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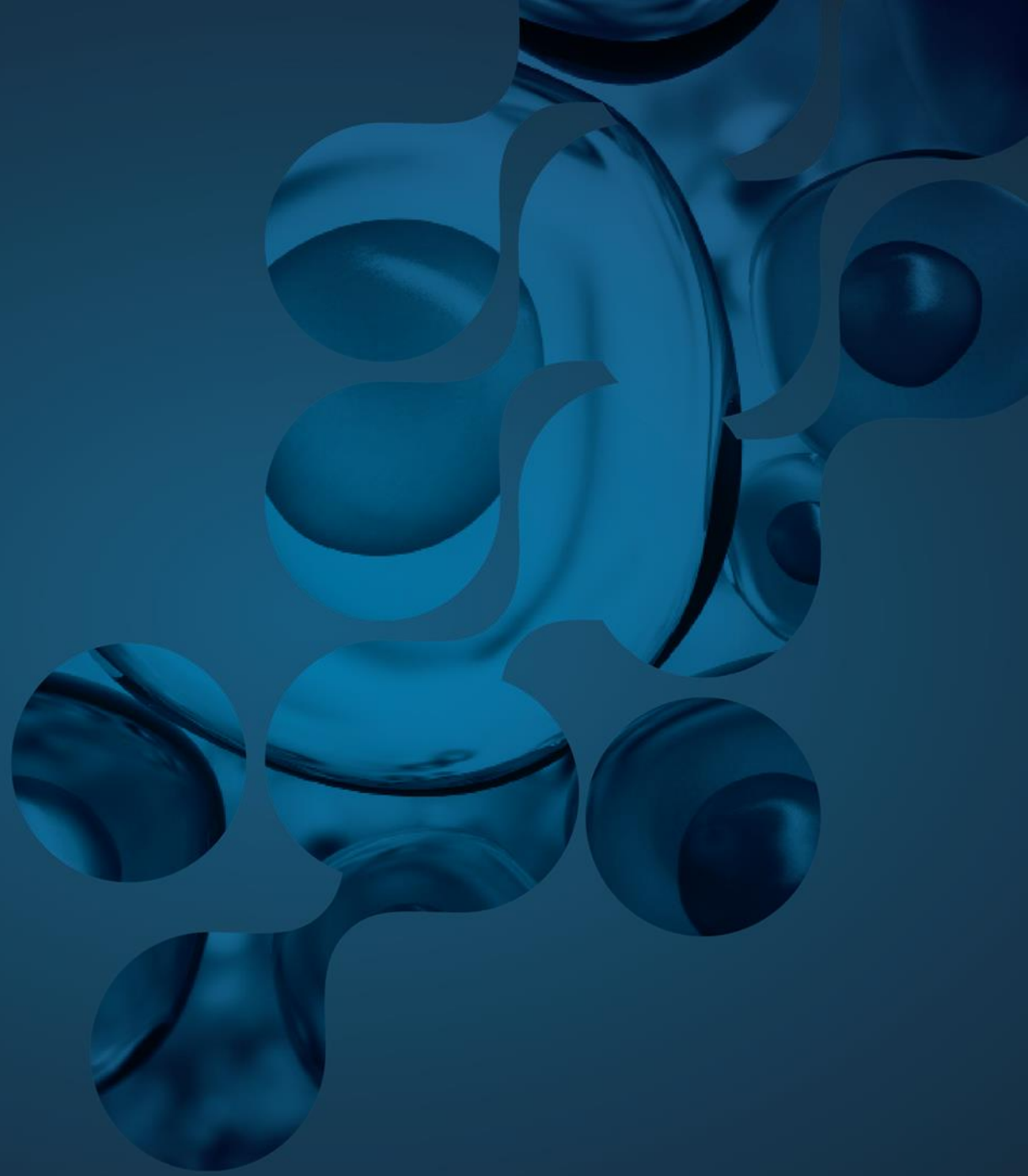
A Next Generation Stem Cell Therapeutics Company

Investor Presentation: Cynata Therapeutics Limited

11 December 2020



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Executive summary

Next generation stem cell company	• Clinical stage therapeutic mesenchymal stem cell (MSC) pipeline: osteoarthritis, COVID-19 (respiratory distress) and, via licensee FUJIFILM, graft-versus-host disease (GvHD) • Multiple additional value creation pathways through expanding the clinical development pipeline
Highly scalable and validated platform	• Cynata's proprietary, patented Cymerus™ platform technology enables commercially scalable production of MSCs from a single donation - overcoming multiple issues with existing manufacturing solutions • Compelling GvHD clinical trial results places Cynata in a strong position to accelerate clinical development, enabling other indications to progress directly to Phase 2 / 3 clinical trials (i.e. bypass Phase 1 studies)
Expanding pipeline	• Opportunity to expand the clinical development to include target indications: critical limb ischemia (CLI); idiopathic pulmonary fibrosis (IPF); renal transplantation; and diabetic foot ulcers (DFU)
Exciting outlook with potential upside	• Multiple upcoming catalysts including clinical development milestones in active and planned trials, potential milestone payments and royalties from the FUJIFILM license in GvHD and other potential strategic collaborations
Capital Raising	• Capital raising of up to approximately A$20.5m via an Institutional Placement (A$15.0m) and a 1 for 15 Non-Renounceable Entitlement Offer (up to A$5.5m) at an offer price of A$0.70 per New Share • Proceeds raised will primarily be used to expand the clinical development pipeline (incl. additional Phase 2 trials) and optimising manufacturing capabilities to enhance scale-up efficiencies for commercialisation

Company overview

Cynata Therapeutics is a clinical stage biotech company with a highly scalable, proprietary platform for developing stem cell therapeutics

About Cynata Therapeutics

- **Our focus: Utilise our proprietary Cymerus™ platform technology to develop commercially scalable mesenchymal stem cell (MSC) therapeutic products to treat serious disorders**
- Stem cell and regenerative medicine company developing technology from the University of Wisconsin-Madison, USA
- First product, CYP-001, licensed to Fujifilm for graft-versus-host-disease
- Multiple further possible license transactions
- 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

Board and Management

Dr Geoff Brooke
Chairman

Dr Ross Macdonald
Managing Director / CEO

Dr Stewart Washer
Non-Exec Director

Dr Paul Wotton
Non-Exec Director

Dr Darryl Maher
Non-Exec Director

Dr Kilian Kelly
Chief Operating Officer

Financial information

Share price (8-Dec-20)	A$0.785
Shares on issue	117m
Market capitalisation	**A$91.9m**
Cash[1]	A$12.3m
Debt	-
Enterprise value	**A$79.6m**

Top Shareholders

Fidelity INTERNATIONAL	**9.9%**
FUJIFILM	**6.9%**
Board and management	**5.8%**

1. Cash as at 30 September 2020 (excludes the proceeds of the capital raising)

Conventional vs. Cynata's Cymerus MSC manufacturing process

The current conventional manufacturing process is ***sub optimal***

Cells donated → **Conventional process** → **MSCs**

Cells from multiple donors

Substantial variability in starting material

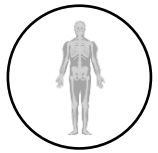
MSC isolation

Limited quantity of MSCs produced per donation

MSC expansion

Large number of MSCs required

Cellular therapies administered



Cynata's Cymerus iPSC-derived process ***optimises manufacturing for scalability***

Cells donated → **Cynata's patented process: Cymerus** → **MSCs**

✓ ***Completed***

Cells from **one** donor

iPSC Derivation

Avoids inter-donor variability

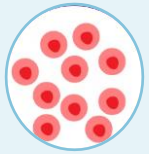
CONSISTENCY

iPSC Expansion

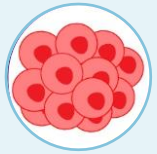
Effectively limitless expansion

QUANTITY

Precursor cells



Generation of MCA Colonies



Differentiation into MSCs

Minimal MSC culture expansion

QUALITY

Cellular therapies administered

EFFICIENCY

iPSC: Induced Pluripotent Stem Cells. iPSC's derived directly from adult cells and can propagate indefinitely.
MCA: Mesenchymoangioblasts. These are produced from iPSCs.

Commercially viable MSC manufacturing process

Cynata has the only clinical-stage platform capable of producing commercial quantities of MSCs from a single source

	Conventional process	Cymerus	*Significance for Cynata*
Donors	Continuous supply of new donors required	One donor, one time *(completed)*	✓ *Lower cost; simplified logistics; highly consistent product*
Comparability testing	Required every time a new donation is used	N/A	✓ *Lower cost, minimised risk*[1]
Number of clinical doses per donation	Significantly limited	Effectively limitless	✓ *Lower cost; simplified logistics; comparative ease of scalability*
Extent of MSC expansion	Higher *(>25 population doublings)*	Lower *(~10 population doublings)*	✓ *Minimised expansion and low "age" ensures Cynata's product is consistently highly potent, with potency maintained*[2]
Cellular "age"	Variable	Low: iPSC-derived MSCs are more primitive	
Infusions per patient[3]	8-12	~2	✓ *Greater convenience for patients and hospitals; lower costs incurred by healthcare system*
Risk of contamination with off-target cell types[4]	Medium to high, depending on process	Negligible	✓ *Lower risk of manufacturing variability and batch failure; significant regulatory benefits*

Cynata's Cymerus produces a consistent and scalable product, with lower cost of goods on a per cell basis and fewer cells required per patient compared to conventional methods

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1. MSC product from different donors must be proven to be comparable: highly risky given every donor is different
2. Conventional manufacturing process requires extensive MSC culture expansion. MSCs change when excessively expanded, causing a loss of potency and decreased efficacy
3. Only 2 infusions per patient required in Cynata's Phase 1 GvHD trial
4. Contamination with off-target cell types – isolation of MSCs in original sample is associated with risk of carry-over of other cell types

FDA focus on manufacturing

Cynata's Cymerus process actively addresses some of the key areas that the FDA is likely to focus on

Potential issues raised

"The issue of reliable prediction of biological activity is particularly challenging for MSCs.

Substantial functional heterogeneity has been observed between MSC batches derived from different donors *and expanded using different tissue culture conditions or duration, even though all of these batches meet the ISCT criteria for MSCs."*

- Excerpt from FDA ODAC Briefing document for 13 August 2020

Key advantages underpinning Cymerus

- ✓ Product derived from a **single donor** provides **a highly consistent product and addresses regulatory concerns**
- ✓ **Effectively limitless iPSC expansion** *before* differentiating into MSCs, maintaining potency
- ✓ MSCs represent a potential efficacious treatment in GvHD, **supporting Cynata's GvHD product CYP-001**
- ✓ FDA advisory meeting observations to be leveraged to **optimise future CYP clinical trial design for FDA approval**

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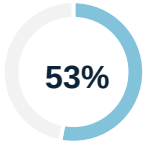
Source: FDA Briefing Document, Oncologic Drugs Advisory Committee (ODAC) Meeting. Session on Product Characterization (AM Session) 13 August, 2020.

Phase 1 clinical trial results

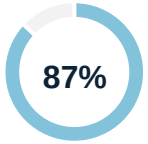
Excellent results in the world-first allogeneic iPSC-derived therapy trial in steroid-resistant acute graft-versus-host disease (GvHD) places Cynata in a strong position to accelerate clinical development

Key clinical trial results[1] - demonstrating efficacy of our technology

All endpoints achieved



Complete response



Overall response

Survival rate

Efficacy endpoints

Endpoints were the **same as those required in a Phase 3 trial** (in contrast to early stage trials for some conditions)

High response rates

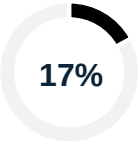
Response rates were **higher than what we expect would be required in Phase 3**, to support marketing approval

Two year follow-up

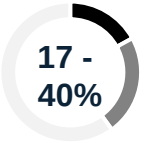
Overall survival Rate

Cynata MSCs

Compares favourably with other results



Standard of care[2]



Other MSC products[3]

Excellent safety results facilitate Cynata progressing directly to phase 2 clinical trials in multiple other indications

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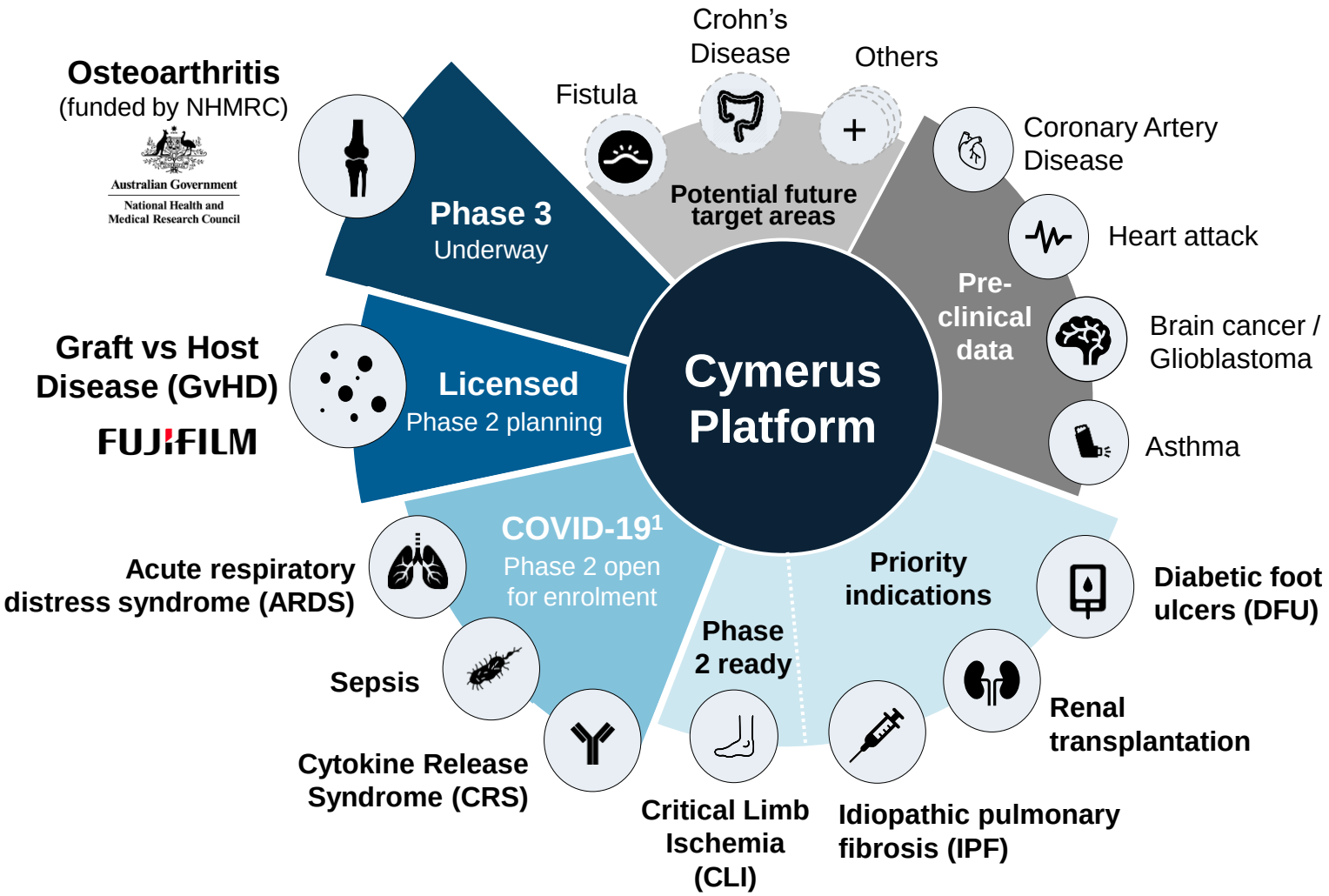
1. Primary evaluation at Day 100
2. Westin JR, et al. Steroid-Refractory Acute GVHD: Predictors and Outcomes. Adv Hematol. 2011; 2011:601953;
3. Elgaz, S. et al. Clinical Use of Mesenchymal Stromal Cells in the Treatment of Acute Graft-versus-Host Disease. Transfus Med Hemother.46:27-34 (2019).

Cymerus platform

Cynata's Cymerus platform has potential applications across a wide range of diseases



1. Investigating efficacy in patients admitted to ICU, commonly experiencing ARDS, sepsis and CRS

Multiple options to create shareholder value

Cynata is executing on a clear scientific and commercial vision and continually assesses pathways to optimise shareholder value

Build value in platform **independently**

Clinical trials – funded by Cynata, grants or collaborations, such as osteoarthritis and COVID-19 trials and advancing pre-clinical development programs

License / partner with big Pharma

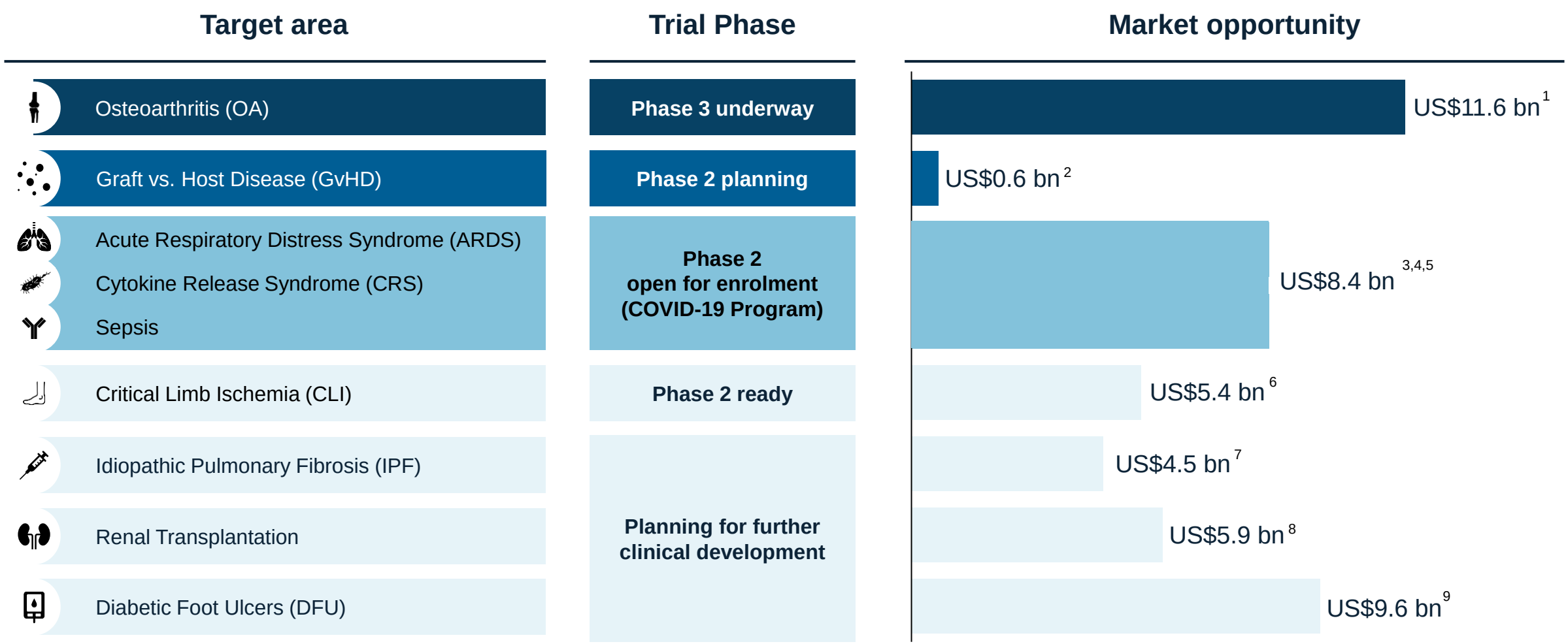
License specific indications for development and commercialisation, such as GvHD (FUJIFILM); in regular discussions with other parties across a range of indications

Strategic exit / merger

Monetisation via a strategic acquirer (e.g. big Pharma); interest demonstrated by previously announced proposal

Significant market opportunities

Cynata is targeting attractive market opportunities across a range of target indications



1. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025) (Reflect OA market by 2025); 2. Global Graft versus Host Disease Market 2019-2029 (Reflects forecast market in 2026). 3. Vasomune Therapeutics company announcement, 2018 (Reflects ARDS global market opportunity of US$2.5bn)
4. GlobeNewswire, 2020 (Represents CRS global market opportunity of US$0.16m in 2017) 5. GlobalData 2017 (Reflects Sepsis global market opportunity of US$5.9bn in 2026). 6. Zion Market Research, 2019 (represents global treatment market in 2025); 7. iHealthcareAnalyst Inc, 2019 (represents global market by 2025); 8. Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc.,2019; 9. Transparency Market Research, 2020 (Reflect global DFU treatment market by 2027).

Expanding clinical development pipeline

	Idiopathic pulmonary fibrosis	Renal transplantation	Diabetic foot ulcer
Disease description	• Incurable disease of unknown cause, which results in extensive scarring / fibrosis of the lungs • Lung damage is often advanced when first diagnosed and invariably progresses to respiratory failure with only 20-30% of patients surviving 5 years from diagnosis[1]	• Treatment for end-stage kidney disease, where the kidneys are no longer able to function and a transplant is required to eliminate patient' reliance on dialysis	• Sores on the feet of patients with diabetes that occur in around 15-25% of patients sometime during their lifetime[2] • Associated with significant morbidity and mortality and can lead to hospitalisation and lower limb amputation if not treated in a timely manner
Rationale for selection	• High unmet medical need; existing treatments have limited effects on disease progression or survival rates ✓ Studies conducted in preclinical rodent models of IPF demonstrated efficacy of Cymerus MSCs, based on statistically significant improvements in multiple clinically relevant outcome measures, including levels of fibrosis, inflammation, dynamic lung compliance and airway resistance	• Current treatments (lifelong immunosuppression) are associated with significant morbidity ✓ Cymerus MSC treatment in a preclinical transplant model demonstrated immunoregulatory effects expected to prevent or reduce organ transplant rejection	• Among the most common and serious complications of patients who have diabetes ✓ Cymerus MSCs achieved encouraging efficacy results in a preclinical model of diabetic ulcers
Next steps	• Preparation for clinical development programs underway • Key elements include: Trial design; Regulatory consultation; Endpoint selection; KOL appointment; Site selection		

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1. Ley B, et al. Clinical course and prediction of survival in idiopathic pulmonary fibrosis. Am J Repsir Crit Care Med. 2011;183(4):431-40.https://www.ihealthcareanalyst.com/report/idiopathic-pulmonary-fibrosis-treatment-market/
2. Mutluoglu M, Uzun G, Turhan V, Gorenek L, Ay H, Lipsky BA. How reliable are cultures of specimens from superficial swabs compared with those of deep tissue in patients with diabetic foot ulcers? J Diabetes Complications. 2012 May-Jun;26(3):225-9

Critical Limb Ischaemia (CLI) trial

Phase 2 ready trial with regulatory and ethics approval received

CLI	• MSC therapy for critical limb ischemia patients who are ineligible for revascularization, to promote angiogenesis and reduce inflammation
Rationale for selection	• Cymerus preclinical studies were impressive; animals treated with Cymerus MSCs experienced improved blood flow and faster blood flow recovery when compared to the control group treated with saline • Development timeline is relatively rapid
Study design	• Cynata anticipates conducting the clinical trial at multiple centres in the UK and Australia • The planned trial aims to recruit 90 patients with Rutherford Classification 5 CLI[1], randomised to one of 3 groups (low dose MSCs; high dose MSCs; placebo) • Primary endpoint is improvement in Rutherford Classification at 12 months • Secondary endpoints include amputation-free survival, ankle-brachial index, wound healing, pain and quality of life (reviewed over 6-24 months)
Key milestones	✓ Regulatory and Ethics approvals received in Australia and UK • Trial timing uncertain due to continued impact on recruitment due to COVID-19; trial is being assessed as part of broader clinical development strategy

1. The Rutherford Classification is a well-established 6-point scale to grade the extent of peripheral artery disease. Grades 4-6 constitute CLI.

Osteoarthritis Phase 3 trial underway

Stem Cells as a symptom- and strUcture-modifying Treatment for knee OsteoaRthritis (SCUlpTOR); new Phase 3 program funded by the National Health and Medical Research Council

Target population

- Assess the effect of Cymerus MSCs on clinical outcomes and knee joint structures of 440 patients with osteoarthritis of the knee (compared to a placebo)

Rationale for selection

- Preclinical research showed MSCs can exert a number of important effects, including release of cytokines and growth factors that reduce inflammation and promote tissue repair, new blood vessel formation, and regeneration of compromised cartilage which may result in improved outcomes for patients

Study design

- Randomised, double-blind placebo-controlled trial to take place at study centres in Sydney and Tasmania
- 440-patient participants will receive intra-articular injections of Cymerus MSCs or placebo on three occasions over a period of 1 year, and will be followed up for a total of two years from enrolment
- Co-primary endpoints at 24 months are: (i) the proportion of participants achieving patient-acceptable symptom state (PASS) for knee pain; (ii) central medial femorotibial (cMFT) cartilage loss from baseline
- Secondary outcomes include assessments of pain, other symptoms, physical function, quality of life

Key milestones

- ✓ Sponsored by the University of Sydney
- ✓ Funded by an NHMRC project grant and in-kind contributions from participating institutions[1]
- ✓ Ethics approval and TGA clearance obtained via the Clinical Trial Notification process
- ✓ **Phase 3 clinical trial in Osteoarthritis underway**

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1. No cash contribution from Cynata - Cynata to supply Cymerus MSCs for use in the trial and will retain full commercial rights to the use of Cymerus MSCs in osteoarthritis

COVID-19 Phase 2 trial open for enrolment

MEseNchymal coviD-19 Trial (MEND); a Phase 2 Program in COVID-19 and related respiratory diseases

Target population	• 24 adult patients with COVID-19 admitted to intensive care with compromised lung function, which can ultimately progress to ARDS
Rationale for selection	• Respiratory distress (and CRS and sepsis) represent significant unmet needs as consequence of a severe COVID-19 infection, as well as other causes beyond COVID-19 • Strong pre-clinical results in indications that can arise from a severe case of COVID-19 • Marked public health interest, allowing accelerated program planning and approval
Study design	• In collaboration with CPA Research Institute[1] and COVID-19 Stem Cell Treatment Group • Open-label, randomised controlled clinical trial based in NSW, Australia • Twelve patients randomised to receive Cymerus MSC infusions in addition to standard care; twelve patients randomised as the control group, to receive current standard of care • Primary endpoints: an improvement in PaO2/FiO2 ratio, and safety & tolerability
Key milestones	✓ Ethics approval obtained ✓ Patient enrolment open • Cynata assessing opportunities to accelerate recruitment

1. CPA = Cerebral Palsy Alliance

GvHD Clinical and Commercial Program led by FUJIFILM

Global licensee FUJIFILM responsible for further development & commercialisation of Cymerus MSCs as a treatment for steroid resistant acute GvHD

GvHD

- GvHD is a complication that can occur after bone marrow transplant when the donor's immune cells (the 'graft') attacks the recipient (the 'host')

Rationale for selection

- Prognosis of patients is poor, with mortality rates in excess of 90%[1]
- Excellent Phase 1 efficacy endpoints results - which are the same endpoints required in a Phase 3 trial

FUJIFILM

- FUJIFILM endorsement with a global GvHD license
- All further development and commercialisation costs met by FUJIFILM

Key milestones

- Further clinical trials in GvHD led by FUJIFILM
- Multiple cash flow events in relation to FUJIFILM license:
  - ✓ A$4m equity @ 35% premium
  - ✓ US$3m upfront licence fee
  - A$2.86m on completion of Phase 2 trial[2]
  - A$100m+ in potential milestone payments and royalties [2]
- Ongoing relationship with potential for further commercial agreements
- FUJIFILM transaction provides validation of Cymerus and supports the licensing of additional target areas

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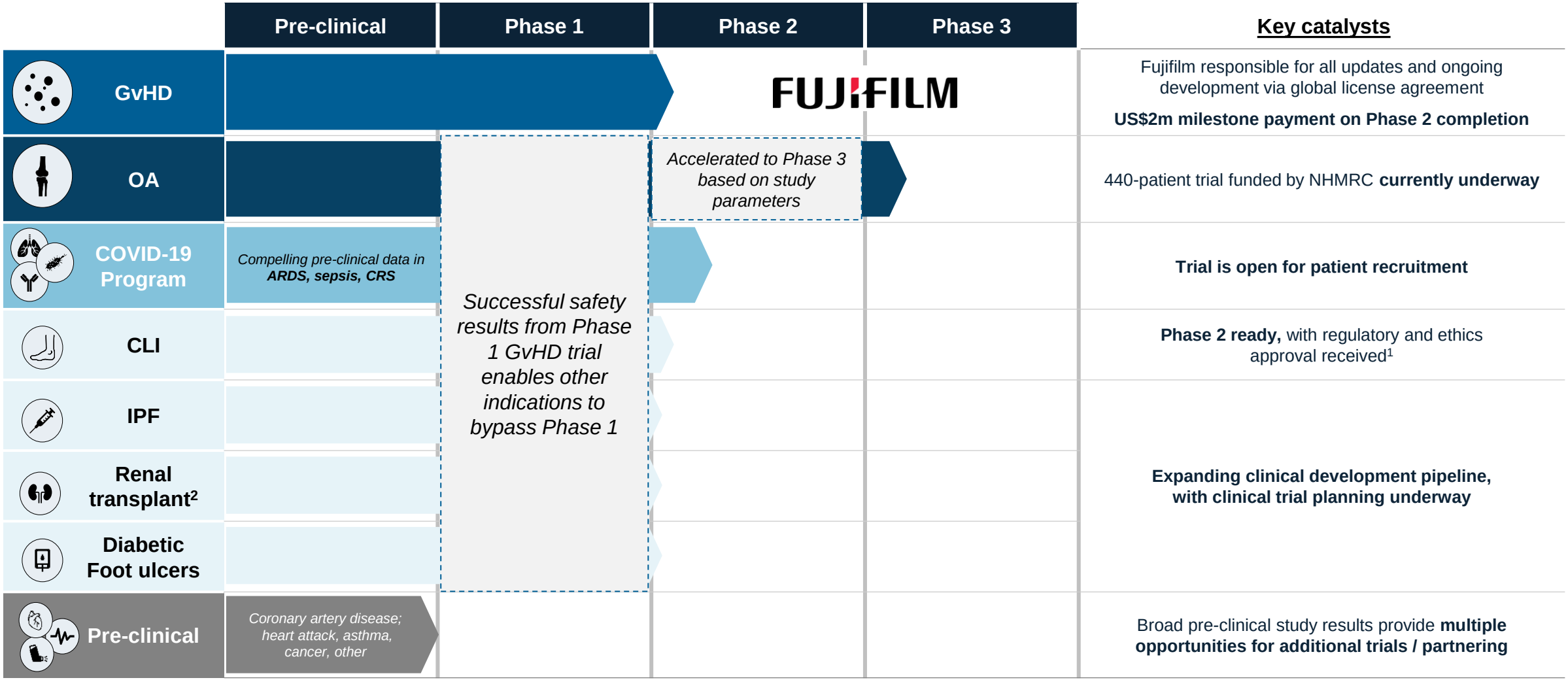
1. Westin JR, Saliba RM, De Lima M, et al. Steroid-Refractory Acute GvHD: Predictors and Outcomes. Adv Hematol. 2011; 2011;601953.
2. US$1.00 = AUD$1.40

Development pipeline

Broad, advanced development pipeline with multiple near-term catalysts



1. Trial timing uncertain due to continued impact on recruitment due to COVID-19, and being assessed as part of broader clinical development strategy
2. Preclinical model of organ transplant rejection complete

Investment summary

Scalable technology	• Patented Cymerus platform technology enables commercial-scale production of mesenchymal stem cells from a single donor, overcoming multiple issues with today's on-market solutions • Value of platform to a range of diseases demonstrated across clinical and pre-clinical studies
Successful clinical trial results	• All clinical endpoints achieved in Phase 1 trial of Cymerus MSCs in acute GvHD, with no safety concerns identified and highly encouraging efficacy • Endorsement by FUJIFILM via licence for GvHD supports further development of Cynata's products in other indications
Broad and attractive pipeline	• Phase 3 osteoarthritis trial (funded by NHMRC) is underway and Phase 2 trial in COVID-19 patients open for recruitment • Preparations to commence further clinical trial in GvHD (via FUJIFILM license) and a Phase 2 trial in CLI; planning for clinical trial programs in idiopathic pulmonary fibrosis (IPF), Renal transplantation, and diabetic foot ulcers (DFU) • Compelling pre-clinical data in other high-value target areas supports further clinical trials
Significant growth potential	• Targeting significant commercial opportunities; global market opportunity in osteoarthritis alone is US$11.6bn • FUJIFILM license granted on attractive terms, including A$100m+ in milestone payments and royalties on product sales; and FUJIFILM responsible for further product development and commercialisation in GvHD
Well positioned in regenerative medicine	• Cell therapeutics is an area of increasing interest from major pharmaceutical companies globally • Cynata's unique Cymerus technology ideally placed to solve current MSC manufacturing challenges

Capital raising details

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Capital raising overview

Cynata is seeking to raise up to approximately A$20.5m via a Placement and Entitlement Offer

Offer Structure	• Institutional placement to raise ~A$15.0m through the issue of 21,440,295 New Shares **(Placement)** • 1 for 15, non-renounceable pro rata entitlement offer to raise up to approximately A$5.5m through the issue of up to 7,808,267 new shares New Shares (**Entitlement Offer**) • The Placement and Entitlement Offer are not underwritten
Offer Pricing	• Placement offer price of A$0.70 per New Share, which represents: – A discount of 10.8% to the last close of A$0.785 per share on 8 December 2020 – A discount of 9.6% to the 5-day VWAP of A$0.774 per share to 8 December 2020 • Entitlement Offer at the same offer price as the Placement
Entitlement Offer	• Record date of Wednesday, 16 December 2020 • Placement shares are not eligible to participate in the Entitlement Offer • Eligible shareholders may apply for New Shares in excess of their entitlement under a shortfall facility
Ranking	• New Shares under the Placement and Entitlement Offer will rank pari passu with existing ordinary shares
Use of funds	• **Expand clinical development pipeline:** Pursue Cynata funded Phase 2 clinical trials in attractive indications. High priority targets include idiopathic pulmonary fibrosis (IPF), renal transplantation, and diabetic foot ulcers (DFU). • **Process development and commercialisation:** Optimise manufacturing capabilities to enhance scale-up efficiencies and progress Cynata's US regulatory strategy, to place the Company in a strong position to commercialise its MSC products. • **Other:** Additional headcount, general working capital, corporate costs etc.

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Timetable

Indicative capital raising timetable[1]	Date
Announcement of the Capital Raising and trading halt lifted – shares recommence trading on ASX	Friday, 11 December 2020
Record date for Entitlement Offer	Wednesday, 16 December 2020
Settlement of Placement	Friday, 18 December 2020
Allotment and commencement of trading of New Shares under the Placement	Monday, 21 December 2020
Despatch of Offer Booklet and Entitlement Offer opens	Monday, 21 December 2020
Entitlement Offer closes	Wednesday, 13 January 2021
Announcement of Entitlement Offer results	Monday, 18 January 2021
New Shares issued under the Entitlement Offer	Wednesday, 20 January 2021
Commencement of trading of New Shares issued under the Entitlement Offer	Thursday, 21 January 2021

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Note: 1. The timetable is indicative only and is subject to change

Risks

This section discusses some of the key risks associated with any investment in Cynata together with risks relating to participation in the Placement and Entitlement Offer which may affect the future operating and financial performance of Cynata and the value of Cynata shares. The risks set out below do not constitute an exhaustive list of all risks involved with an investment in Cynata.

Cynata seeks to reduce risk to its business through appropriate risk mitigants, however, if any of the following risks materialise, business, financial condition and operating results are likely to be adversely impacted.

Before investing in Cynata, you should carefully consider whether this investment is suitable for you. Potential investors should consider publicly available information on Cynata (such as that available on the ASX website), and consider consulting a stockbroker, legal advisor, accountant or other professional advisors before making an investment decision.

Risk	Description
COVID-19 and global health risks	Global health risks or the potential for these events could have a negative impact on the Company. Since early 2020 the coronavirus pandemic, now known as COVID-19, has spread rapidly to many countries globally. The impact of COVID-19 has led to the adoption of extreme preventative measures by governments and other authorities, including the imposition of limits on public gatherings, restrictions on travel, the closure of borders, requirements for self-isolation, restriction of access to services and the closure of stores and businesses, including in Australia. Given the high degree of uncertainty surrounding the extent and duration of COVID-19 it is not possible to assess the impact of COVID-19 on the Company's business. These events have had and can be expected to continue to precipitate sudden significant changes and volatility in regional and global economic conditions and financial markets. If there is a significant increase in the number of COVID-19 cases, this may burden hospitals and healthcare institutions to the extent that all non-urgent medical procedures, including clinical trials, may be cancelled or postponed indefinitely. This may impact the ability of the Company to progress the phases of their clinical trials. As a result, the operations of the Company may be significantly adversely affected by such events.
Clinical development risk	The nature of clinical drug development is inherently risky, with many drug candidates failing to be successfully developed into marketable products. The Company is positioning its drug candidates for clinical trialling. Clinical trials have many associated risks which may impact commercial potential and therefore future profitability. Such trials may fail to recruit patients, be terminated for safety reasons, or fail to be completed within acceptable timeframes as a result of delay. Clinical trialling may reveal drug candidates to be unsafe, poorly tolerated or non-effective. Any of these outcomes will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its drug candidates. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.
Regulatory and reimbursement approvals	The research, development, manufacture, marketing and sale of products developed by the Company are subject to varying degrees of regulation by a number of government authorities and institutional bodies (e.g. ethics committees) in Australia and overseas. Pharmaceutical products must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. The process includes a requirement for approval to conduct clinical trials, and the provision of data relating to the quality, safety and efficacy of the products for their proposed use. There is no guarantee that regulatory approvals to conduct clinical trials and/or to manufacture and market the Company's products will be granted. Products may also be submitted for cost reimbursement approval to relevant agencies. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of products in some jurisdictions. There is no guarantee that such approvals will be granted.
Risks associated with partnership model	The Company is pursuing a license partnership model, which typically involves entering into commercial arrangements with other companies by which Cynata licenses its Cymerus technology to the partner in one or more indications and/or geographies and the partner assumes responsibility for progressing, and paying for, the clinical trials and eventual commercialisation in that indication. This strategy involves the risk that the Company will lose control of the development timetable of its products to its commercial partner, which may give rise to an unanticipated delay in any commercial returns. Further, the Company may be unable to enter into arrangements with suitable commercial partners in respect of relevant indications. If either of these outcomes occurred, the Company's business and operations may be adversely affected.

Risks

Risk	Description
Competition and regulation	The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant change. A number of companies, both in Australia and abroad, may be pursuing the development of products that target the same markets and/or diseases that the Company is targeting. The Company's products may compete with existing products that are already available to customers. The Company may face competition from parties who have substantially greater resources than the Company. Competing products may be superior to the Company's products in terms of any or all of price, convenience, safety or efficacy, which would adversely impact the commercial viability of the Company's products.
Dependence upon key personnel	The Company depends on the talent and experience of its personnel as an important asset. There may be a negative impact on the Company if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel of the Company who leave to work for a competitor may adversely impact the Company. In summary, the Company's ability to attract and retain personnel will have a direct impact on its ability to deliver its project commitments. Additionally, increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.
Research & Development (R&D) Tax Rebate	The Company is currently entitled to receive an R&D rebate on part of its expenditure in research and development. There is a risk that the Australian Government may make material changes to the rebate scheme, which may adversely impact the funding available to the Company to fund its operations.
Intellectual property	The Company's ability to commercialise products depends substantially upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights.
Revenues and profitability	The Company does not currently generate revenue from product sales nor are revenues anticipated in the short to medium term. and continues to incur significant research and development and other expenses related to its ongoing operations. The Company's ability to achieve both revenues and profitability is dependent on a number of factors, including its ability to execute on its business strategy, complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise those products. There is no guarantee that the Company's products will be commercially successful.
Manufacturing risk	The Company's products are manufactured using a unique, novel and highly specialised manufacturing process. The Company relies on supply and manufacturing relationships with third party contract manufacturing organisations to manufacture its products. An inability of these third party contract manufacturing organisations to continue to manufacture the Company's products in a timely, economical and/or consistent manner, including any scale up of manufacturing processes, or to maintain legally compliant manufacturing to maintain product supply, could adversely impact on the progress of the Company's development programs and potentially on the financial performance of the Company.

Risks

Risk	Description
Economic	General economic conditions, movements in interest and inflation rates and currency exchange rates may have an adverse effect on the Company's business and production activities, as well as on its ability to fund those activities.
Market conditions	Share market conditions may affect the value of the Company's quoted shares (and options to acquire quoted shares) regardless of the Company's operating performance. Share market conditions are affected by many factors such as: a) general economic outlook; b) introduction of tax reform or other new legislation; c) interest rates and inflation rates; d) changes in investor sentiment toward particular market sectors; e) the demand for, and supply of, capital; and f) terrorism or other hostilities. The market price of securities can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general and pharmaceutical stocks in particular. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.
Litigation	There is a risk that the Company may in future be the subject of or required to commence litigation. There is, however, no litigation, mediation, conciliation or administrative proceeding taking place, pending or threatened against the Company.
Tax risks	Changes to the rate of taxes imposed on the Company (including in overseas jurisdictions in which the Company operates now or in the future) or tax legislation generally may affect the Company and its shareholders. In addition, an interpretation of Australian tax laws by the Australian Taxation Office that differs to the Company's interpretation may lead to an increase in the Company's tax liabilities and a reduction in shareholder returns. Personal tax liabilities are the responsibility of each individual investor. The Company is not responsible either for tax or tax penalties incurred by investors.
Additional requirements for capital	The Company's capital requirements depend on numerous factors. Depending on the Company's ability to generate income from its operations, the Company may require further financing in addition to amounts raised under the Capital Raising. Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations, its production levels, or scale back its research and development and/or clinical trials as the case may be. There is however no guarantee that the Company will be able to secure any additional funding or be able to secure funding on terms favourable to the Company.

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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