

CYNATA 2017 AGM Chairman's Address

Good morning everyone and welcome to this year's AGM. I am delighted to be here today and to take this opportunity to reflect on the progress that Cynata has made this year as well as to share my own thoughts on the exciting future that is starting to become reality for cell therapeutics.

I joined the Company's Board in June of 2016 and earlier this year became non-executive chairman. I'd like to begin by sharing with you some of the reasons that attracted me to the Company.

I have spent many years in the biotech sector and I am incredibly passionate about regenerative medicine and cell therapeutics. Using cells as medicine is no longer a therapy of the future and cell based therapeutics are being investigated to treat a wide array of diseases. We are witnessing the dawn of a new era of medicine and several cell-based products have now reached the market. Cynata's unique Cymerus platform, its world first clinical trial and its ability to manufacture mesenchymal stem cells at scale positions the Company at the forefront of this market. The therapeutic potential of MSCs is extraordinary and validated by the numerous clinical trials being undertaken using MSCs.

The ability of the Cymerus™ platform to create and manufacture MSCs at scale to retain high potency gives the business a truly unique position in the market that I am very excited about. I truly believe that the Cymerus platform is ground-breaking technology that has the potential to not only create new regenerative therapeutic medicines but the ability to revolutionise how they are created.

And, the size of the market is tremendous. In graft vs host disease alone, an orphan indication, the market is estimated to be worth half a billion dollars in four years¹. And, our MSCs are not limited in their potential to treat only a few diseases. The regenerative medicine market was worth nearly \$20bn last year² and as therapeutic treatments continue to develop it will only continue to grow. Whether you look at the recent US\$12 Billion M&A transaction between Gilead and Kite or one of the largest Series A financings ever for BlueRock at US\$250 million, it is clear that the time for cell therapies is upon us.

Commercialisation of the platform is a key focus for us and we have made excellent progress this year towards this goal. Our strategic partnership with FUJIFILM saw us partner with a leading Japanese regenerative medicine company, who also became a substantial shareholder in the business. The licence option agreement with FUJIFILM is potentially worth over \$60 million in milestone payments together with a double-digit royalty on product sales. All future development costs for GvHD will be met by Fujifilm and we look forward to the future development of this partnership.

I would like to briefly touch on iPSCs and their unique abilities. The ground-breaking discovery by Shinya Yamanaka and others in 2006 that would later see him win a Nobel Prize has made the scalable manufacture of our MSCs possible. The discovery that Yamanaka made was a new way to reprogram adult cells into

¹ [https://www.visiongain.com/Report/1794/Global-Graft-versus-Host-Disease-\(GVHD\)-Market-2017-2027](https://www.visiongain.com/Report/1794/Global-Graft-versus-Host-Disease-(GVHD)-Market-2017-2027)

² Research and Markets - Global Regenerative Medicine Market Analysis & Forecast

pluripotent stem cells that can then be made into any cell type in the human body has been a game-changer for stem cell technology and its associated market. Notably, Cynata sourced the iPSC starting material from Cellular Dynamics International, a US-based company that was subsequently acquired by Fujifilm for US\$307 million.

It is this unique ability of iPSCs that make them the optimal starting material for our MSCs and this also enables us to overcome the existing challenges faced by stem cell therapies, which can require multiple donations, often from a more invasive procedure, such as bone marrow donation – limiting the scalability and expandability. Importantly the use of this technology allows us to build in reproducibility and robust quality control into the cell performance which is a fundamental requirement for successful development and regulatory approval.

This year we commenced a world first clinical trial: the first allogeneic iPSC clinical trial in the world. Obtaining this status required significant guidance and input from each Board member, and an enormous amount of effort by Ross Macdonald and Kilian Kelly and the team. Their contribution to the advancement of the science, clinical trial design and regulatory understanding in this area cannot be underestimated. Our CYP-001 product is now being used in that trial to treat patients with steroid resistant graft vs host disease and we were delighted to announce on Wednesday that we dosed our eighth patient. This eighth patient represents the final patient in the first of two groups of patients to be dosed. This will be followed by the Data Monitoring and Safety Board (DMSB) review and, subsequently, the expected commencement of the second Cohort of a further 8 patients.

It is worth remembering that acute graft-versus-host disease (GVHD) remains one of the major limiting factors in successful allogeneic bone marrow transplantation. Standard treatment for GVHD consists of corticosteroids and those who fail initial therapy have mortality rates as high as 95%.³ With these grim statistics in mind Cynata is energised to be developing a potential treatment in this very serious condition. Whilst it is presently too soon to tell whether CYP-001 will be a success, we remain very hopeful that we will eventually be able to offer a viable treatment option to patients, their families and their health carers.

We now have seven sites recruiting patients across Australia and the UK. Commencing the first clinical trial for a product is a huge milestone for biotech companies. In Cynata's case it is even more noteworthy given the extraordinary progress in taking a totally new product from university lab bench to the clinic in less than four years. It is also worth noting that data drives value and that is exactly what the Company is generating. Importantly the experience generated from taking this proprietary platform through the regulatory process in more than one country means that this expertise can be leveraged across all future development programs.

This year we will continue to focus on the commercialisation of our Cymerus platform and we have a vigorous partner engagement activity, being led by both the Board and the Management team. Our strategic partnership and licence option agreement with FUJIFILM stands us in good stead on our path to building robust shareholder value. We are also working hard to attract other high-quality potential partners, to maximise the value of the business and to build sustainable shareholder returns. This effort is helped by the

³ S. Arai, J. Margolis, M. Zahurak, V. Anders, and G. B. Vogelsang, "Poor outcome in steroid-refractory graft-versus-host disease with antithymocyte globulin treatment," *Biology of Blood and Marrow Transplantation*, vol. 8, no. 3, pp. 155–160, 2002.



fact that our Cymerus MSCs have shown strong pre-clinical data across a range of prominent diseases including heart attack, asthma and critical limb ischemia. We also added a pre-clinical trial in acute respiratory distress syndrome (ARDS) earlier this year – a disease that is responsible for 10% of all ICU admissions. The broad therapeutic potential supported by these pre-clinical findings has allowed Cynata to build a strong partnering dossier.

Our licence driven business model means that we are able to partner with pharmaceutical and biotechnology companies across a wide range of indications. Cynata has identified a number of potential indications that would benefit from its therapies – all of which represent significant target markets. We are not limited to one disease target area and our MSC products have significant potential in many markets and we have laid a solid scientific and development foundation to create an efficient product development machine for the future with numerous potential applications to revolutionize patients' lives

Cynata entered the December quarter with a strong cash balance of over \$8m. This is following the successful capital raise of \$10m earlier this year, which included the \$4m investment from our strategic partner, FUJIFILM. We enter 2018 well positioned to advance our product pipeline. We will complete Phase I in our world first clinical trial this year, that will be a pivotal moment in our Company's history and I look forward to sharing our progress with you.

I would like to take this opportunity to thank our shareholders for their continued support and I look forward to sharing in the success of our vision with you all.