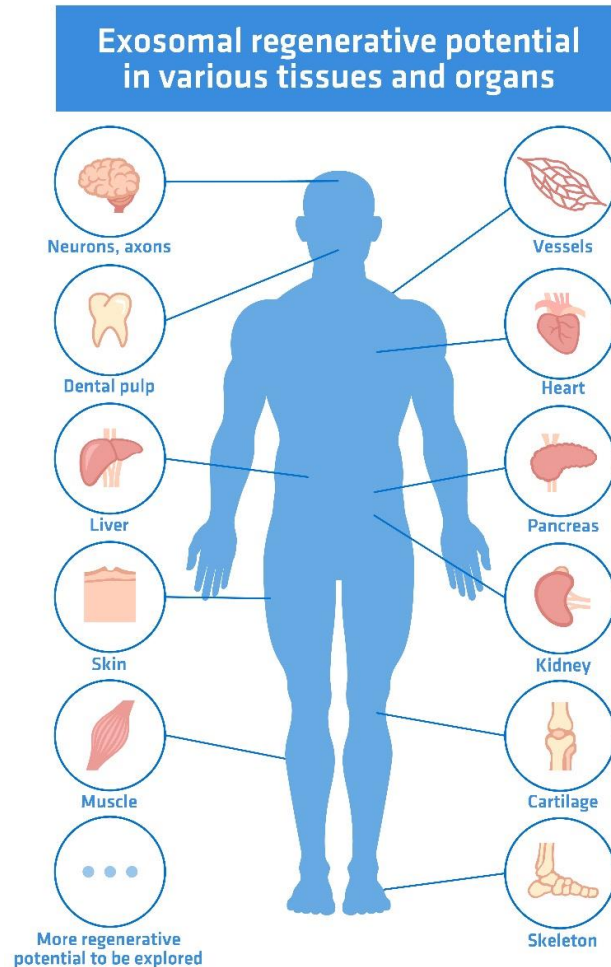


Figure adapted from Jing et al 2018  
doi.org/10.1016/j.trsl.2018.01.005

"These chronic diseases account for 75% of our healthcare costs, amounting to approximately \$3 trillion in costs last year alone." "Given the diverse roles of blood-borne EVs in modulating not only the immune response, but also angiogenesis and tissue regeneration, they likely play a key role in modulating the aging process."

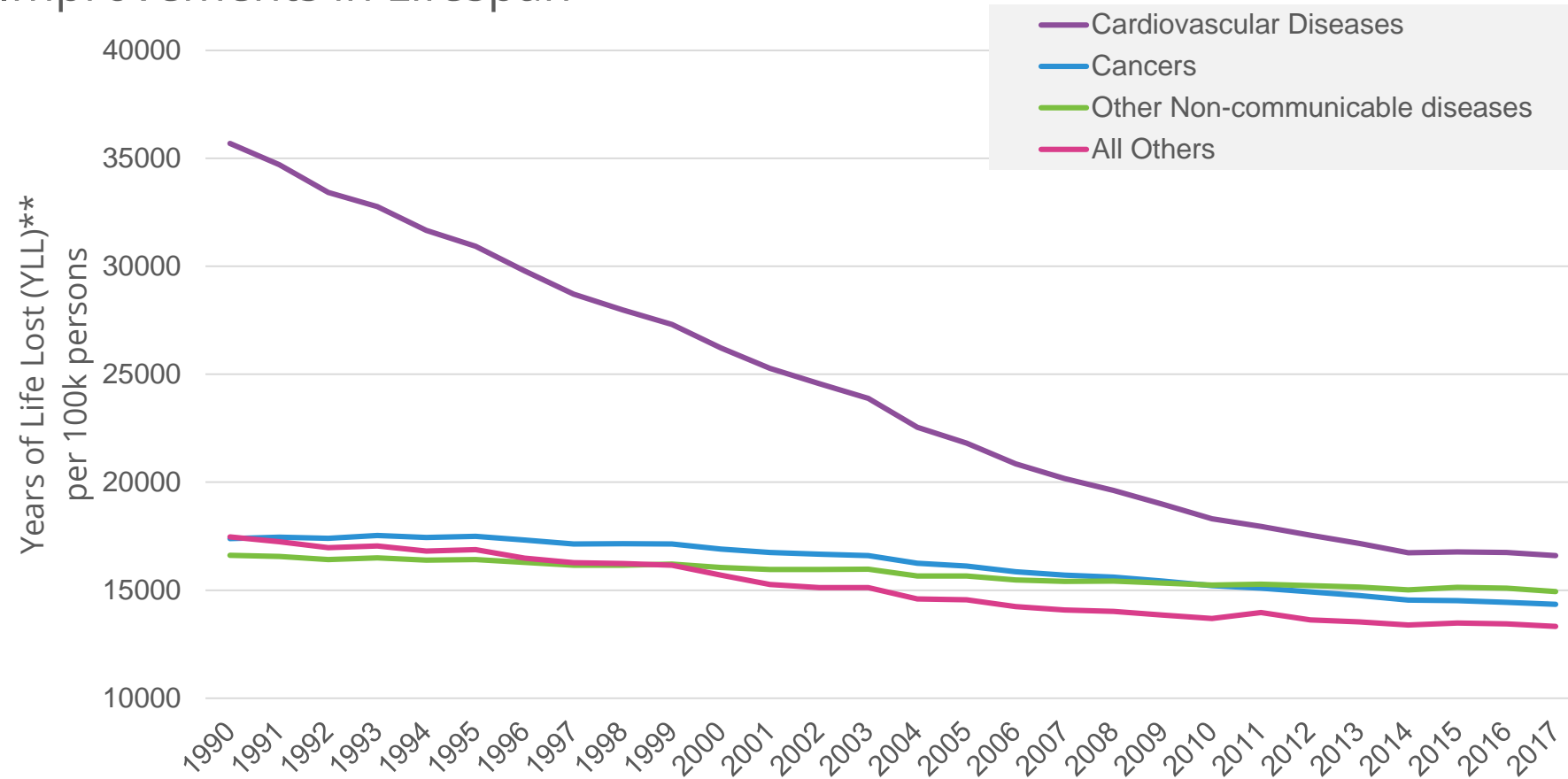
## **We believe that**

1. EV treatments are an entirely new therapeutic modality that will reshape biomedicine in the years to come
2. EV medicines will help people worldwide overcome disabilities that accumulate later in life
3. Exopharm will be a world leader in the:
  - Development and commercialization of technologies for generating, manufacturing, and characterizing EV's
  - Clinical advancement of EV-based medicines

# Extending Life: Healthcare's Success



## Improvements in Lifespan\*



\* Figures apply to 70+ year old's from High SDI countries

\*\* YLL (Years of Life Lost) is a WHO-defined measure to calculate the total number of years a disease shortened the lives of a population.

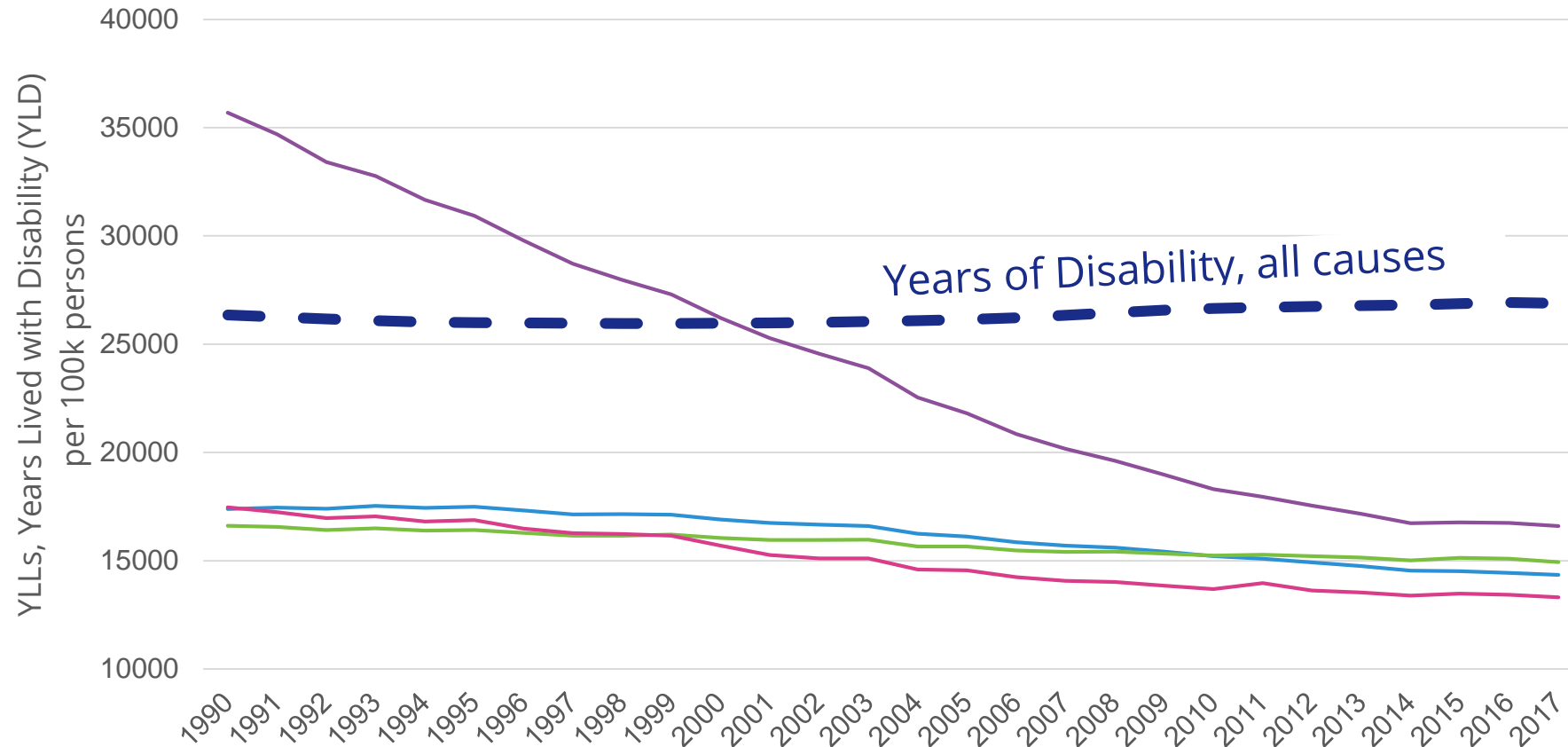
Source: 2019 Institute for Health Metrics Evaluation. Used with permission. All rights reserved.



# Reducing Disability: Healthcare's Failure



Improvements in Lifespan, Disability\*



Today, we are far more likely to experience years of disability than lose years to **cardiovascular disease and cancer combined**

**Disability is rising**

**Disability improvement is our greatest unmet need**

\* For 70+ year old's from High SDI countries

\*\* YLD (Years Lived with Disability) is a WHO-defined measure to calculate the total number of years a disease creates disability weighted by the degree of disablement) in the lives of a population.

Source: 2019 Institute for Health Metrics Evaluation. Used with permission. All rights reserved.

# Sources of Disability\*: The Hot Spots

	Sources of Disability	YLD
1	Musculoskeletal disorders	5,045
2	Sense organ diseases	3,535
3	Cardiovascular diseases	3,249
4	Neurological disorders	2,326
5	Diabetes and kidney diseases	2,316
6	Unintentional injuries	2,243
7	Chronic respiratory diseases	2,089
8	Mental disorders	1,526
9	Other non-communicable diseases	1,241
10	Skin and subcutaneous diseases	810
	All other	1,539

Hearing	2,562
Low back pain	2,476
Neck pain	996
Osteoarthritis	886
Vision	828
All other	832

\* Excluding cancer, for 70+ year old's from High SDI countries

Source: 2019 Institute for Health Metrics Evaluation. Used with permission. All rights reserved.

# Sources of Disability: Can EV's Help?

Disability Hot Spot	YLD
Hearing	2,562
Low back pain	2,476
Neck pain	996
Osteoarthritis	886
Vision	828

Lu et al. *Stem Cell Research & Therapy* (2017) 8:108  
DOI 10.1186/s13287-017-0563-9

Stem Cell Research & Therapy

## RESEARCH

## Open Access

Exosomes as potential alternatives to stem cell therapy for intervertebral disc degeneration: in-vitro study on exosomes in interaction of nucleus pulposus cells and bone marrow mesenchymal stem cells

Kang Lu<sup>1</sup>, Hai-yin Li<sup>1</sup>, Kuang Yang<sup>1</sup>, Jun-long Wu<sup>1</sup>, Xiao-wei Cai<sup>2</sup>, Yue Zhou<sup>1</sup> and Chang-qing Li<sup>1\*</sup>

Wang et al. *Stem Cell Research & Therapy* (2017) 8:189  
DOI 10.1186/s13287-017-0632-0

Stem Cell Research & Therapy

## RESEARCH

## Open Access

Exosomes from embryonic mesenchymal stem cells alleviate osteoarthritis through balancing synthesis and degradation of cartilage extracellular matrix

Yafei Wang<sup>1,2†</sup>, Dongsheng Yu<sup>1,2†</sup>, Zhiming Liu<sup>1,2</sup>, Fang Zhou<sup>1,2</sup>, Jun Dai<sup>1,2</sup>, Bingbing Wu<sup>1,2</sup>, Jing Zhou<sup>1,2,3</sup>, Boon Chin Heng<sup>4</sup>, Xiao Hui Zou<sup>5</sup>, Hongwei Ouyang<sup>1,2,6,7</sup> and Hua Liu<sup>1,2,8\*</sup>

frontiers  
in Cellular Neuroscience

ORIGINAL RESEARCH  
published: 29 November 2019  
doi: 10.3389/fncel.2019.00530

## Extracellular Vesicles From Auditory Cells as Nanocarriers for Anti-inflammatory Drugs and Pro-resolving Mediators

Gilda M. Kalinec<sup>1</sup>, Lucy Gao<sup>2</sup>, Whitaker Cohn<sup>3</sup>, Julian P. Whitelegge<sup>2</sup>, Kym F. Faul<sup>1</sup> and Federico Kalinec<sup>1\*</sup>

<sup>1</sup>Department of Head and Neck Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States, <sup>2</sup>Pasarrow Mass Spectrometry Laboratory, Department of Psychiatry and Biobehavioral Sciences, Jane and Terry Semel Institute for Neuroscience and Human Behavior, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States

Journal of Neurotrauma, Vol. 34, No. 24 | Original Articles

## Systemic Administration of Exosomes Released from Mesenchymal Stromal Cells Attenuates Apoptosis, Inflammation, and Promotes Angiogenesis after Spinal Cord Injury in Rats

Jiang-Hu Huang, Xiao-Ming Yin, Yang Xu, Chun-Cai Xu, Xi Lin, Fu-Biao Ye, Yong Cao and Fei-Yue Lin

Published Online: 15 Dec 2017 | <https://doi.org/10.1089/neu.2017.5063>

## Research Paper

PAIN

## Mesenchymal stem cell exosomes as a cell-free therapy for nerve injury-induced pain in rats

Sheng-Jie Shiu<sup>a</sup>, Ruey-Hong Rau<sup>b</sup>, Han-Shiang Shiu<sup>c</sup>, Yi-Wei Hung<sup>a</sup>, Zhi-Xiang Li<sup>d</sup>, Kuender D. Yang<sup>d,e,f</sup>, Jen-Kun Cheng<sup>a,h,\*</sup>

PAIN 160 (2019) 210–223

© 2018 International Association for the Study of Pain



Biomaterials

Volume 156, February 2018, Pages 16–27



MSC exosomes mediate cartilage repair by enhancing proliferation, attenuating apoptosis and modulating immune reactivity

Shipin Zhang<sup>a</sup>, Shang Jiunn Chuah<sup>a</sup>, Ruenn Chai Lai<sup>b</sup>, James Hoi Po Hui<sup>c,d</sup>, Sai Kiang Lim<sup>b,e</sup>, Wei Seong Toh<sup>a,d</sup>

## Therapeutic Potential of Mesenchymal Stem Cell-Derived Exosomes in the Treatment of Eye Diseases

C. Randall Harrell, Bojana Simovic Markovic, Crissy Fellabaum, Aleksandar Arsenijevic, Valentin Djonov, Nebojsa Arsenijevic, and Vladislav Volarevic

Substantial evidence from animal studies shows that EV's protect against damage and promote the repair of tissues across the body

## **CORE:** Greater Investment, Later Partnering

### **Because**

- Age-related disability is a growing and under-treated area of healthcare
- EV's demonstrate regenerative capabilities in a host of applications aged-related degeneration
- Exopharm has unique access to large quantities of exosomes through its LEAP technology

### **Exopharm will focus clinical trials in two key disability areas**

1. MOBILITY (Musculoskeletal disorders)
2. SENSORY (Sense organ disorders)

## **NON-CORE:** Lesser Investment, Earlier Partnering

### **Because therapeutic areas such as cancer, cardiovascular and neurological diseases**

- Require resource intensive, time-consuming clinical pathways
- Have highly capable and competitive incumbents

### **Exopharm will focus on early-stage partnering relationships in these areas, including**

- Serving as exosome technology partner
- Collaborating on producing pre-clinical efficacy data

# PLEXOVAL I Update (autologous Plexaris)



## ASX ANNOUNCEMENT & MEDIA RELEASE

### PLEXOVAL EXOSOME WOUND HEALING HUMAN STUDY STARTS

- A world-first study using cell free exosome product manufactured using Exopharm's LEAP Technology
- Study sites at the Royal Melbourne Hospital and Australian Red Cross Blood Service
- Results by mid 2020

26 August 2019

**Melbourne, Australia:** Regenerative medicine company Exopharm Limited (ASX:EX1) announces the start of the PLEXOVAL Phase 1 study, the first human clinical trial using exosomes for wound healing.

This is an important step forward as a clinical stage company and world leader in exosome therapeutics for regenerative medicine.

All regulatory and site approvals have been obtained and sites are currently preparing for the initiation of recruitment and dosing.

20 participant Phase I study to evaluate the safety, tolerability and biological activity of Plexaris™ in a wound healing context

- Cohort 1: 15 participants - 42 day wound healing evaluation
- Cohort 2: 5 participants - 30 day biological activity assessment

Initial dosing began in January

**Planning underway for Plexoval II – Phase I study to evaluate Allogeneic Plexaris**

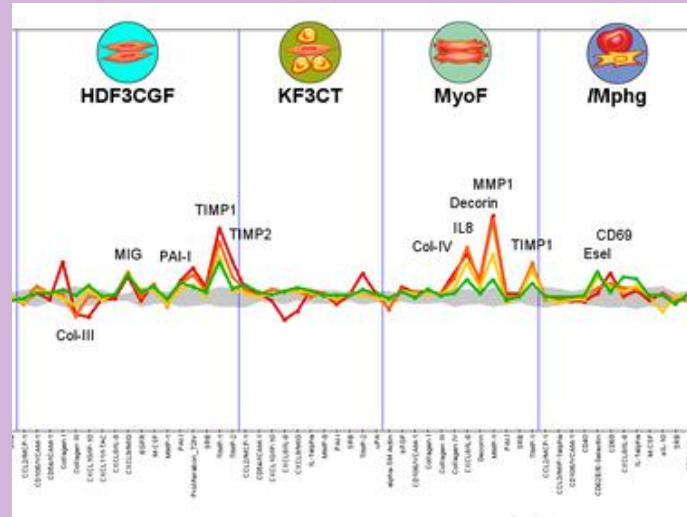


# Cevaris Pre-clinical Update

**BioMAP®  
(Eurofins)**

**Diversity PLUS  
Data Report**

- Cevaris is neither cytotoxic nor antiproliferative
- Changes in cell biomarkers positive for tissue remodelling, inflammation, immunomodulation



**Mobility: Active  
studies in animals**

- Joint
- Muscle
- Nerve

**Sensory: Active  
studies in animals**




- Eye
- Hearing



*Cevaris products are isolated from mesenchymal stromal cells, previously referred to as "Exomere"*



# Development Summary

	Early POC	Mobility	Sensory	Other/ Partnership
<b>Early Indications</b>	<ul style="list-style-type: none"> <li>Wound healing</li> </ul>	<ul style="list-style-type: none"> <li>Osteoarthritis</li> <li>Hip Tendinopathy</li> </ul>	<ul style="list-style-type: none"> <li>Dry AMD</li> <li>ED</li> </ul>	<ul style="list-style-type: none"> <li>Anti-fungal</li> <li>CAR-T (Cancer)</li> <li>Cardiac</li> <li>CNS</li> </ul>
<b>Non-clinical</b>				
<b>Phase I</b>				
<b>Phase II</b>				

AMD: Age-related Macular Degeneration  
ED: Erectile Dysfunction

# Executional Priorities



1. **EV Technology:** Create new know-how and build processes that provide a platform for growth
2. **Mobility:** Deliver EV treatments to improve mobility
3. **Sensory:** Deliver EV treatments to improve sensory perception

## Innovation Pillars:

How we expand value scientifically and clinically

4. **Capability:** Improve Exopharm's capacity to bring solutions to the market, including efficiencies, accreditations, etc.
5. **Partnership:** Collaborate with companies, researchers and institutions to expand Exopharm's impact and growth

## Enablers:

How we leverage our innovation to deliver out-sized growth

# Leadership: Global corporate experience



Ivan Jasenko  
Regulatory Affairs



Dr Angus Tester  
Clinical Trials



Michael Whitmore  
Manufacturing



Dr Patrick James  
Analytics



Dr Andrew Coley  
Research



Dr Lieven Huang  
Business  
Development



# Our Senior Team



**Dr Ian Dixon**  
*Founder*  
*Managing Director*

- Over 20 years experience in bringing cell-derived therapies to patients
- Founded Cynata Inc (now ASX:CYP) – a clinical-stage, world-wide leader in iPSC-derived cell therapy technology
- Co-inventor and original investor in Exopharm's LEAP technology

**Dr Gregor Lichtfuss**  
*Chief Operating Officer*



- Co-inventor of the LEAP technology, a patent-pending advance in exosome isolation
- Leads R&D, manufacturing, and clinical trials
- Previous experience launching biotechnology companies

**Dr Chris Baldwin**  
*Chief Commercial Officer*



- Twenty years experience in pharma, blood and plasma products, and medical devices
- Leads strategy, partnerships and marketing
- Strategy, sales and marketing experience across Asia Pacific, North America, and Europe

- EX1's early IP for exosome isolation is being leveraged to create a broad range of exosome manufacturing know-how
- EX1's Plexaris is the first proprietary exosome-based medicine to reach human clinical trials
- EX1's technical and management capabilities make it an excellent candidate for collaboration with biopharmaceutical companies
- EX1's management team has the broad scientific and commercial experience to grow the business and generate shareholder value

# Thank you

## **Exopharm Ltd (ASX-EX1)**

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