18 December 2017



### End of Year Newsletter



Dear Investors,

As 2017 draws to a close, I wanted to take this opportunity to reflect on the progress and achievements made this year and share with you some of the milestones we have to look forward to in 2018. This year, Cynata has delivered on the benchmarks we set out to accomplish, and I am immensely proud of our achievements.

# Achievements in 2017

- ✓ Commenced world first clinical trial of Cymerus™ MSC's in steroid resistant graft-versus-host disease (GvHD)
- ✓ Completed treatment of the first of two cohorts in the GvHD clinical trial
- ✓ Gained further **US patent protection**
- ✓ Progressed regulatory discussions with the US FDA, Health Canada, and more
- ✓ Received **positive preclinical data** from heart attack and asthma studies
- ✓ Entered strategic partnership with Fujifilm corporation of Japan
- ✓ Successful A\$6m capital raising

## **Milestones for 2018**

- **Complete** the Data and Safety Monitoring Board (DSMB) review, providing preliminary results from the GvHD clinical trial
- **Complete** the GvHD Phase 1 clinical trial
- **Pre-clinical results** from multiple studies, including:
  - Heart attack
  - ARDS
  - Glioblastoma
- **Potential exercise** of the license option by FUJIFILM

### CYNATA HAS A UNIQUE AND SCALABLE PLATFORM

Cynata's unique, scalable Cymerus<sup>™</sup> platform can effectively mass-produce mesenchymal stem cells (MSCs). No other company in the world has the capability to produce MSCs at an equivalent commercial scale without requiring multiple donors. To recap, MSCs are a highly promising type of stem cell with enormous therapeutic potential as they can elicit unique and powerful biological and immune responses. The potential market for therapeutic MSCs is large, active, and growing rapidly, with over 650 trials investigating the efficacy of MSCs in treating numerous diseases including cardiovascular disease, lung disease (such as asthma) and stroke.



#### WE CONTINUE TO DEMONSTRATE THE BROAD APPLICABILITY OF OUR PLATFORM

Cynata is focused on proving the broad applicability of its Cymerus MSCs across a range of target diseases. Successful pre-clinical and clinical results will pave the way for Cynata to leverage its technology platform across multiple disease targets, and provide significant opportunities for monetisation and commercial partnerships. The robust data we have demonstrated in a widely accepted model of asthma is one example.

Graft-versus-host disease (GvHD) is Cynata's first target area for clinical evaluation of its Cymerus platform for several medical and commercial reasons, including a short trial duration and the previously established efficacy of MSCs against GvHD. GvHD is a significant problem affecting bone marrow transplant patients, with limited treatment options.

This year, Cynata commenced a world first clinical trial using Cymerus MSCs to treat steroid resistant GvHD. This represents an important milestone, and we are incredibly proud of our rapid progress, having taken an entirely new therapy from the lab bench to the clinic in under four years. This achievement was only made possible through the commitment of the Cynata team and our collaborators.

We were delighted to announce last month that we have dosed the eighth patient in the trial, completing the enrollment of the first (Cohort A) of two groups to be studied. We now have seven sites recruiting patients in the UK and Australia, accelerating the rate at which we enroll patients for the final cohort. We are working closely with each of these sites and they are highly supportive of our therapy

#### WE HAVE MULTIPLE HIGH POTENTIAL PATHS TO COMMERCIALISATION

We have consistently shared our intent to commercialise our highly scalable platform. One path to monetisation is via licensing out our platform for use in a specific disease target area. Our license option agreements with FUJIFILM and apceth are the first examples of this strategy being executed.

Our partnership with FUJIFILM saw Cynata sign a license option agreement for GvHD potentially worth over A\$60 million in milestone payments including an initial upfront USD\$3 million licensing fee upon exercise of the option, together with a double-digit royalty on product sales.

Our partnership also saw FUJIFILM invest approximately A\$4 million in Cynata and become a significant shareholder in the Company. Their support this year has been incredibly valuable to the business and I am looking forward to continuing to work closely with FUJIFILM and its subsidiaries.



#### CONTINUED ENGAGEMENT WITH RELEVANT REGULATORY BODIES

We were also pleased to receive written advice from the US Food and Drug Administration (FDA) that provided guidance on the regulatory approval pathway for our Cymerus platform in the US. We have also progressed our discussions with Health Canada.

#### WE WILL REMAIN ACTIVE WITH CURRENT AND POTENTIAL INVESTORS

This year we have also been focused on enhancing our investor communication program, both domestically and internationally, with increased investor activity in Australia, the US, Europe and Japan. Last week I was in Japan for a series of investor meetings with investment funds and high net worth individuals. There is a strong appetite in international markets for quality regenerative medicine stocks and we have received an overwhelmingly positive response from investors. We have been continuously raising our profile in new markets and in 2018 we will continue to drive interest in the investment opportunity.

We are well funded as we enter 2018, with A\$8.7 million cash as at the end of the September quarter in addition to the recently announced receipt of a A\$1.3m R&D Tax Incentive Refund. This funding provides us with a runway beyond the primary evaluation period of the GvHD trial.

#### 2018 WILL BE AN EXCITING YEAR FOR CYNATA

2018 promises to be another year of the business meeting key milestones. Management are confident in its abilities and the capability of its product development partners. We are well positioned to advance the pipeline and commercial activities, and further build shareholder value.

I wish you a safe and happy holiday season and thank you for your continued support and interest in our Company.

Yours sincerely, Dr Ross Macdonald CEO & Managing Director

Ends

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#### About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical stage stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus<sup>™</sup>, originating from the University of Wisconsin-Madison, a world leader in stem cell research. The proprietary Cymerus<sup>™</sup> technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus<sup>™</sup> utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus<sup>™</sup> platform provides a source of MSCs that is independent of donor limitations and provides an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical product business model and economies of scale. This has the potential to create a new standard in the emergent arena of stem cell therapeutics and provides both a unique differentiator and an important competitive position.