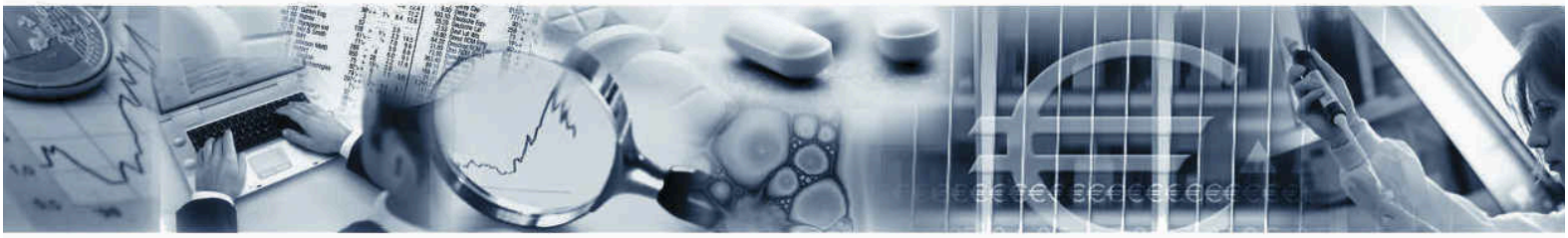

Initiating Coverage Report

Cynata Therapeutics Ltd

Emerging Industry Leader in Regenerative Medicine

Chief Research Analyst

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Date: 9 October 2017

Name:	**Cynata Therapeutics**
Country:	**Australia**
Price:	**AUD 0.65**
ISIN Code:	**AU000000CYP7**
Reuters Code:	**CYP.AX**
Market Cap (AUD m):	**58.5**
EV (AUD m):	**48.2**
Cash & cash eq. (AUD m):	**10.3**
Shares outstanding (m):	**90.0**
Volume:	**144,911**
Free float:	**91%**
52-week Range:	**0.37-0.81**

AUD million	2014/15A	2015/16A	2016/17A
Total Revenues	0.375	1.247	3.000
Net (Loss)/Profit	(3.712)	(4.939)	(4.000)
Net (loss)/profit ps (cents)	(6.12)	(6.82)	(4.42)
R&D costs	1.920	4.155	4.000
Cash increase/(decrease)	(0.424)	0.208	5.121
Cash and marketable sec.	4.704	4.879	11.000

Contents

Executive Summary

- Cynata Therapeutics Limited (ASX: CYP) is a clinical stage Australian stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus™, originating from the University of Wisconsin-Madison. The proprietary Cymerus™ technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve batch-to-batch consistency and economic manufacture at commercial scale.

- Japanese multinational Fujifilm (major shareholder with ~9%), has an exclusive worldwide option to a license to market and sell Cynata's lead product CYP-001 for graft-versus-host disease (GvHD). In May 2017, Cynata announced the commencement of a world-first Phase I trial with a first patient with GvHD treated. A total of 16 patients are expected to participate in the phase 1 trial and participating patients will receive two infusions of CYP-001, with a week between doses. The potential GvHD peak annual sales are estimated to be USD 300 million.

- During the last few years, a number of partnerships and M&A activity in the stem cell domain set compelling benchmarks for Cynata. Notable such transactions include the USD 307 million acquisition of Cellular Dynamics International by Fujifilm, the USD 50 million investment made by Novartis into Israeli Gamida Cell and the USD 379 million acquisition of Ocata Therapeutics by Astellas. In our view, Cynata could easily sign several partnership transactions, each with upfront payments of several million and total milestones of USD 50-100 million, along with potential future royalties on net sales of products using the Cymerus™ platform.

- The Company's current cash position is AUD 10 million which should be sufficient to carry

out the further development of its pipeline beyond 2018. Beginning of this year, Cynata raised AUD 10 million including an equity stake of 9% that Fujifilm took as part of the partnership in GvHD. The funds will be used to continue to develop its Cymerus therapeutic MSC products in its key target areas of GvHD, cardiovascular disease, oncology (glioblastoma) and respiratory disease.

- **Based on NPV based valuation, we believe that Cynata Therapeutics is substantially undervalued at the current share price of AUD 0.67. Using our valuation model and taking into account the future revenues from its Cymerus™ platform, the company's current total value should be AUD 150-175 million, or AUD 1.67-1.95 per share. This represents a substantial upside from the current share price.**

Company Profile

Cynata Therapeutics Limited is a clinical stage Australian stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus™, using discoveries made at the University of Wisconsin-Madison (UWM). The Cymerus™ 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. Stem cells, and particularly mesenchymal stem cells (MSCs, also known as mesenchymal stromal cells), are the subject of widespread research and use in 650+ clinical trials around the world.

Business Strategy and Partnerships

Cynata aims to develop the Cymerus™ technology into an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical business model and economies of scale. If development continues to be successful, this will create a new standard in the fast growing arena of stem cell therapeutics. The company's strategy for commercialising specific Cymerus™ therapeutic products and technology will be through the formation of development and commercialisation partnerships. Cynata already has formed several collaborative partnerships that form part of the company's strong commercialisation and R&D platforms. A vigorous partner engagement program will likely see the Company form additional revenue-yielding partnerships in the near term.

Apceth

In May 2016, Cynata entered into a partnership with German private company apceth & Co., GmbH. It is a clinical stage biopharmaceutical company and a contract development & manufacturing organization (CDMO) for complex cell-based and gene therapy products. apceth's

modular platform technology is based on genetically modified MSCs. Its lead program Agenmestencel is a first-in-man, genetically modified MSC product for the treatment of cancer. In addition, apceth develops new cell therapy candidates for the treatment of lung diseases and for immunomodulation. The agreement provides for an immediate upfront cash payment to Cynata, followed by a series of success-based milestone payments. Royalties on product sales will be also payable to Cynata. Given the substantial unmet medical needs that this relationship seeks to address, the agreement has the potential for substantial revenues to Cynata. In March 2017, apceth completed its evaluation of Cynata's Cymerus™ platform. It demonstrated the necessary characteristics required for use with apceth's own technology. However, apceth has undertaken a strategic review of its core areas and these have shifted to non malignant indications. It has therefore returned the license rights in oncology to Cynata but retained an option to non-exclusive rights to several other disease target areas.

Fujifilm Corporation

Beginning of 2017, Cynata signed a license option agreement with Fujifilm Corporation of Japan for the development and commercialization of certain Cynata technology, including Cynata's lead product CYP-001. Fuji has taken an equity stake in Cynata which now equates to around 9%. Under the agreement, Fujifilm has an option to an exclusive worldwide licence to market and sell Cynata's lead product CYP-001 as a treatment of GvHD. The potential future upfront and milestone payments are in excess of AUD 60 million. Cynata will also have the right to double digit royalties on future net sales of CYP-001. All development costs post-Phase I will be met by Fujifilm. Fujifilm has successfully transformed its business strategy by expanding away from traditional photographic film and toward new priority business fields – significantly in regenerative medicine. Fujifilm is making a major strategic commitment and investments into the area, encouraged by supportive dedicated regulations and policies in Japan. Earlier in 2015, Fujifilm acquired US firm Cellular Dynamics International (CDI) for the sum of USD 307 million. CDI manufactures and modifies

human cells for ongoing research and development of therapies. CDI emerged from the same founders behind Cynata and they know the technology very well, so there is a logical fit between CDI, Fujifilm and Cynata. Fujifilm recognized that Cynata's technology was the missing piece in the puzzle to making viable stem cell treatments

Aging population and the rise in chronic degenerative diseases dictate the need for novel therapies to regenerate the damaged tissue. Stem cell technologies have a potential to significantly improve management of medical conditions associated with tissue damage, diseases which include such commercially important targets such as stroke, osteoarthritis, heart attack and asthma. Stem cell therapies are rapidly developing. Recently, significant effort has been made to translate pluripotent stem cell technologies into the clinic. Within several years we will see more clinical trials with stem cell therapies. In 2014, the Japanese government approved the law that provide rapid approval process for human stem cell-based therapies allowing such products to now come to market at the end of Phase II clinical trials. This law will facilitate swift translation of novel stem cell technologies into the clinic and into the market.

Pipeline: Strong Platform in Regenerative Medicine

Cynata's proprietary Cymerus Technology Platform can be used for the development of products for various indications. Potentially any of the indications being pursued in the more than 650 clinical trials being undertaken around the world with MSCs could be available to Cynata's Cymerus products. In the past quarter, the company commenced a Phase I clinical trial with CYP-001 in GvHD. This study is a world first in using an iPSC-derived allogeneic MSC product; Cynata's advance has received considerable global attention from the industry. Furthermore, the company also started to investigate the use of Cymerus MSCs as a treatment for acute respiratory distress syndrome (ARDS). The study evaluates the effectiveness of Cymerus MSCs in sheep with ARDS. A successful evaluation would lead to a potential clinical study.

The company also received positive preliminary data from its preclinical heart attack study. The results indicated that Cymerus MSCs have the potential to restore cardiac function and reduce scare size after a heart attack. A final report is due later in 2017. Compelling results have also been described in an asthma model where Cynata's MSCs demonstrated significant beneficial effects on all three key components of asthma: airway hyper-responsiveness, inflammation and airway remodeling. The scale and nature of these beneficial effects had not been seen with equivalent doses of human bone marrow-derived MSCs, or other stem cells, in the same model. Cynata has also published data on the utility of its Cymerus MSCs in an animal model of critical limb ischaemia (CLI), a circulatory condition that frequently occurs in diabetes patients.

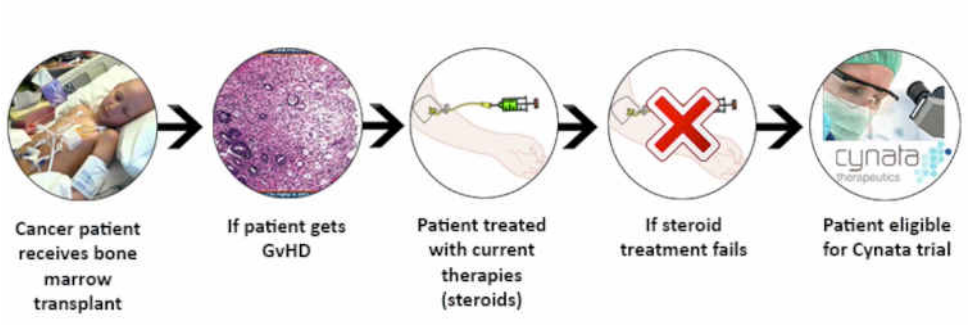
Therapeutic Area	Indication	Preclinical	Phase 1	Comments
Immunological Disorders	Graft versus host disease			World first trial
	Organ transplant rejection			
Pulmonary Disorders	Pulmonary fibrosis			
	Asthma			Compelling pre-clinical data
Circulatory Disorders	Critical limb ischaemia			Compelling pre-clinical data
	Myocardial Infarction (heart attack)			Compelling pre-clinical data
Cancer	Glioblastoma (brain tumour)			

Source: Cynata Therapeutics Ltd

CYP-001 in GvHD

In May 2017, Cynata commenced patient treatment in a world-first Phase I clinical trial to investigate the safety and efficacy of CYP-001 for the treatment of adult patients with steroid resistant acute GvHD. Patients that will be enrolled in the trial have undergone an allogeneic haematopoietic stem cell transplant (HSCT) to treat a haematological disorder and subsequently have been diagnosed with steroid resistant Grade II-IV GvHD. The first eight patients will be enrolled in Cohort A and receive two infusions of CYP-001 at a dose of 1 million cells per kilogram bodyweight, up to a maximum dose of 100 million cells. There will be one week between the two infusions. The next eight patients will be enrolled into Cohort B and receive two infusions of CYP-001 at a dose of 2 million cells/kg up to a maximum dose of 200 million cells. Efficacy will be assessed on the basis of response to treatment as determined by change in GvHD grade as well as overall survival at 28 and 100 days after the administration of the first dose. The trial has been

opened for recruitment at several major transplant centres in the UK and Australia with the first patient treated at one of the UK centres.



The start of the trial is a very important milestone for the company as it is the first time ever that a patient has been treated with an allogeneic induced pluripotent stem cell (iPSC)-derived therapeutic MSC product. CYP-001 is manufactured in a scalable process using Cynata's proprietary Cymerus platform with iPSCs as the starting material. The iPSCs are sourced from CDI, part of Fujifilm. The iPSCs were derived from a single blood donation using a non-viral and non-integrating episomal reprogramming method without any genomic modification. Thanks to the Cymerus process there is no need to source multiple donors that would bring about variability in products derived from multiple donations.

GvHD is the attack of a transplant donor's immune system (graft) against the recipient's body (the host), after an allogeneic HSCT. Typically, the onset of acute GVHD is 21–28 days after transplantation, but may be considerably later if lower dose conditioning is used. The organs most commonly affected are the skin, liver, and gastrointestinal tract. Immunosuppression with corticosteroids is the primary preferred form of therapy in acute GVHD. A response was seen in 55% in one large series of 443 patients but a durable response was maintained in only 35%. The prognosis for patients refractory to corticosteroid therapy is poor, with approximately 30% alive at one year. An MSC-based product was approved in Japan in 2016 for the treatment of acute GvHD; the product is marketed by JCR Pharma as "Temcell".

Progress of other indications in the product pipeline

Cynata has made significant advancements with its pre-clinical studies, with positive results in the treatment of heart attack and asthma. The Company also expanded its product pipeline with additional new indications, including the investigation of Cymerus'™ mesenchymal stem cells (MSC) as a treatment for acute respiratory distress syndrome (ARDS).

Cardiovascular disease (Heart Attack)

Positive preliminary data from the heart attack study conducted at the Westmead Institute for Medical Research found that Cynata's Cymerus™ therapeutic MSCs have the potential to restore cardiac function and reduce scar size after a heart attack in the animal model used in this study. The study continues and is expected to conclude this calendar year.

Respiratory and pulmonary diseases

Asthma

Cynata's preclinical asthma study with Monash University confirmed Cymerus™ MSCs have a significant and beneficial impact on all three components of asthma: hyper-responsiveness, inflammation and airway remodelling. The study examined Cymerus'™ MSCs in a mouse model of chronic allergic airways disease and found that the MSCs may provide an efficacious and safe treatment for asthma. The paper was published in the FASEB Journal; one of the world's most cited peer reviewed biology journals. The findings from the study led to a further preclinical study in the treatment of asthma with a comparison to corticosteroids and the data from this study is paving the way for a future clinical trial in asthma patients. In August Cynata announced further data supporting the efficacy of its proprietary Cymerus™ mesenchymal stem cells (MSCs) in a second preclinical asthma study. The study was conducted under the supervision of Associate Professor Samuel and Dr Simon Royce of the Monash Lung Biology Network, focusing on the effects of

Cymerus MSCs in combination with or in comparison to the corticosteroid dexamethasone, which is commonly used to treat exacerbations of asthma in human patients. The study used a well-established mouse model of chronic allergic airways disease that closely resembles asthma in humans. This part of the study focused on airway hyperresponsiveness (AHR), which is a key clinical manifestation of asthma. Initial results from this study have demonstrated that, as expected, treatment with dexamethasone alone significantly improved AHR compared to untreated controls.

Acute Respiratory Distress Syndrome (ARDS)

Cynata expanded its product development pipeline with the addition of a preclinical investigation into the use of its Cymerus MSCs as a treatment for acute respiratory distress syndrome (ARDS) with the Critical Care Research Group in association with the Prince Charles Hospital in Brisbane. The study will evaluate the effectiveness of Cymerus™ MSCs in sheep with ARDS who are currently being supported by a treatment called extracorporeal membrane oxygenation (ECMO), which acts as an artificial lung to oxygenate the blood. If the study is successful, it is anticipated that the data would support progression to a clinical trial of Cymerus™ MSCs in humans with ARDS undergoing ECMO support.

Oncology

Cynata's work with the Brigham and Women's Hospital, part of Harvard Medical School, continues to investigate the use of its Cymerus™ MSCs in the targeting of killing cancerous cells and is making good progress. The study is expected to conclude in the first quarter of 2018.

Other Developments

In August, the company announced that it had completed a successful and informative meeting with the Canadian regulatory authority, Health Canada, regarding the clinical development of

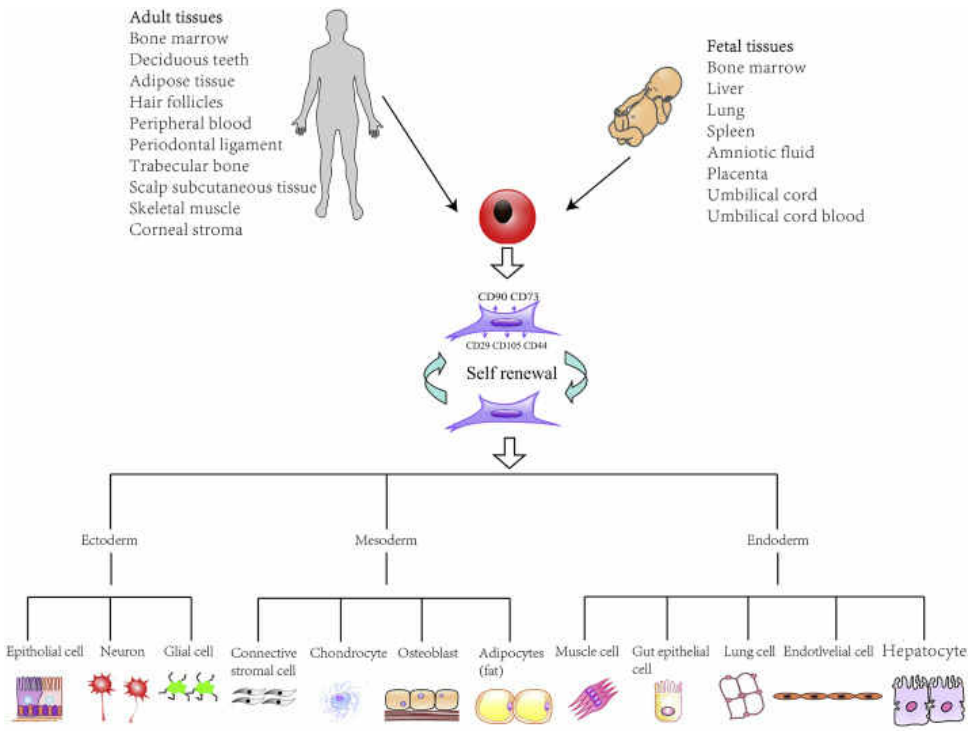
Cynata's proprietary Cymerus mesenchymal stem cell (MSC) products in Canada. Health Canada agreed in principle that the unique Cymerus process, including donor screening and testing, the induced pluripotent stem cell (iPSC) derivation process and the manufacture and testing of the final product, meets its expectations for a product entering clinical trials. Cynata also received clarification from Health Canada on the design of preclinical studies required to support a Clinical Trial Application in Canada. This advice was consistent with that recently obtained from the US FDA

Regenerative Medicine: The New Holy Grail?

Regenerative medicine represents a new paradigm in human health with the potential to resolve unmet medical needs by addressing the underlying causes of disease. The emerging field of regenerative medicine is unique in its aim to augment, repair, replace or regenerate organs and tissue that have been damaged by disease, injury or even the natural ageing process. This rapidly evolving, interdisciplinary field is transforming healthcare by translating fundamental science into a variety of regenerative technologies including biologics, chemical compounds, materials and devices. It differs from other fields of medicine in the array of disciplines it brings together and in its ability to create or harness the body's innate healing capacity.

The use of Stem Cell Technology in Regenerative Medicine

Ever since their discovery, stem cells have been a focal point in regenerative medicine. In 1963, Canadian scientists Ernest McCulloch and James Till discovered a self-renewing cell found in the bone marrow of mice. The late 60's brought about the discovery of mesenchymal stem cells in bone marrow by Friedenstein. It was not until 1978 that similar cells were found in human umbilical cord blood and named hematopoietic stem cells. The most potent stem cells, still capable of differentiating into cell types of all three embryonic germ layers, are embryonic stem cells, which are referred to as pluripotent. However, the ongoing intense ethical and political debate restricts their use. A multipotent stem cell with important therapeutic potential is provided by adult, bone marrow-derived mesenchymal stem cells (MSCs), present within the bone marrow stroma and in certain other tissues. These multipotent bone marrow-derived stromal cells have already demonstrated efficacy in multiple examples of cellular therapies, some of which have sought to exploit their differentiation and immunomodulatory capacity as shown in the graph below.



Source: Journal of Cellular Immunotherapy, Volume 2, Issue 1: March 2016

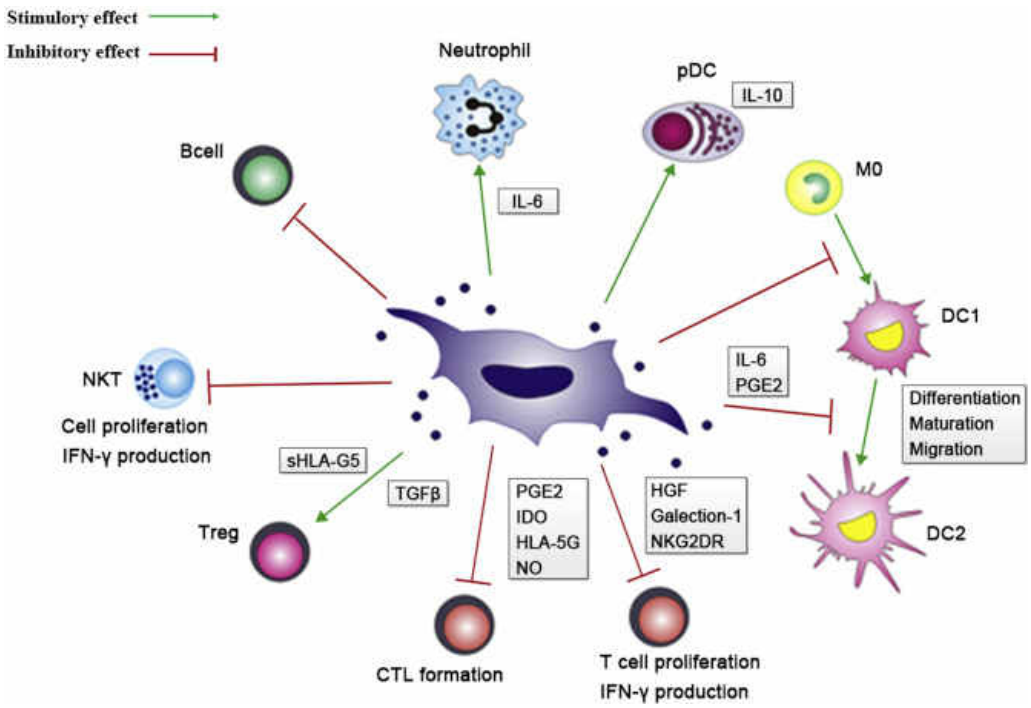
There are many different types of stem cell, and they vary in their abilities to reproduce themselves and differentiate. However, they can be broadly categorised into two major groupings being pluripotent and adult stem cells. The characteristics of these two groups of stem cells are described further below:

- Pluripotent Stem Cells: Pluripotent stem cells are the most versatile cells of all, having the ability to reproduce themselves indefinitely, and also differentiate into any other type of cell in the body. There are two main types of pluripotent stem cell, being embryonic stem cells (ESC), and induced pluripotent stem cells (iPSC).

- Multipotent (or Adult) Stem Cells: Apart from embryonic and re-programmed sources described above, stem cells can also be isolated from adult tissue (and also from tissues in

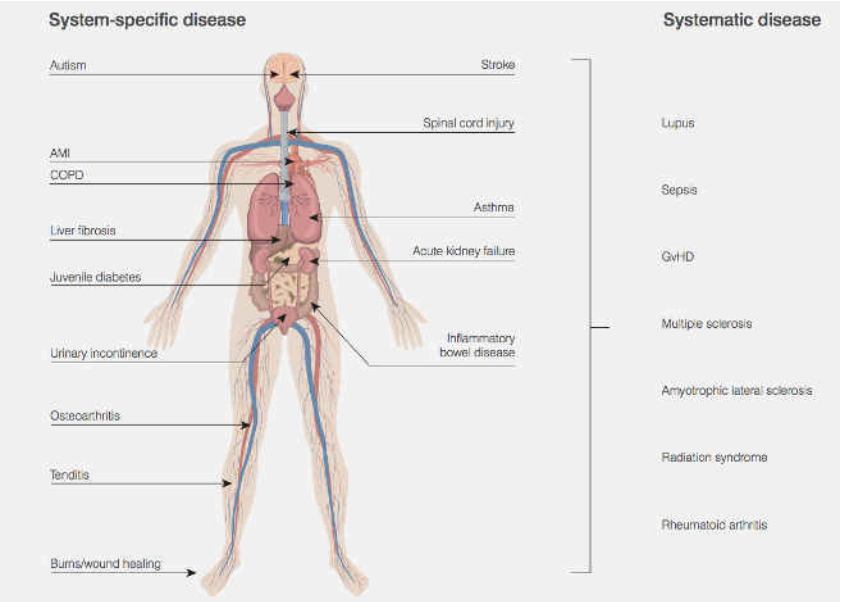
infants and children). Such stem cells are typically called "adult stem cells"; "somatically derived MSCs" or "adult MSCs" are examples of adult stem cells.

The MSCs exert their immune suppressive potential by cell to cell contact and by secretion of immune regulatory molecules. MSCs display broad immunomodulatory properties, MSCs can inhibit the proliferation and function of T cells, Natural killer T (NKT) cells, T regulatory cells, B cells and dendritic cells (DCs). However, MSCs secrete IL-6 and preserve neutrophils viability by inhibiting apoptosis. Several soluble factors have been shown to play a major role in the immunosuppressive effects of MSCs, including prostaglandin E2 (PGE2), transforming growth factor (TGF)-β1, indoleamine 2,3-dioxygenase (IDO), nitric oxide, hepatocyte growth factor (HGF), interleukin (IL)-6 and IL-10.

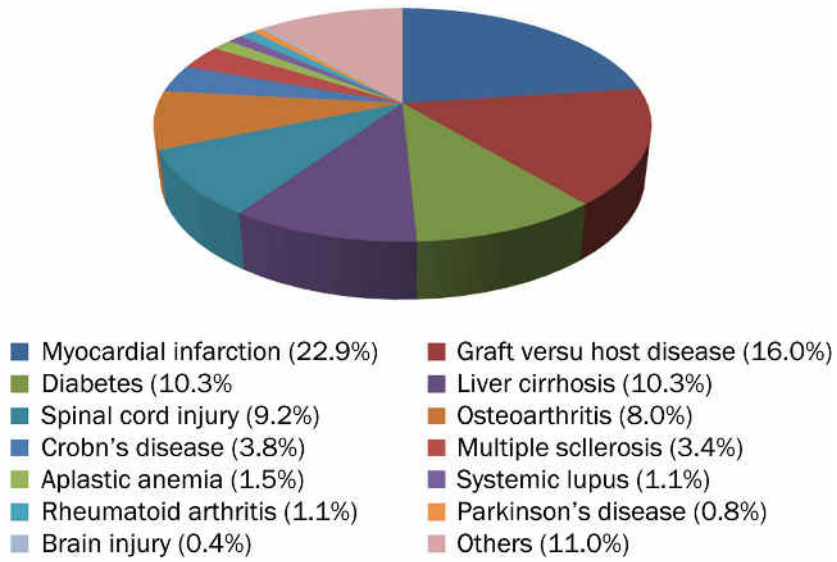


The range of diseases in which stem cells are being studied is illustrated in the graphs below.

In addition to their property of treating tissue injury, MSCs are also applied to alleviate immune disorders because MSCs have a powerful capacity of regulating immune responses. Various studies have evaluated the therapeutic effect of MSCs in preclinical animal models and demonstrated great clinical potential. For example, MSCs have been successfully applied to reverse graft-versus-host disease (GvHD) in patients receiving bone marrow transplantation, especially in patients diagnosed with severe steroid resistance. Similarly, in systemic lupus erythematosus (SLE) and Crohn's disease patients, both autologous and allogeneic MSCs were able to suppress inflammation and reduce damage to the kidneys and bowel through the possible induction of regulatory T cells in patients. It also has been reported that BM-MSCs can improve multiple system atrophy (MSA) multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and stroke, likely through immediate immunomodulatory effects. Osiris' Prochymal, the world's first stem cell drug approved in Canada on May 12, 2012 (but never launched), concluded a Phase III clinical trial for treating GvHD. The trial failed to meet its primary endpoint and the product only received conditional approvals in NZ and Canada, in a limited subset of patients. This is relevant to Cynata, as it has been suggested that the reasons for the failure of these trials are due to shortcomings of the bone marrow-derived MSC manufacturing process The product was launched in Japan in 2016 as "Temcell" by JCR Pharma.



Range of potential uses for MSCs



Source: Acta Pharmacologica Sinica (APS) (2013)

Cymerus Technology Platform

Cymerus Technology Platform

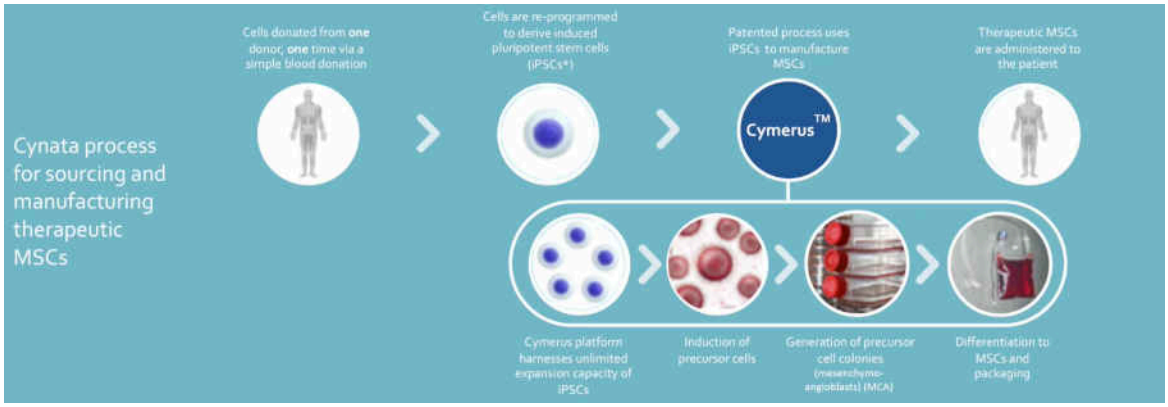
Limitations in conventional methods of MSC production include the dependence upon donors, the variability between donors, the relative scarcity of MSCs in adult tissue, and the low proliferative capacity of adult stem cells compared to pluripotent stem cells. The numbers of adult stem cells in the tissue sources commonly used are very small. For example in one study, only 0.001-0.01% of cells isolated from bone marrow were MSCs with a typical bone marrow donation yielding around 20,000 MSCs. Similarly, from 1g of adipose tissue, only 5,000 MSCs can be isolated. This scarcity means the isolated cells have to be expanded (ie multiplied) in culture to provide sufficient numbers of cells for a single dose (typically around 100-200 million cells). This raises a significant challenge to commercial development of adult stem cell-based therapies, in the limited expandability in culture of such cells. Thus, it has been suggested that attempts to maximise the number of potential treatment "doses" from a donor through expansion in culture could compromise the quality of the product and the clinical outcome. This is one of the major reasons why doses per donor in many clinical studies are limited to the range of about 5-10 and why recommendations are often to undertake only limited expansion prior to clinical use. This problem substantially limits the commercial application of the therapeutic MSC products.

Mesenchymoangioblasts (MCAs) are a newly identified and important class of early clonal mesoendodermal precursor cells, meaning that they are the common precursor for both MSCs and endothelial cells. The commercial potential of the cells was identified by Cynata, following a process which sought to identify the ideal "next generation" stem cell technology. Through the Cymerus™ technology, Cynata seeks to address the limitations inherent in current adult stem cell technologies, specifically:

- donor dependence and variability;

- contamination with non-target cells; and
- limited scalability

Cynata's Cymerus™ technology which incorporates MCA-derived MSCs has the potential to address these issues, and in addition, has the possibility of being able to derive multiple cell therapeutics platforms. The Cymerus™ technology utilises induced pluripotent stem cells (iPSC) and a recently identified precursor cell, known as a mesenchymoangioblast (MCA), to achieve economic manufacture with batch-to-batch consistency of MSC cell therapy products, at commercial scale.

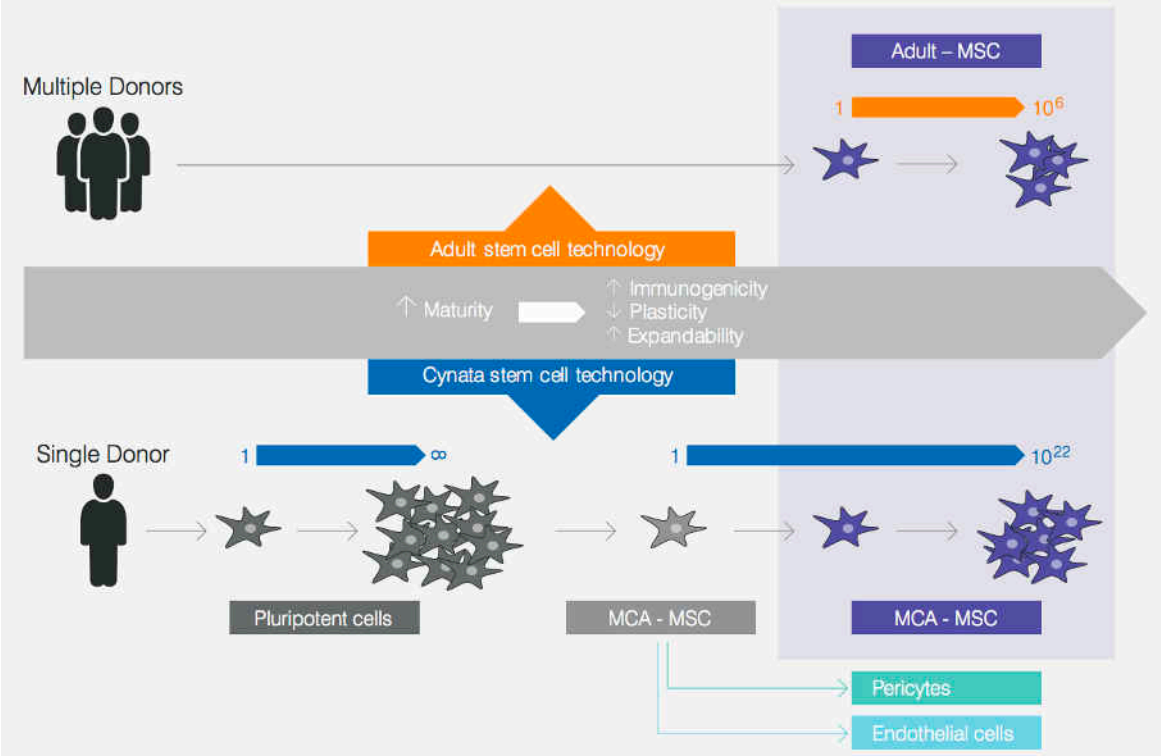


As noted above, limitations in using adult-derived MSCs include the dependence upon donors, the variability between donors, the relative scarcity of MSCs in adult tissue, and the low proliferative capacity of adult stem cells compared to pluripotent precursors. The Directors believe that the Cynata Technology may address all of these issues and the Company's proposed activities in relation to the Cynata Technology are aimed at demonstrating that.

Since iPSCs can proliferate indefinitely, and MCAs themselves can expand into extremely large quantities of MSCs Cynata should be able to manufacture all of the MCAs that it will ever need from a single Master Cell Bank of iPSCs – derived from a single donor. The means of producing

MCAs from pluripotent precursors, and the defining pattern of MCA cell surface markers, are the subjects of US patent 7,615,374, and a number of other patent applications in process around the world, licensed to Cynata. See also Patent Position on page 26.

Comparison Adult MSC technology with Cymerus



Source: Cynata Therapeutics

Key Features of the Cymerus™ Technology:

Versatility

MCAs can be used to make a range of cell types, each of which has different properties and may be suited to the treatment of different diseases. In the first instance, Cynata is using MCAs as the basis for producing commercially relevant quantities of very pure and well characterised mesenchymal stem cells (MSCs). Cynata believes that it can produce cells much more efficiently than companies using first generation MSC manufacturing technology.

Manufacturing scalability

As cells mature, they become less and less "expandable". So, MSCs derived from adult tissues have a limited expansion capacity, meaning that manufacturers constantly need to be identifying, qualify and screening new cell donors. This is an expensive and time-consuming process. Cynata manufactures its MCAs – and in turn MSCs – using induced pluripotent cells (iPSCs) as a starting material. Pluripotent cells are immortal – effectively, meaning that they have infinite expansion capacity. Consequently, Cynata expects to be able to source all of the cells it will ever need from a single donor. Furthermore, it means that Cynata does not need to excessively expand MSCs in culture in order to produce large numbers of doses. This is important, as excessive culture expansion has been shown to result in changes in the functionality of MSCs.

Manufacturing costs and complexity

Because Cynata is developing its products from a pluripotent cell source, it is able to eliminate the need to repeatedly source, screen and qualify new donors. This will substantially reduce the costs and complexity of manufacturing. In addition, Cynata expects to have far fewer batch-to-batch variability issues, since all of its cellular material will be sourced from a single donor.

Clinical predictability

Inevitably, batches of cells produced from different donors will have different properties. Cynata's expected reduced batch-to-batch variability may increase the predictability of clinical outcomes. This will need to be confirmed in clinical trials.

Safety

MSCs are immunoprivileged, meaning that they can generally be infused or injected into recipients without provoking a dramatic immune response. However, antibodies to injected cells have been detected in some clinical trials. One reason for this may be the presence of non-immunoprivileged contaminating cells, left over from the process of extracting and purifying cells from adult donors. Cynata's cells are manufactured from iPSCs, rather than being purified from primary tissue sources such as bone marrow and adipose tissue. Consequently, it is expected that the level of purity of Cynata's cell products will be extremely high, which may translate into a lower likelihood of stimulating an immune response in the recipient.

SWOT Analysis

Strengths	Weaknesses
Strong management and highly experienced in the development and early stage commercialization of new therapeutics	Operating losses cumulating year on year
Addresses the current issues with MSCs	
	Relatively early stage development company

Opportunities	Threats
Ageing population offers predictable and ongoing strong growth in number of patients	Increased competition from larger companies
Strong emerging technology	Delays in pipeline development
Ongoing development with cash rich partners	Patent issues or expiry of patents

Patent Position

The Cymerus™ technology is subject to a portfolio of patents and patent applications of which Cynata is a licensee. Cynata does not own the core Cymerus technology, having acquired a license to the relevant patents from the owner, Wisconsin Alumni Research Foundation (WARF) a non-profit Wisconsin corporation. The Company owns the trade mark for 'Cymerus™' worldwide. Cynata's interest as licensee of the Cynata Technology is reliant on the License Agreement with WARF. There is no guarantee that other companies will not legally challenge the Cynata Technology or the License Agreement or that WARF will comply with the License Agreement. Cynata also owns a number of patent applications outright.

The means of producing MCAs from pluripotent precursors, and the defining pattern of MCA cell surface markers, are the subjects of US patent 7,615,374, and a number of other patent applications in process around the world, licensed to Cynata. The original, published method for producing MSCs through MCA intermediates utilised cell feeder layers derived from mice, which is not recommended for manufacturing a product for use in humans. However, a refined version of the process, which does not involve the use of feeder layers, was subsequently developed. These refinements are also the subject of patents licensed to Cynata, and form the basis for Cynata's current feeder-free and serum-free method of production, which is appropriate for the manufacture of products for human use.

The iPSCs used in Cynata's Cymerus™ manufacturing process were derived from a fully consented donor, in compliance with the FDA's GMP requirements, and manufactured by Cellular Dynamics International (CDI; Nasdaq: ICEL), using a non-integrating episomal reprogramming method. This method of iPSC production is also covered by a series of patents and patent applications in process, which have been licensed to Cynata.

In June Cynata filed a new patent application with IP Australia for oncology-related therapeutic uses of its proprietary Cymerus™ mesenchymal stem cell (MSC) technology. The patent would cover the application of Cymerus in immunotherapy treatments, including chimeric antigen receptor T cell (CAR-T) and checkpoint inhibitor-based therapies. Cynata recently announced the filing of another patent application with IP Australia covering uses of Cymerus in oncology.

Financials

Cynata Therapeutics showed incurred a net loss from operations for the full financial year ended 30 June 2017 of AUD 4,553,536 (2016: AUD 4,939,471). At 30 June 2017, the company had a cash balance of AUD 10,349,764 (2016: AUD 4,879,173) and net assets of AUD 13,864,596 (2016: AUD 8,583,138). The net cash outflow from operating activities for the financial year was AUD 4,115,408 (2016: AUD 4,326,353). The Company's first mesenchymal stem cell (MSC) product, CYP-001, advanced to a Phase I clinical trial during the year for the treatment of GvHD, with the first patient dosed in UK.

Cynata made significant progress towards realising its commercialisation objectives. It secured a strategic partnership and licence option agreement with FUJIFILM, worth over AUD 60 million in potential milestone payments, together with double-digit royalties on eventual product sales. Cynata will receive an upfront USD 3 million payment when the option is exercised, which can occur at any time during or up until 90 days after the completion of the current Phase I clinical trial. The agreement also provides for FUJIFILM to fund all future product development and commercialisation activities after Phase 1. The strategic partnership saw FUJIFILM take a AUD 3.972 million equity position in Cynata, making them the largest shareholder in the Company with a 8.98% holding. In a further connection with FUJIFILM, the starting material for Cynata's Cymerus™ process, clinicalgrade induced pluripotent stem cells or iPSCs, are sourced from Cellular Dynamics International, a FUJIFILM subsidiary company

Cynata also secured AUD 6 million (before costs) in an equity placement from institutional and sophisticated investors, bringing the total capital raised during the year to AUD 10 million. Additionally, the Company received an R&D Tax Incentive refund of AUD 1.748 million.

Profit & Loss Statement

AUD million	2014/15A	2015/16A	2016/17A
Total Revenues	0.375	1.247	1.843
Total costs	4.087	6.186	6.397
Operating Loss	**(3.712)**	**(4.939)**	**(4.553)**
Financial Income/(Expenses)	(0.)1	-	-
Net Profit/(Loss)	**(3.713)**	**(4.939)**	**(4.553)**

Consolidated statement of cash flows

AUD million	June 30th 2016A (12 months)	June 30th 2017A (12 months)
Cash flow from operating activities	(4.353)	(4.048)
Cash flow from investing activities	-	-
Cash flow from financing activities	4.535	9.586
Cash and cash equivalents at beginning of the period	4.671	4.879
Net change in cash and cash equivalents	0.181	5.538

Management Capabilities

Cynata was founded by seasoned biotechnology innovators. The company is led by an experienced Board and management team, which has been responsible for the successful development of the business and has built up a successful track record of developing, protecting and commercializing innovative scientific products and processes. The management team has proven to be highly experienced in the development and early stage partnering of new therapeutics.

Management Team

Ross Macdonald, Managing Director and CEO

Dr Macdonald has over 30 years' experience and a track record of success in pharmaceutical and biotechnology businesses. His career history includes positions as Chief Executive Officer of Hatchtech Pty Ltd, Vice President of Business Development for Sinclair Pharmaceuticals Ltd, a UK-based specialty pharmaceuticals company, Vice President of Business Development for Connetics Corporation (Palo Alto, CA), and Vice President, Corporate Development for Stiefel Laboratories Inc, the largest independent dermatology company in the world and acquired by Glaxo Smith Kline in 2009 for STG 2.25 billion. Dr Macdonald has also served as Vice President of Research and Development of F H Faulding & Co Ltd and CEO of Living Cell Technologies Ltd. His other positions have included non-executive director roles at iSonea Ltd, Telesso Technologies Ltd, Hatchtech Pty Ltd and Relevare Pharmaceuticals Ltd. Dr Macdonald currently serves as a member of the Investment Committee of UniSeed Management Pty Ltd. Dr Macdonald holds a PhD in Biochemistry, Monash University, a Graduate Diploma in Business Administration, Swinburne University, and he is a member of the Licensing Executives Society.

Dr Kilian Kelly, Vice President Product Development

Dr Kilian Kelly has approximately 15 years' experience in pharmaceutical/biotechnology research and development, in both commercial and academic settings. His previous appointments include Senior Director, Drug Development at Biota Pharmaceuticals (NASDAQ: BOTA), Vice President, Regulatory and Clinical at Mesoblast Limited (ASX:MSB), and various regulatory affairs and project management positions with Kendle International (now INC Research), Amgen (NASDAQ: AMGN) and Astrazeneca (LSE: AZN). Dr Kelly holds a Masters in Pharmacy from Robert Gordon University, Aberdeen and a PhD in Pharmaceutical Sciences from Strathclyde University, Glasgow. He is a registered pharmacist and a member of the Royal Pharmaceutical Society, The Organisation for Professionals in Regulatory Affairs (TOPRA) the International Society for Cellular Therapy and the Australasian Society for Stem Cell Research.

Board of Directors

Paul Wotton, Chairman

Dr. Wotton joined Cynata's Board of Directors in June, 2016. He was previously President and CEO of Ocata Therapeutics, Inc. (NASDAQ: OCAT) joining the company in July 2014 and managing it through a take-over by Astellas Pharma, Inc., in a US$379 million all cash transaction. Prior to Ocata, Dr. Wotton had served as President and CEO of Antares Pharma Inc. (NASDAQ: ATRS), since October, 2008. Prior to joining Antares, Dr. Wotton was the CEO of Topigen Pharmaceuticals and prior to Topigen, he was the Global Head of Business Development of SkyePharma PLC. Earlier in his career he held senior level positions at Eurand International BV, Penwest Pharmaceuticals, Abbott Laboratories and Merck, Sharp and Dohme. Dr. Wotton is a member of the board of Vericel Corporation, a US company developing autologous cellular therapies and also past Chairman of the Emerging Companies Advisory Board of BIOTEC Canada. Dr. Wotton received his Ph.D. in pharmaceutical sciences from the University of Nottingham and an MBA from Kingston Business

School. In 2014 he was named New Jersey EY Entrepreneur of the Year in Life Sciences.

Dr Stewart Washer, Non Executive Director

Stewart has 20 years of CEO and Board experience in medical technology, biotech and agrifood companies. In addition to his role as Executive Chairman at Cynata, he is also the Chairman of Orthocell Ltd, who culture tendon cells to repair damaged tendons and Chairman of Minomic International Ltd who have an accurate non-invasive test for prostate cancer. Stewart was previously the CEO of Calzada Ltd (ASX:CZD), the founding CEO of Phylogica Ltd (ASX:PYC) and before this, he was CEO of Celentis and managed the commercialisation of intellectual property from AgResearch in New Zealand with 650 Scientists and $130m revenues. He was also a founder of a NZ$120m New Zealand based life science fund and Venture Partner with the Swiss based Inventages Nestlé Fund. He is currently Investment Director with Bioscience Managers. Stewart has held a number of Board positions in the past as the Chairman of iSonea Ltd (ASX:ISN), Resonance Health Ltd (ASX:RHT) and Hatchtech Pty Ltd, a Director of iCeutica Pty Ltd, Immuron Ltd (ASX:IMC) and AusBiotech Ltd. He was also a Senator with Murdoch University and is currently the Chairman of Firefly Health.

Dr John Chiplin, Non Executive Director

Dr Chiplin has significant international experience in the life science and technology industries, from both an operational and investment perspective. Recent transactions that Dr Chiplin has been involved in include US stem cell company Medistem (acquired by Intrexon), Arana (acquired by Cephalon), and Domantis (acquired by GlaxoSmithKline). Prior to his role at Arana, Dr Chiplin was head of the $300M ITI Life Sciences investment fund in the UK and his own investment vehicle, Newstar Ventures Ltd, has funded more than a dozen early stage companies in the past ten years. Dr Chiplin is a Director of Benitec Biopharma (ASX: BLT) and also serves on the boards of Adalta Pty Ltd and ScienceMedia, Inc. His Pharmacy and Doctoral degrees are from the University of Nottingham, UK.

Competitive Landscape

In setting up a peer group for Cynata, we focussed on companies in Regenerative Medicine that also have stem cell therapy products in development.

Tigenix

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is an biopharmaceutical company developing novel therapies for serious medical conditions by exploiting the anti-inflammatory properties of allogeneic, or donor-derived, expanded stem cells. TiGenix´ lead product, Cx601, has successfully completed a European Phase III clinical trial for the treatment of complex perianal fistulas - a severe, debilitating complication of Crohn's disease. Cx601 has been filed for regulatory approval in Europe and a global Phase III trial intended to support a future U.S. Biologic License Application (BLA) started in 2017. TiGenix has entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the U.S. TiGenix' second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis. Finally, AlloCSC-01, targeting acute ischemic heart disease, has demonstrated positive results in a Phase I/II trial in acute myocardial infarction (AMI).

Cytori Therapeutics

Cytori Therapeutics, Inc. (Cytori) is a biotechnology company engaged in the development of treatments and devices for a range of disorders using cells as a key part of the therapy. The Company develops cellular therapeutics formulated and optimized for specific diseases and medical conditions and related products. It is focused on developing primary product, Cytori Cell Therapy, for patients with scleroderma hand dysfunction, orthopedic disorders, cardiovascular

disease, urinary incontinence and thermal burns, including those complicated by radiation. Its cellular therapeutics are collectively known by the name, Cytori Cell Therapy, which consists of a heterogeneous population of specialized cells, including stem cells that are involved in response to injury, repair and healing. These cells are extracted from an adult patient's own adipose tissue using its automated, enzymatic, sterile Celution System devices and consumable sets at the place where the patient is receiving their care.

Histogenics Corp.

Histogenics Corporation is a regenerative medicine company. The Company is focused on developing and commercializing products in the musculoskeletal segment of the marketplace. The Company's product candidate, NeoCart utilizes various aspects of regenerative medicine platform to develop a tissue implant intended to treat tissue injury in the field of orthopedics, specifically cartilage damage in the knee. NeoCart is a cartilage-like implant created using a patient's own cartilage cells through a series of tissue engineering processes. The patient's cells are separated from a tissue biopsy specimen extracted from the patient and multiplied in its laboratory. The cells are then infused into its scaffold that provides structure for the developing implant. Before NeoCart is implanted in a patient, the cell- and scaffold construct undergoes a bioengineering process in the Company's Tissue Engineering Processor (TEP). The Company has operations in the United States and Israel.

Orthocell

Orthocell Limited is an Australia based regenerative medicine company. The Company is engaged in the development and commercialization of cell therapies and related technologies. The Company's products include CelGro, a collagen medical device for soft tissue repair in use as an augment to rotator cuff repair, guided bone regeneration and repair of articular cartilage, and Autologous Tenocyte Implantation (Ortho-ATI) for chronic, treatment resistant tendon regeneration. CelGro is targeted on a range of orthopedic, reconstructive and surgical applications.

Ortho-ATI is a treatment that uses a minimally invasive, non-surgical approach that uses each patient's own tendon derived stem cells to stimulate tendon regeneration and is delivered through ultrasound guided injection under local anesthetic. The Company's Autologous Chondrocyte Implantation (Ortho-ACI) offers treatment for symptomatic defects of the articulating cartilage of the joints, including the knee and ankle.

Biotime

BioTime, Inc. is a clinical-stage biotechnology company focused on developing and commercializing products addressing degenerative diseases. Its clinical programs are based on two platform technologies: pluripotent stem cells and cell/drug delivery platform technologies. The foundation of its cell delivery platform is its HyStem cell and drug delivery matrix technology. Its clinical programs are targeting three primary sectors, aesthetics, ophthalmology and cell/drug delivery. Its facial aesthetics product, Renevia, is a potential treatment for facial lipoatrophy. It is in a pivotal clinical trial in Europe to assess its safety and efficacy in restoring normal skin contours in patients whose subcutaneous fat, or adipose tissue, has been lost due to the use of certain drugs often used to treat patients with human immune virus. OpRegen is its lead product for ophthalmological disorders. It is a suspension of retinal pigment epithelial cells that are derived from pluripotent stem cells.

Athersys

Athersys, Inc. is an international biotechnology company that is focused primarily in the field of regenerative medicine. The Company's MultiStem cell therapy, an allogeneic stem cell product, is its lead platform product and is in later-stage clinical development. Its clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other conditions where the standard of care is limited or inadequate for many patients. In the neurological area, the Company evaluated

in a completed Phase II trial, the potential for MultiStem treatment of patients with a history of neurological damage from an ischemic stroke. The Company initiated a Phase II clinical study in the United States for the administration of MultiStem cell therapy to patients with a history of an acute myocardial infarction, or AMI.

Pluristem Therapeutics

Pluristem Therapeutics Inc. is a developer of placenta-based cell therapy product candidates for the treatment of multiple ischemic, inflammatory and hematologic conditions. The Company's lead indications are critical limb ischemia (CLI), recovery after surgery for femoral neck fracture and acute radiation syndrome. Its operations are focused on the research, development, clinical trials and manufacturing of cell therapeutics and related technologies. The Company's products include PLX-PAD and PLX R18. The Company's PLX cells are adherent stromal cells (ASCs) that are expanded using a three dimensional (3D) process. The system utilizes a synthetic scaffold to create an artificial 3D environment where placental-derived stromal cells can grow. The Company's PLX products are administered using a standard needle and syringe. The Company's PLX products are in clinical-stage development for multiple indications, such as cardiovascular, orthopedic, pulmonary and women's health diseases.

Brainstorm Cell Therapeutics

Brainstorm Cell Therapeutics Inc. is a biotechnology company. The Company is engaged in developing adult stem cell therapies for debilitating neurodegenerative disorders, such as Amyotrophic Lateral Sclerosis (ALS, also known as Lou Gehrig's disease), Multiple Sclerosis (MS) and Parkinson's disease (PD), among others. Its subsidiary, Brainstorm Cell Therapeutics Ltd. (the Israeli Subsidiary), holds rights to commercialize the technology, NurOwn. NurOwn is in clinical development for the treatment of ALS. The Company has completed over two clinical trials of NurOwn in patients with ALS at Hadassah Medical Center (Hadassah). The first study, a Phase I/II safety and efficacy study of NurOwn in ALS patients administered either intramuscularly or

intrathecally. The Company conducted Phase IIa combined (intramuscular and intrathecal) treatment, dose-escalating trial. It had completed treatment of over 10 patients in its ALS Phase IIa NurOwn dose-escalating clinical trial.

Reneuron

ReNeuron Group plc is a clinical-stage company. The Company, through its subsidiaries, is engaged in researching and developing cell-based therapies. The Company's products are allogeneic. Its CTX stem cell therapy is used for the treatment of patients left disabled by the effects of a stroke. Its human retinal progenitor cells (hRPC) stem cell candidate is used for the treatment of retinitis pigmentosa (RP). Its second CTX stem cell candidate is for the treatment of critical limb ischaemia. The Company's exosomes nanomedicine platform focuses on generating early pre-clinical data in cancer. Its ReNcell Products include ReNcellVM and ReNcellCX cell lines. It is engaged in Phase II clinical trial of CTX cells for stroke disability. It is engaged in Phase I clinical trial of CTX cells for Critical Limb Ischaemia. It is engaged in Phase I clinical trial of hRPC stem cell candidate. The Company has completed pre-clinical trials CTX-derived exosomes.

Cellular Biomedics Group

Cellular Biomedicine Group, Inc. (CBMG) is a biomedicine company. The Company is engaged in the development of treatments for cancerous and degenerative diseases utilizing cell-based technologies. The Company operates in Biomedicine Cell Therapy segment. The Company's technology includes platforms, such as Immune Cell therapy for treatment of broad range of cancers using Vaccine, T Cells Receptor (TCR) clonality analysis technology and T Central Memory Cell (Tcm) preparation methodologies, Chimeric Antigen Receptor T cell (CAR-T), and human adipose-derived mesenchymal progenitor cells (haMPC) for treatment of joint and autoimmune diseases, with primary research and manufacturing facilities in China. It is focused on developing and marketing cell-based therapies based on its cellular platforms, to treat serious chronic and

degenerative diseases, such as cancer, orthopedic diseases, including osteoarthritis and tissue damage, various inflammatory diseases and metabolic diseases.

Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of latestage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

Osiris Therapeutics

Osiris Therapeutics, Inc. is a cellular and regenerative medicine company. The Company is focused on researching, developing and marketing products in the wound, orthopedic, and sports medicine markets. The Company operates through Biosurgery business segment, which focuses on products for wound care, orthopedics, and sports medicine to harness the ability of cells and novel constructs to promote the body's natural healing. The Company's products include Grafix, Stravix, TruSkin, Cartiform and BIO4. The Company produces and distributes Grafix for acute and chronic wounds; Stravix for tendon repair; TruSkin for wound closure; Cartiform, a viable cartilage mesh for cartilage repair, and BIO4 for bone growth. The Company's BioSmart cryopreservation process retains the native characteristics and inherent functionality of tissue. Its BioSmart process includes preservation of the three dimensional (3D) matrix, endogenous growth factors, and tissue-resident cells.

Analyst: Marcel Wijma MSc
Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.

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