



ASX ANNOUNCEMENT

15 November 2017

Company Investor Presentation

Melbourne, Australia; 15 November 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), is pleased to release a new investor presentation to be presented at a series of upcoming institutional investor meetings.

Paul Wotton (Cynata Chairman) and Ross Macdonald (Cynata CEO) will be meeting with a series of new and existing institutional investors prior to the upcoming AGM on November 17.

Cynata Therapeutics provides investors with excellent exposure to a rapidly growing regenerative medicine and stem cell sector via its patented Cymerus™ technology, a platform able to manufacture mesenchymal stem cells (MSCs) at a commercial scale. The new investor presentation highlights Cynata Therapeutics' compelling investment case and provides information about the Company's progress.

Operational progress

- **8 participants now enrolled in world first clinical trial of CYP-001** for the treatment of steroid-resistant graft-versus-host disease (GvHD)
- **Enrolment of the 8th and final patient in Cohort A represents the half-way point of the trial**, and an independent safety and monitoring review will be triggered 28 days after this participant receives the infusion of CYP-001

Investment highlights

- **Unique platform to efficiently mass-produce mesenchymal stem cells (MSCs)**, a highly promising type of therapeutic stem cell
- **Large, active and growing market, with over 650 trials investigating the efficacy of MSCs** in treating diseases including osteoarthritis, stroke and cardiovascular disease
- **Scalable business model intended to target a broad range of disease target areas over time**, and monetise these through licensing & partnerships
- **Cynata's initial target area is GvHD, intended to prove the quality of the MSC's** produced by its patented Cymerus platform
- **Monetisation of the business model has already commenced**, with license option and strategic alliance transaction entered into with Fujifilm, Cynata's largest shareholder with 9%

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™, originating from the University of Wisconsin-Madison, a world leader in stem cell research. 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 economic manufacture at commercial scale. Cymerus™ utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ 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.

About the Phase 1 clinical trial (Protocol Number: CYP-GvHD-P1-01)

The trial is entitled “*An Open-Label Phase 1 Study to Investigate the Safety and Efficacy of CYP-001 for the Treatment of Adults With Steroid-Resistant Acute Graft Versus Host Disease*”. Participants must be adults who have undergone an allogeneic haematopoietic stem cell transplant (HSCT) to treat a haematological (blood) disorder and subsequently been diagnosed with steroid-resistant Grade II-IV GvHD. The first eight participants will be enrolled in Cohort A and receive two infusions of CYP-001 at a dose of 1 million cells per kilogram of body weight (cells/kg), up to a maximum dose of 100 million cells. There will be one week between the two CYP-001 infusions in each participant. The next eight participants 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. The primary objective of the trial is to assess safety and tolerability, while the secondary objective is to evaluate the efficacy of two infusions of CYP-001 in adults with steroid-resistant GvHD. The primary evaluation period will conclude 100 days after the first dose in each participant. Efficacy will be assessed on the basis of response to treatment (as determined by change in GvHD Grade) and overall survival at 28 and 100 days after the administration of the first dose. After the completion of the primary evaluation period, participants will enter a longer term non-interventional follow-up period, which will continue for up to two years after the initial dose.

A Next Generation Stem Cell Company

Investor Presentation
Cynata Therapeutics Limited
November 2017

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Investment overview

1

Unique technology to efficiently mass-produce mesenchymal stem cells (MSCs), a highly promising type of therapeutic stem cell

2

World first clinical trial, going from concept to clinic in less than 4 years & providing a springboard for further clinical studies

3

Large, active and growing market, with over 650 trials investigating the efficacy of MSCs in treating diseases including osteoarthritis, stroke & cardiovascular disease

4

Scalable business model intended to target a **broad range of disease target areas** over time, and monetise these through licensing & partnerships

5

Cynata's initial target area is GvHD, intended to prove the quality of the MSC's produced by its patented Cymerus™ platform

6

Monetisation of the business model has already commenced, as license options have been entered with Fujifilm, who are Cynata's largest shareholder with 9%

Corporate overview: A biotech company with a world-first clinical trial and leading technology platform

Company profile

- Cynata Therapeutics is an Australian clinical-stage biotechnology company developing disruptive regenerative medicines. Cynata shows strong potential for 2018, with a strategic partnership and license option agreement in place with Fujifilm

Financial information

Share price (13-Nov-17)	A\$0.60
52 week low / high	A\$0.785 / A\$0.400
Shares on issue ¹	90.1m
Market capitalisation	A\$54m
Cash (as at 30-Sep-17)	A\$8.7m
December quarter expected cash burn	~\$2.1m
Debt (as at 30-Jun-17)	-
Enterprise value	A\$45.3m

Source: IRESS

Notes: Excludes 10.4m unquoted options with exercise prices ranging from \$0.40 to \$1.022 and expiry dates between 27-Sep-2018 and 4-Aug-2020, and 750k unlisted incentive options with exercise price \$0.49 and expiring 16 December 2018 (500k subject to vesting conditions)

6 month share price performance




Shareholder overview (as at 2 Oct-17)

Shareholder	%
Fujifilm corporation	8.98
Board and Management	7.08%
Number of shareholders	2304

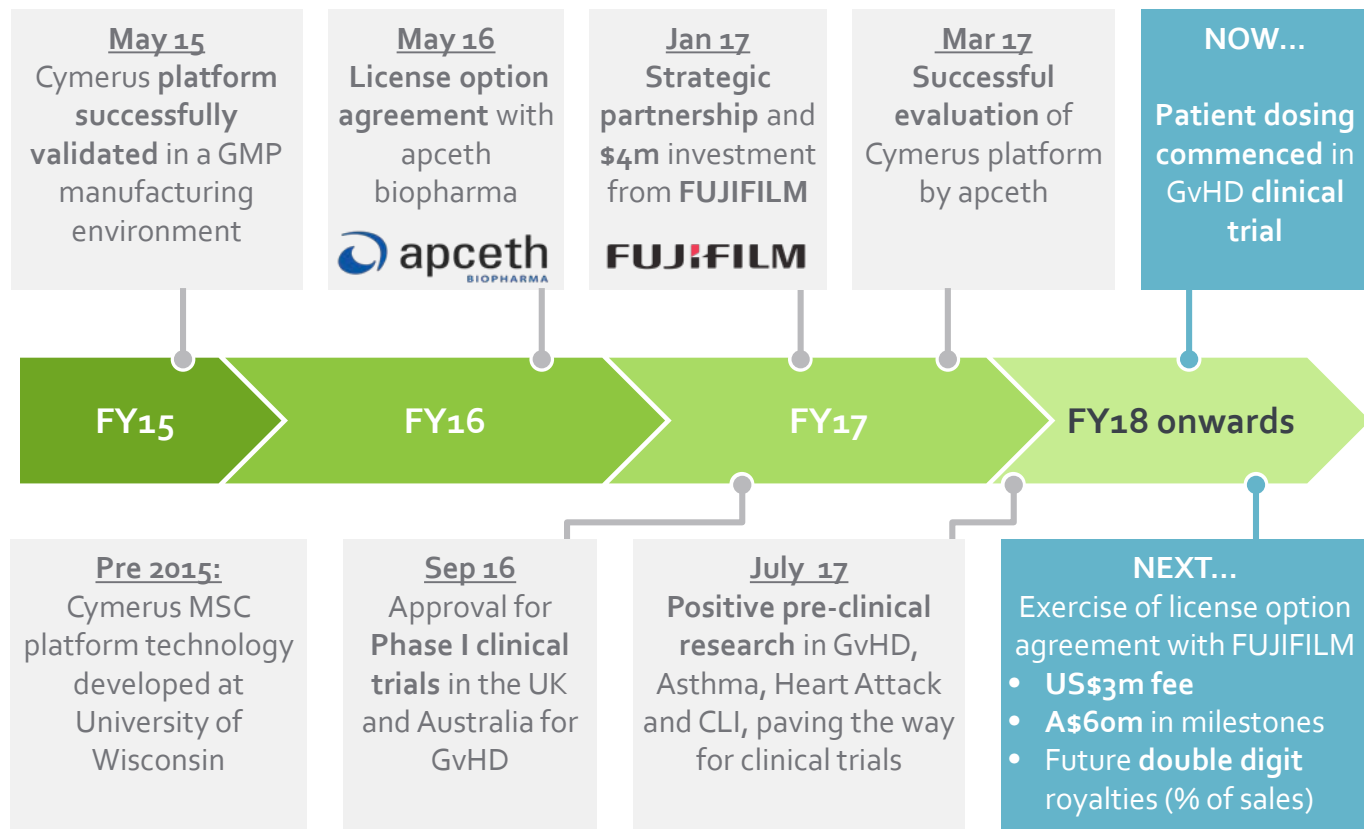
Notes: ASX listed peers incorporates the average share price movements of MSB, RGS, CTE, OCC, LCT over the last 6 months

Cynata Therapeutics is at an inflection point as it accelerates clinical testing



World firsts:

- Scalable manufacture of MSCs without reliance upon multiple donors
- First clinical trial of an allogeneic, iPSC-derived MSC product



Clinical development, product and technology validation and manufacturing optimisation → *Execution of clinical trial and commercialisation strategy*

Why MSCs?

What are MSCs?

- Mesenchymal stem cells (MSCs) are highly potent adult stem cells found in bone marrow and certain other tissues.

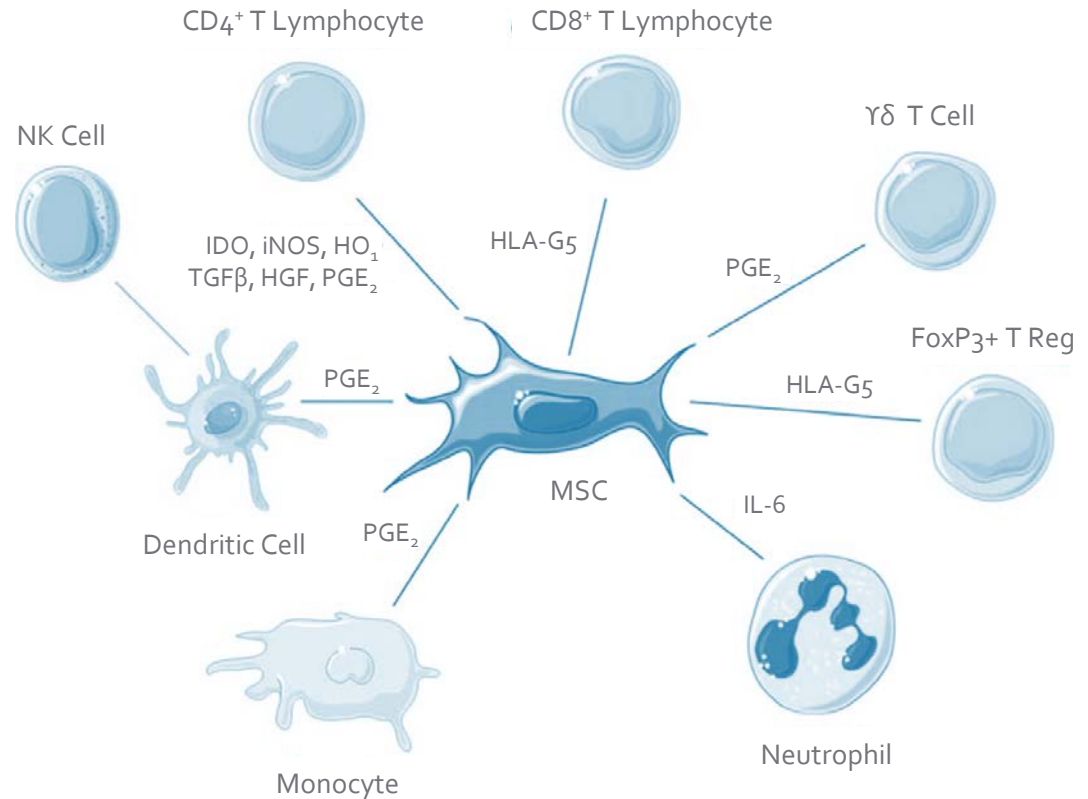
What do they do?

- They have the ability to self renew.
- They secrete bioactive molecules and have immunosuppressive and immunoregulatory properties – giving them enormous therapeutic potential.

How much commercial interest is there?

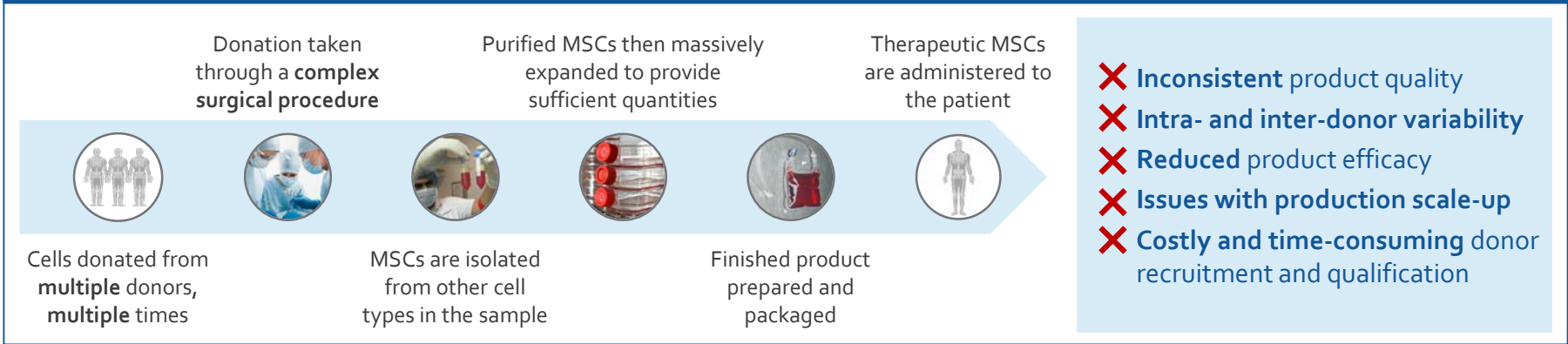
Over 650 clinical trials investigating the efficacy of MSCs in treating diseases have been initiated.¹

Promising results have been shown in conditions such as heart attack, stroke, GvHD, Crohn's disease, multiple sclerosis, osteoarthritis and diabetes complications

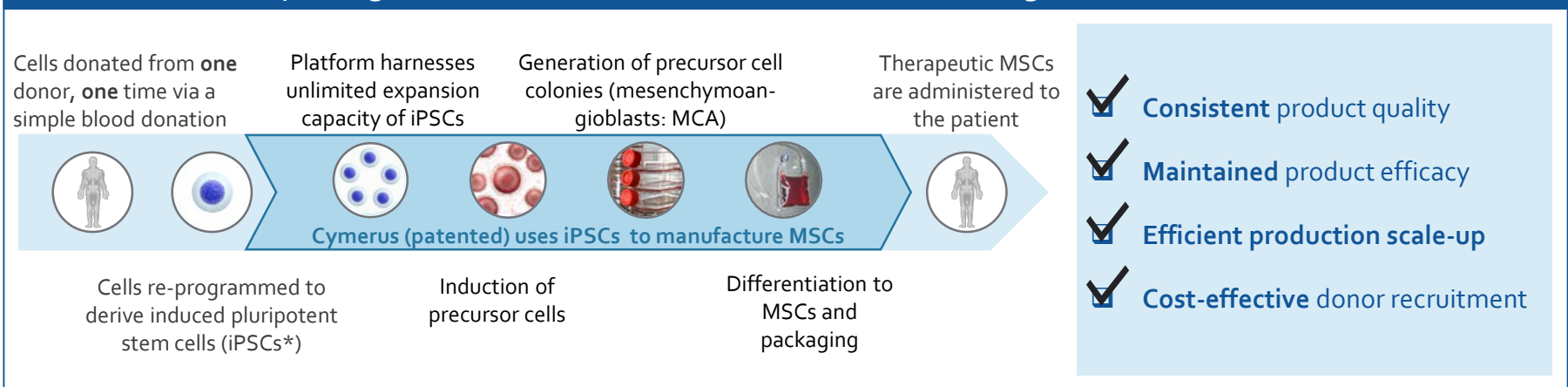


Only company in the world with a platform to mass-produce MSCs without multiple donors

First generation process has multiple shortcomings



Cynata's patented Cymerus platform overcomes these challenges by using induced iPSCs that are derived from a single blood donation



*iPSCs are derived from e.g. blood cells and have been reprogrammed back into an embryonic-like state that enables the development of an unlimited source of virtually any type of human cell."

Regenerative medicine market growing rapidly and MSCs are a major growth driver

How big is the market for regenerative medicine?

“Global regenerative medicine market was worth \$18.9 billion in 2016 and will grow to over \$53.7 billion by 2021¹”

“Stem cells are the cornerstone of contemporary regenerative medicine applications²”

How feasible are MSCs as a treatment?

Over 650 clinical trials investigating the efficacy of MSCs in treating diseases have been initiated.³

Promising results have been shown in conditions such as heart attack, stroke, GvHD, Crohn's disease, multiple sclerosis, osteoarthritis and diabetes complications

Cynata is operating in a highly active market

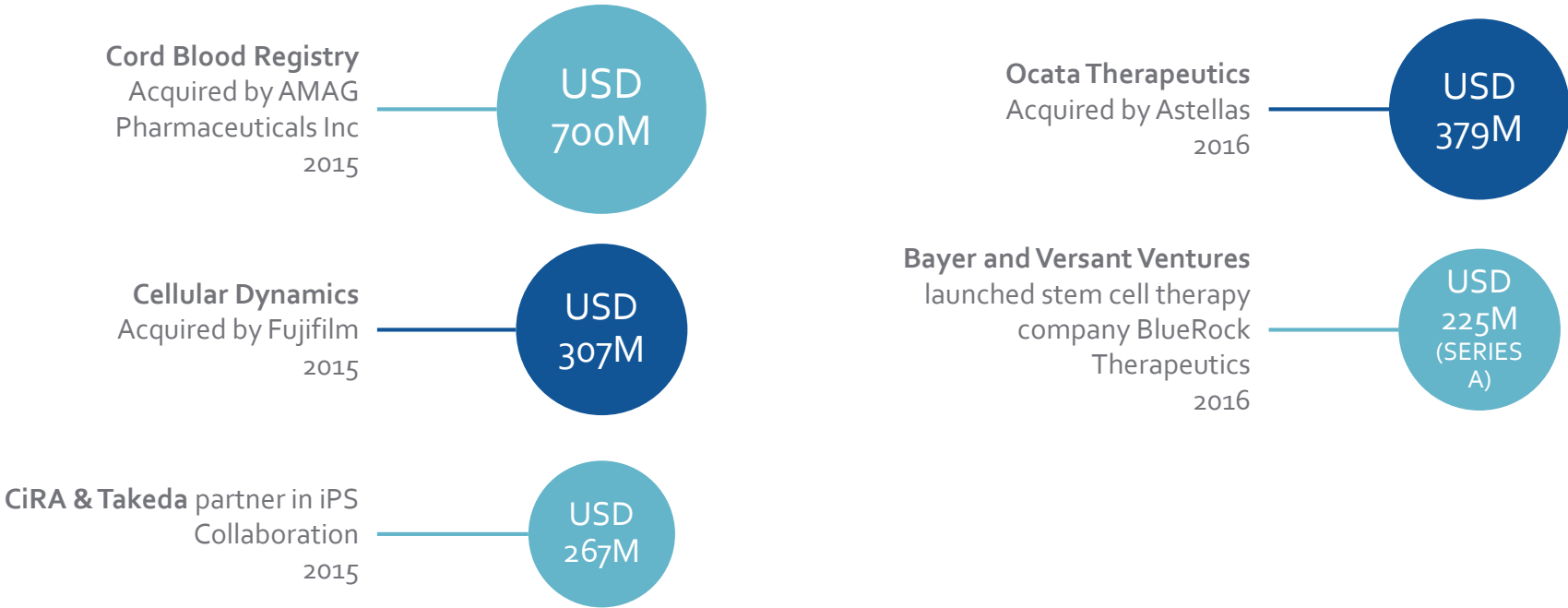


Cellular therapy is a key category and no longer an evolving market

August: US FDA approved Novartis' product, Kymriah, a T cell (CAR-T) treatment for leukemia

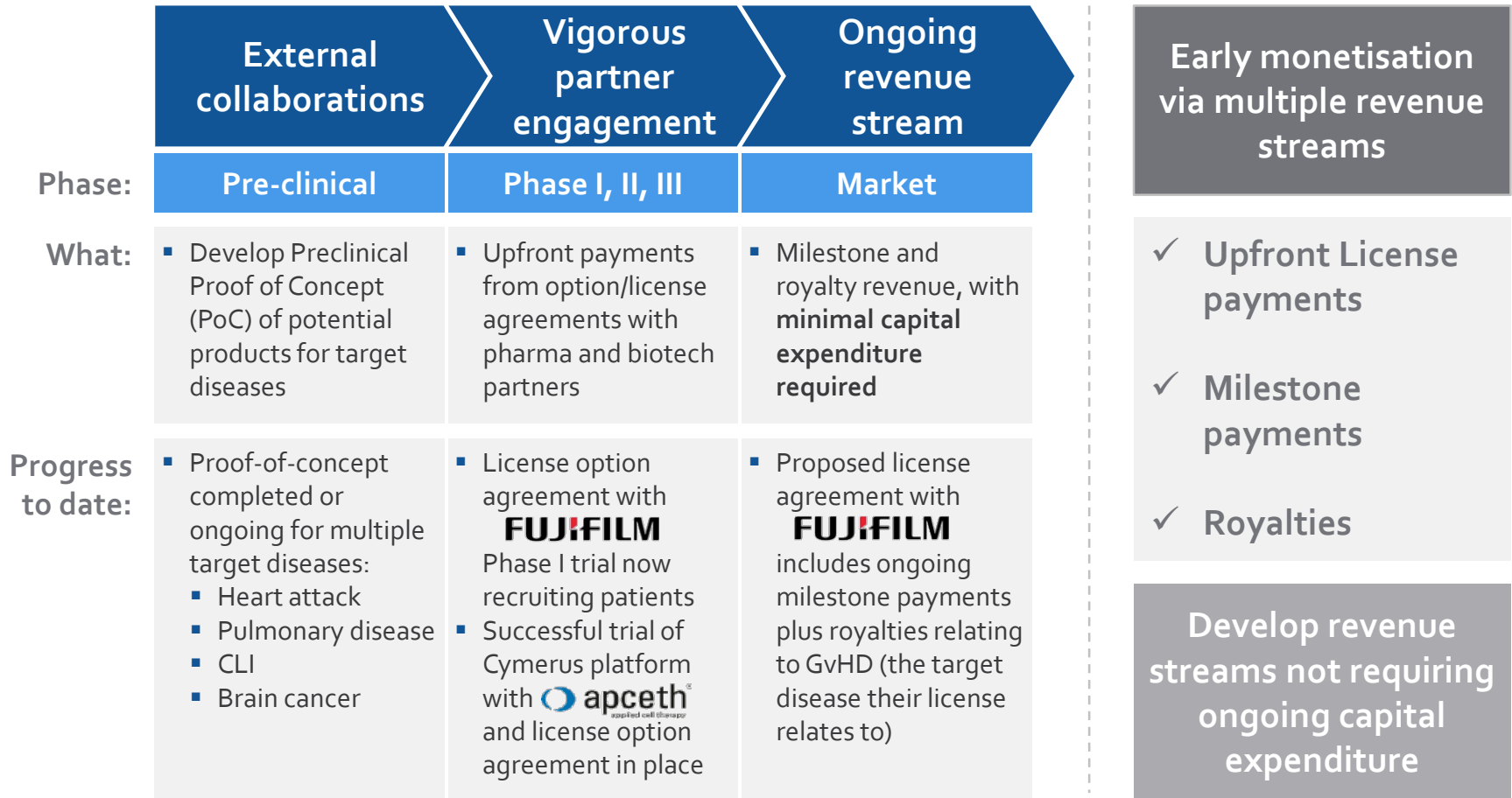
August: Gilead to acquire Kite Pharma for US\$11.9b. Kite develops similar CAR-T cell products for cancer treatment

October: FDA approved Kite Pharma's product, Yescarta, a CAR-T treatment for leukemia









+ multiple license agreements over recent years

Our platform provides a scalable business model, applicable to a broad range of disease targets



Progress made against business model

Disease target area	External collaborations		Vigorous partner engagement		Further revenues	Key highlights
	Pre-clinical trials started	Proof of concept completed	Deal secured	Clinical trial started	Product in-market	
Graft v Host Disease (GvHD) University of Massachusetts 	✓	✓	✓	✓		<ul style="list-style-type: none"> Pre-clinical research with University of Massachusetts show Cymerus MSCs to be highly effective in GvHD Half a billion dollar market by 2021
Asthma Monash University 	✓	✓				<ul style="list-style-type: none"> Cymerus MSCs demonstrated significant beneficial effects on three key components of asthma: airway hyper-responsiveness, inflammation and airway remodeling.
ARDS Critical care research group 	✓					<ul style="list-style-type: none"> Study to commence to evaluate effectiveness of Cymerus MSCs in sheep with ARDS in association with the Prince Charles Hospital in Brisbane.
Heart attack University of Sydney 	✓					<ul style="list-style-type: none"> Pre-clinical trials suggest Cymerus MSCs may have the potential to restore cardiac function and reduce scar size after a heart attack (US\$18.2 billion market by 2019¹)
Brain Cancer / Glioblastoma Harvard/BWH 	✓					<ul style="list-style-type: none"> Research collaboration in genetically modified MSCs in cancer: involves modifying stem cells to target cancer
Critical Limb Ischemia University of Wisconsin-Madison 	✓	✓				<ul style="list-style-type: none"> Pre-clinical study published in peer reviewed journal <i>Cytotherapy</i>, <i>The Journal of Cell Therapy</i>. Study found treatment with MSCs demonstrate beneficial impact on CLI.

Successful outcomes open many other disease targets potentially benefiting from MSC treatment

Note: ARDS – Acute Respiratory Distress Syndrome

Source: 1. <http://gbiresearch.com/media-center/press-releases/cardiovascular-disease-market-us-to-lead-modest-growth-forecasts-gbi-research>.

Business is focused on progressing the world-first clinical trial of CYP-001 in GvHD

Pre-clinical	<input checked="" type="checkbox"/> Cymerus™ MSCs demonstrated a significant survival benefit in a pre-clinical rodent model of Graft vs. Host Disease	Completed
	<input checked="" type="checkbox"/> License option agreement secured with Fujifilm, including upfront payments and potential for ~US\$30m annual royalties	Completed
World first clinical trial of CYP-001	<input type="checkbox"/> Cohort A: 8 participants recruited and receive two CYP-001 infusions at lower dose level (1 million cells / kg)	8/8 patients recruited
	<input type="checkbox"/> Independent safety and monitoring review (DSMB) triggered 28 days after last member of cohort A receives infusion	Not yet commenced
	<input type="checkbox"/> Cohort B: Further 8 participants receive two CYP-001 infusions at the higher dose level (2 million cells / kg)	Not yet commenced
	<input type="checkbox"/> Results from phase 1 trial shared	Not yet commenced

GvHD was the optimal first target area for several medical and commercial reasons

- MSCs have already shown to be an effective treatment against GvHD
In Japan MSCs have been approved for use as a treatment for GvHD
- Short trial duration, with expected completion in early 2018
- Successful Cynata trial outcome opens the door to multiple further indications

1
million

Stem cell transplants
worldwide ³

25
million

International Marrow
Donor Registries and
Potential Donors ⁴

70%

GvHD occurs in up to 70
per cent of patients
receiving stem cell
transplant to treat blood
cancer¹

\$500m

market value for the
treatment of GvHD²
by 2021

FUJIFILM's projections for the GvHD market show peak revenues of US\$300m p.a. which would result in >US\$30m per year in royalties for Cynata

Sources: 1. <http://www.qimrberghofer.edu.au/2017/04/immune-cell-discovery-opens-possibility-new-treatment-deadly-disease/>

2. [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)

3. http://www.fcarreras.org/en/a-total-of-1-million-stem-cell-transplants-have-been-performed-worldwide_147898

4. <https://bethematch.org/news/news-releases/international-marrow-donor-registries-reach-25-million-potential-donors--give-hope-to-searching-blood-cancer-patients-around-the-world/>

Fujifilm has demonstrated confidence in Cynata's platform through a licensing agreement for GvHD

FUJIFILM is one of the largest global investors in regenerative medicine

- **2014: Fujifilm takes a controlling stake in Japan Tissue Engineering Co. (J-Tec)**
 - J-Tec is a leading manufacturer of tissue engineered medical products, used in regenerative medicine
- **2015: Fujifilm paid US\$307m for CDI, Cellular Dynamics International**
 - CYP sourced its iPSC's from CDI
- **2016: Fujifilm acquires Takeda Pharmaceuticals' >70% stake in Wako Pure Chemical Industries for US\$1.3bn. Synergies include:**
 - Regenerative medicine (particularly cell based therapies); Contract Development and Manufacturing Organization (CDMO) in Pharmaceutical Business
- **2017: Fujifilm Holdings Corp said it aimed to spend 500 billion yen in strategic acquisitions over 3 years (all outside its photo film business)**

License overview: Development and commercialisation of Cynata's MSCs for GvHD

Strategic equity
(A\$4m)

- Fujifilm receives **9%** equity in Cynata via Placement

Exercise of Fujifilm option
(US\$3m)

- Any time up to 90 days after completion of Phase 1 trial.
- Upfront **US\$3m** milestone payment
- Fujifilm responsible for all further development activities and costs

Phase 2 and beyond
(US\$30m+ p.a.)

- Fujifilm to pay Cynata **agreed milestones (\$60m+)** and **double-digit royalties** on product sales
- FUJIFILM's projections for the GvHD market show **peak revenues of US\$300m p.a.** correlating to **>US\$30m** per year in royalties for Cynata

Board and management overview



Dr Paul Wotton
Chairman

- Former CEO of Ocata Therapeutics (NASDAQ: OCAT) managing it through a take-over by Astellas Pharma, in a US\$379m transaction
- Previous executive roles with Antares Pharma Inc. (NASDAQ: ATRS), Topigen Pharmaceuticals and SkyePharma
- Founding CEO, Sigilon Therapeutics; member of the boards of Vericel Corporation and Veloxis; past Chairman of the Emerging Companies Advisory Board of BIOTEC Canada

Expertise running and monetising Ocata Therapeutics, acquired by Astellas



Dr Ross Macdonald
Managing Director
Chief Executive Officer

- 30 years' experience and a track record of success in pharmaceutical and biotechnology businesses
- Previous senior management positions with Hatchtech, Sinclair Pharmaceuticals, Connetics Corporation (Palo Alto, CA), and Stiefel Laboratories, the largest independent dermatology company in the world and acquired by GSK in 2009 for £2.25b

Track record of success in pharmaceutical and biotechnology businesses



Dr Stewart Washer
Non-Executive
Director

- 20+ years of CEO and Board experience in medical technology, biotech and agrifood companies
- Chairman of Orthocell Ltd and Minomic International.
- Previously CEO roles with Calzada (ASX:CZD), Phylogica (ASX:PYC) and Celentis and managed the commercialisation of intellectual property from AgResearch in New Zealand with 650 Scientists and \$130m revenues

Deep experience growing companies as CEO and on the Board



Dr John Chiplin
Non-Executive
Director

- Significant international experience in the life science and technology industries
- Recent transactions include US stem cell company Medistem (acquired by Intrexon), Arana (acquired by Cephalon), and Domantis (acquired by GSK)
- Was head of the \$300M ITI Life Sciences investment fund in the UK and his own investment vehicle, Newstar Ventures.

Overseen and managed a broad range of life sciences transactions



Mr Peter Webse
Non-Executive Director
Company Secretary

- +25 years' company secretarial experience
- Managing Director of Platinum Corporate Secretariat Pty Ltd, a company specialising in providing company secretarial, corporate governance and corporate advisory services

25+ years company secretarial and management experience



Dr Kilian Kelly
Vice President,
Product Development

- 15 years' experience in pharmaceutical/ biotechnology research and development, in both commercial and academic settings
- Previous appointments include Senior Director, Drug Development at Biota Pharmaceuticals (NASDAQ: BOTA), Vice President, Regulatory and Clinical at Mesoblast Limited (ASX:MSB)

Academic and commercial excellence, extensive relevant management experience

Investment Summary

- **Scalable, world-first technology:** Cymerus platform overcomes inherent challenges of other production methods, and enables mass-production of therapeutic MSCs
- **Technology already being monetised:** Licensing agreements with Fujifilm and apceth Biopharma. Fujifilm license option worth up to \$60m plus royalties
- **Clear regulatory path:** Japan, US and EU accelerating legislative changes to accelerate stem cell therapy research and uses
- **Clinical trials ongoing:** Phase I clinical trials commenced in UK and Australia in GvHD
- **Near-term news flow:** Value-accretive news flow expected in near term, with a DSMB 'halfway update' expected for the phase I GvHD trial following recruitment of the 8th patient



Thank you for your attention

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