ShawandPartners

# Cynata (CYP)

Shaw and Partners Flashnote

## Partnering Highlights Value (Rec: Not covered)

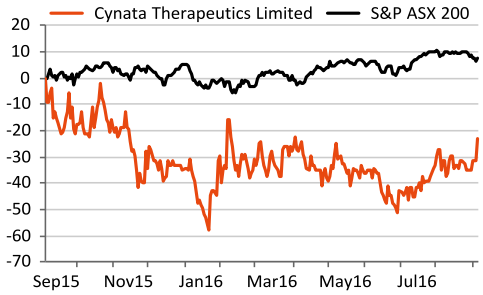
**Key Information**

| | |
|---|---|
| Price (cps) | 43.0 |
| Market Cap ($M) | 31 |
| 52 week Hi-Lo ($) | 1.11 - 0.23 |
| Cash ($m) | 6.4 |
| Debt ($m) | 0.0 |

**Investment Fundamentals**

| 30-Jun | FY14 | FY15 | 1H16 |
|---|---|---|---|
| Gross Income ($m) | 0.0 | 0.0 | 0.0 |
| EBITDA ($m) | -3.1 | -3.3 | -2.3 |
| Cash ($m) | 5.1 | 4.8 | 6.4 |

**CYP vs S&P/ASX Market Index**




**Company Activities**

CYP is a stem cell and regenerative medicine company which has developed a platform for manufacturing stem cells that don't lose potency with expansion over succesive generations and are infinitly expanadable. The Technology was initially developed by the University of Wisconsin- Madison which was behind the discovery of MSCs and the spin out of Cellular Dynamics which was acquired by Fujifilm.

**Major Shareholders**

| | Shareholding |
|---|---|
| Intersuisse Nominees | 4.6% |
| Merrill Lynch Nominees | 3.5% |
| Celtic Capital | 3.3% |

**Directors and Management**

Stewart Washers (Ch)

Ross Macdonald (MD)

Peter Webse (Secretary & Non - Executive Director)

John Chiplin (Independent Non - Executive Director)

**Disclaimer**
Shaw acted for the company in a corporate capacity within the past 12 months for which it received a fee. See the back page of this report for the full disclaimer.

### Event

CYP has announced the signing of a non-binding term sheet with Fujifilm, which once finalized will be its second partnering deal this year. We look at Fuji's rationale, the stem cell industry's need for commercial scale mesenchymal stem cell (MSC) production capability, the validation supporting CYPs technology and the unique manufacturing capability it offers, all of which suggests it is positioned to be the only scalable MSC producer for an industry that is now seeing significant acquisition activity.

### Highlights

- Finalisation of the deal with Fujifilm for development and commercialisation of CYPs Cymerus technology will be industry validation from one of the largest investors in stem cell technology. The proposed deal to market CYPs MSC product for prevention and treatment of graft-versus-host disease worldwide and possibly other diseases, in return for as yet undisclosed upfront and milestone payments and a $US3mn investment in CYP at a 35% premium to CYPs 6 month VWAP is a significant vote of confidence in its technology from a leading industry participant.
- The proposed deal reflects the fact that Cymerus™ is the only technology for generating medicinal MSCs from iPS cells, that it is increasingly viewed as a likely therapeutic solution and will enable Fujifilm to better leverage its own iPS technology and the MSC industry's production problems.
- The MSC opportunity, to repair damaged or diseased tissues such as heart, bone and cartilage, and or, treat diseases such as diabetes and cancer is the biggest and most prospective field of stem cell endeavour. Mesoblast Ltd. (MSB:ASX, $500mn) and TiGenix N.V. (TIG:BE, $251mn), are examples of some of the global companies investing billions developing MSC therapeutics. Despite this investment there remain numerous issues – essentially potent MSCs cannot be produced commercially at scale. This flaw in the business model of MSC companies is not well recognised by investors, but CYP provides a unique solution which may be required by all MSC based therapeutics targeting indications with large populations.
- We are not aware of any competing technology under development that is a scalable method of growing MSCs, which don't lose potency as successive generations of cells are produced and do not rely on multiple cell donors. Positive results from CYPs Graft verse Host Disease (GvHD) trial in 2017 should provide important confirmatory evidence that its MSCs are at least equivalent to MSCs extracted from bone marrow and are safe to administer to humans which will open it to commercial uses as a production method and as a therapeutic product for multiple indications across markets worth billions.

### Recommendation – Not rated

CYP is not currently rated by Shaw and Partners. Since CYP acquired its Cymerus™ technology in 2013 significant clinical developments, both its own and by external groups have propelled the technology forward as the only likely viable MSC solution for large scale clinical applications. This is now being reflected in the partnering deals CYP is starting to secure. The clinical developments, partnering and recent appointment of Paul Wotton to the board, have de-risked CYP creating significant, but as yet largely unrecognised value (CYP still only has a market cap of $31m). The risk is that CYP gets acquired at way too low market capitalisation. Fujifilm and other Japanese companies are likely acquirers. CYPs GvHD trial will be the next de-risking development and we expect if positive will be the next catalyst for a significant rerating, however this is six or more months away.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## Partnering highlights value

Finalisation of the deal with Fujifilm for development and commercialisation of CYPs Cymerus technology will be industry validation from one of the largest investors in stem cell technology. The proposed deal to market CYPs MSC product for prevention and treatment of graft-versus-host disease worldwide and possibly other diseases, in return for as yet undisclosed upfront and milestone payments and a $3mn investment in CYP at a 35% premium to CYPs 6 month VWAP can be viewed as a vote of confidence in its technology from a leading industry participant.

The proposed deal reflects the fact that Cymerus™ is the only technology for generating MSCs from iPS cells, that it is a likely therapeutic solution and will enable Fujifilm to better leverage its own iPS technology and the MSC industry's production problems.

### The industry's flaw - production and potency problems

Because of ethical issues associated with using embryonic stem cells (ESCs) in the early 2000's stem cell companies adopted what was then new technology - extracting donor MSC typically from bone marrow and relying upon their ability to replicate themselves. One cell becomes two, two become four, four become eight, but there is now solid evidence (corporate disclosures[1], academic literature[2] and our conversations with numerous independent academics and executives involved in MSC development) that MSCs lose potency as they are expanded. Given hundreds of millions of cells are needed for each treatment, this is an issue.

The loss of potency associated with existing methods of growing MSCs is a flaw in the business model of MSC based companies. It is an issue for: 1) Later stage MSC clinical trials which are not producing results equivalent to early stage trials because of the increased number of cells required which are of lower quality, 2) regulators which have indicated that follow up donor cells, which are not necessarily identical, will require their own testing and approval, and therefore 3) costs for treating any disease with large populations.

Without the capability to produce potent cells at scale, the entire industry will be held back.

### Fuji already own part of the solution

Then in 2007 scientists first manufactured what they called Induced pluripotent stem cells (iPS cells) by reprogramming adult somatic cells (body cells such as skin cells that can't divide further) by adding four expression vectors, the science is complex but now well established. iPS cells have over the last few years been shown to effectively have the same properties and capabilities as ESC (see appendix 1 – this is important it equates to significant de-risking of CYP), and theoretically have the ability to differentiate into all cell types found in the body without losing potency.

Multiple different technologies for generating iPS cells now exist. Fuji invested in iPS cell technology in 2015 acquiring CYPs sister company out of the University of Wisconsin – Cellular Dynamics. There is relatively little risk in this technology, it is well understood and increasingly widely used for research and drug development[3] but, without CYPs Cymerus™ it is unlikely to be developed for therapeutic purposes.

[1] Kimbrel, Lanza, (Ocata Therapeutics) Mesenchymal Stem Cell Population Derived from Human Pluripotent Stem Cells Displays Potent Immunomodulatory and Therapeutic Properties, March 20, 2014 'MSCs are being tested in a wide range of human diseases; however, loss of potency and inconsistent quality severely limit their use.'; The Alliance for Regenerative Medicine survey of Big Pharma found "the most significant challenge is product consistency and standards, the second most significant challenge is manufacturing/scaleup."

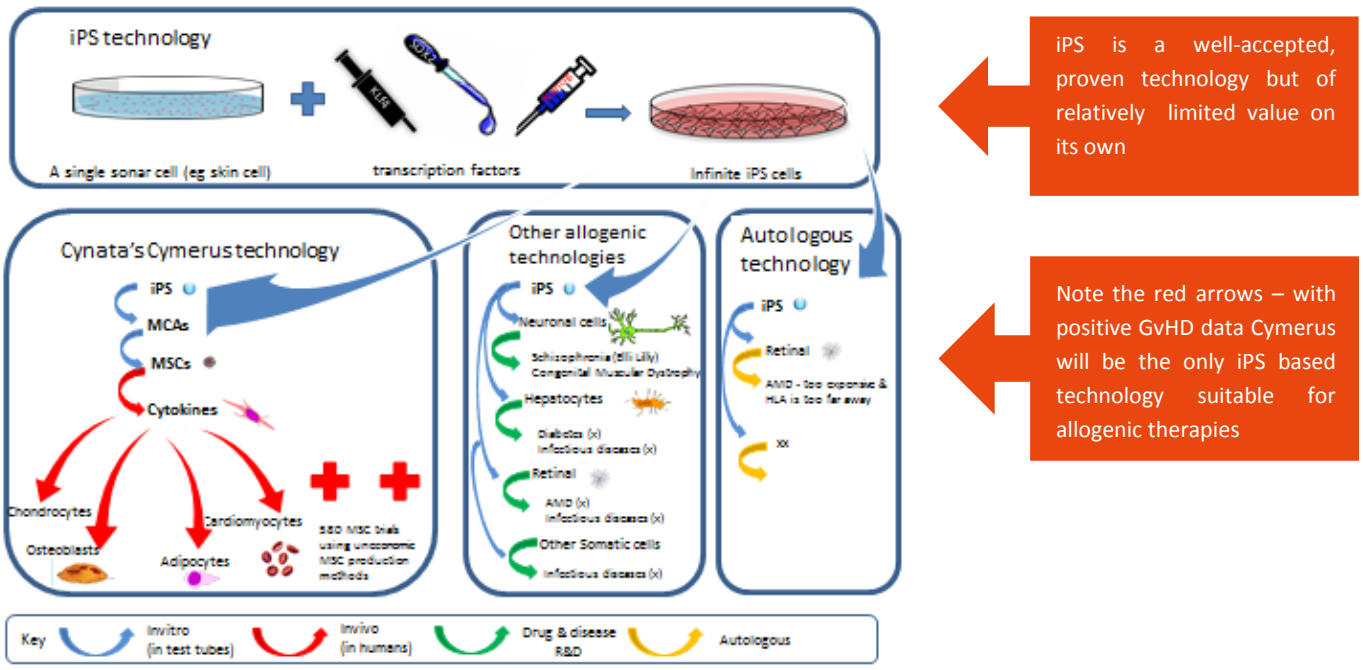
[2] Jacques Galipeau, ISCT, Why Prochymal failed. Cytotherapy, 2013; LeBlanc etal, Expansion of MSCs – low v high, 2012.

[3] CYP has a non-exclusive license from Cellular Dynamics/Fujifilm to manufacture iPS cells using its technology for the life of the patents. Royalties payable to Fujifilm for IPS technology have not been publicly disclosed, we expect the technology would command royalties reflecting a low single digit percentage of net sales.

## CYP has the most valuable part of the solution

There are a number of autologous[4] [5] processes for generating differentiated cells from iPS cells, however CYP's Cymerus is the only commercially scalable technology that can make off the shelf MSCs that can be used inside human bodies for therapeutic purposes.

**Figure 1: iPS commercialisation opportunities**




*Source: Shaw and Partners*

The patents[6] CYP has licensed have wrapped up the most significant opportunity to emerge from the iPS breakthrough - MSCs.

• **MSCs generate a multitude of different cells.** MSCs generate Somatic cells[7] including: cardiomyocytes (heart cells), adipocytes (fat cells), osteocytes (bone cells), chondrocytes (cartilage cells), and smooth muscle cells. More significant to the therapeutic setting MSCs also produce a large amount and number of different growth factors (cytokines,

[4] Autologous, cells derived from the recipient. Allogenic, cells derived from a donor which enables scalable manufacturing.

[5] There are a limited number of groups using technologies downstream of iPS to generate somatic cells from autologous procedures. None are in the clinic or have resulted in approved products. Riken (Japan) was the most advanced, it did a single Retinal transplant but halted its trial for unspecified reasons, and later stated autologous iPS is not a commercial proposition and that it now hopes to progress from autologous iPS cells to allogeneic iPS cells. However, Somatic cells derived from allogenic iPS cells are unlikely to be used for therapeutic purposes in humans because they carry markers (MHC class 2 antigens) that attract the hosts immune system. Notably MSCs and cytokines do not carry these markers. Riken hope to match donars and recipient HLA -human leukocyte antigens, but recognises additional immunology issues may also exist and the technology is at best pre-clinical. We note autologous transplantation in mouse models have produced inconsistent results with immune reaction observed in some studies.

[6] CYP's licensed patents cover MSCs, MCAs and other similar cells to MSCs giving it broad coverage across the field – which is significant given there is a debate over what constitutes a MSC. – The patents are licensed from The Wisconsin Alumni Research Foundation (WARF), holds all rights to all the intellectual property created at the University of Wisconsin. The key patent application was granted in the US in November2009 as No. 7,615,374. CYP has also licensed two other WARF patent families – Primate embryonic stem cells, WO/1996/022362 (priority date 20/1/1995), and Serum-free cultivation of primate embryonic stem cells, WO/2001/066697 (priority date 9/3/2000). These two patent families cover the embryonic stem cell line from which MCAs were first derived, and a technique of expanding these cells without fetal bovine serum.

[7] In therapeutic uses the MSCs being developed by CYP and others are not turning into somatic cells, rather once administered into a human body they are generating a cocktail of cytokines (growth factors), specific to different situations and controlled by the MSC, which in turn attract immune cells to a disease site and help the body to generate its own somatic cells. – If MSC differentiated into a somatic cell (eg chondrocyte) they would develop markers on the cell that show it to be foreign and the immune system would destroy it. MSCs and Cytokines don't have this marker.

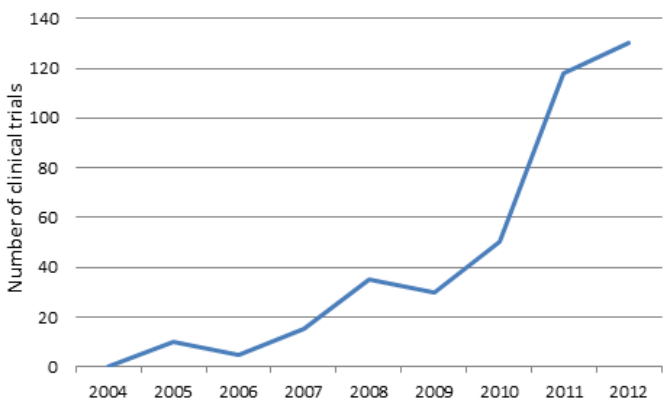
fibroblasts, and pericytes) that perform multiple functions associated with tissue regeneration, inflammation management and immunomodulation. Many of these factors are critical mediators in angiogenesis and the prevention of cell apoptosis, such as vascular endothelial growth factor (VEGF), insulin-like growth factor 1 (IGF-1), basic fibroblast growth factors (bFGF), hepatocyte growth factor (HGF), IL-6 and CCL-26;

• **MSC research makes up the bulk of stem cell research.** MSCs accounted for ~40% of stem cell IND submissions to the FDA between 2006 and 2013. 493 clinical trials have been completed or are currently underway investigating not only treating symptoms, but also addressing underlying causes of disease. MSCs have shown efficacy in trials up to phase 2b, and ,

• **MSCs represent the largest market opportunity.** The diseases MSCs potentially treat are currently generating sales of $bns pa from drugs that are often ineffective. Key diseases that MSCs are expected to have a roll in treating include: Stroke, heart disease, diabetes, lupus, Crohns disease, osteoarthritis, MS, and cancer.

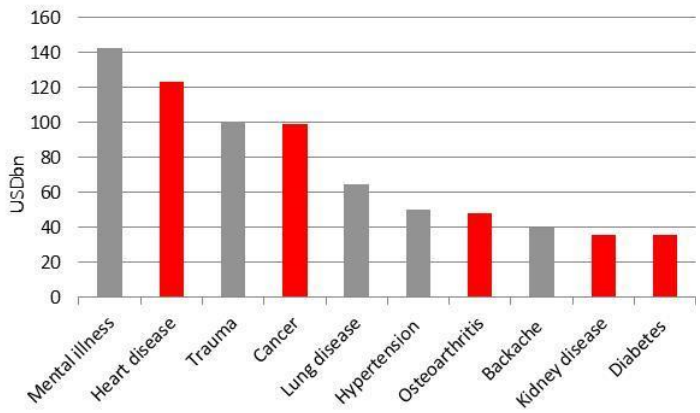
Because a substantial amount of research and clinical success has already been achieved with therapies based on MSCs derived from bone marrow, CYP upon proving its MSCs are at least equivalent should leap frog the industry.

**Figure 2: Stem cell trials**




*Source: Shaw and Partners*

**Figure 3: Top 10 diseases and US$ value**




*Source: Forbes, Shaw and Partners*

## Proving CYPs MSCs are equivalent is key

CYP's pre-clinical program has demonstrated the sterility, purity, potency, stability, safety and indicative efficacy of Cymerus™ MSCs. Similarly CYPs contract manufacturer, Waisman Biomanufacturing[8], has established indicative efficacy using assays which helps validate CYP's animal data[9]. The one outstanding point that regulators require CYP to demonstrate is that its iPS derived MSCs are equivalent to MSCs derived from human bone marrow. This is the key reason for CYP's Graft-versus-Host Disease trial[10]. Risks associated with the

[8] A US firm, Waisman Biomanufacturing has established process development, scale-up and clinical-grade production of CYPs iPS-derived MSCs notably this is the same company that Fuji has contracted to manufacture its iPS cells. Scale-up has demonstrated commercial viability. The ability to make stem cells under GMP at scale was paramount to its endeavour and positions it at the forefront of regenerative medicine globally.

[9] Numerous studies, conducted by CYP and external labs, have shown indications that CYPs MSCs are equivalent: I) CYP conducted a pre-clinical trial in a humanised mouse model of critical limb ischemia ( a severe blockage in the arteries of the lower extremities) showing its MSCs restored blood flow in the ischemic limbs, where mice treated with saline ended up losing limbs) II) A humanised mouse model of severe acute graft versus host disease (GvHD) The study was conducted at WuXi AppTec's GLP-compliant, FDA-registered facility in St Paul, Minnesota. A humanised mouse model of severe acute GvHD was induced by infusing human peripheral blood mononuclear cells into mice. The interim data demonstrated that CYP-001 treatment substantially prolonged survival in this model and confirmed biological activity iii) Waisman, CYPs manufacturer of its cells, and other accredited laboratories subjected the MSCs to a range of immunotherapy assays to measure the ability to supress the immune system, to confirm that the cells are equivalent to donor MSCs and have the characteristics required of MSCs for therapeutic use. iv) CYP expects to receive additional data from a proof of concept (PoC) study of CYP-001 progressing at the University of Massachusetts Amherst (UMass), USA. This PoC study is assessing the response to CYP-001 in animals with an experimental form of severe GvHD and is expected to provide a more robust data package for the MHRA clinical trial application

[10] The body of a person with GVHD is attacked by immune cells in transplanted bone marrow or blood. According to the Japan Society of Hematopoietic Cell Transplantation, about 1,200 people develop acute GVHD every year. Standard of care, steroids, do not work for about 500 of these patients of the disease, and some of them die. MSCs are known to blunt the inflammatory response of GvHD. This is well established a number of other MSC-producing companies have generated favourable data in GvHD and we are aware of at least one approved MSC-derived product, Prochymal, in Canada and New Zealand for this indication. CYP001 will be administered to patients that

trial is the usual risk associated with moving into human trials and emerging evidence that possibly not all MSCs are the same.

Based on its preclinical studies CYP has received favourable advice from the Medicines and Healthcare Products Regulatory Agency (MHRA), the principal healthcare regulatory body in the United Kingdom, regarding moving ahead with clinical testing of a candidate based on the firm's proprietary Cymerus™ technology platform. CYP filed an application with the MHRA to conduct a Phase 1 clinical trial of CYP-001 in July 2016. CYP expects results from the trial to be available in 2017.

If positive, we expect the data will: 1) establish benefits clearly outweigh any remaining small risks, which is the way regulators typically consider applications, 2) enable CYP to develop its own programs to commercialise, 3) attract a greater number of other groups to use, under license, CYP's cells in various studies of their own, and 4) takeover.

### With positive GvHD data Fuji is likely to acquire CYP

The deal that is expected to be announced with Fuji will give it a low risk entrée into CYP and a solid position to potentially launch an acquisition, possibly once the GvHD data substantiates CYPs Cymerus™ technology.

Fuji already has half the likely answer to future stem cell treatment, through its ownership of Cellular Dynamics and its iPS technology, but there are shortcomings to its position which the company wants to evolve away from[11]. The shortcomings include: 1) its iPS technology is not unique, 2) there is limited opportunity to leverage iPS technology, and 3) returns from supplying iPS technology or iPS cells are low margin.

With Cymerus™ Fuji would move into a much stronger position with exclusive rights that would lock up a large part of the stem cell market. It would give Fuji end to end production capability (iPS manufacture through to MSC production) CYPs production capability and therapeutic product opportunities. Without Cymerus Fuji can't realise its potential and Fuji's MD has stated 'We want our cells to be used for cell therapy'.

Fujifilm does own another stem cell business, Japan Tissue Engineering Co. which has autologous cartilage and skin products on the market, used by burn victims and others. It currently has three cell therapies: 1) aged related MD. Which had treated 10 people as at October 2014, 2) Parkinson's, and, 3) a cell therapy for the replacement of scarred heart muscle following heart attack. All of these indications could potentially be developed to use CDIs iPS technology, however it won't happen quickly given the markers iPS derived somatic cells carry. As such these programs are not going to enable Fuji to maximise the potential of CDI and won't come close to doubling its health-care revenue to 1 trillion yen by 2018 as it has stated it wants to.

Fuji has stated it intends to spend more than 400 billion yen on acquisitions by 2017, add new product lines and make a more aggressive push into health care. It has also stated that a part of that mission will be driven by regenerative medicine. Because other technologies that could leverage Fuji's iPS technology are so far behind Cymerus™, acquiring CYP makes a lot of sense.

### Fuji is not the only possible Japanese acquirer

Given we expect CYP is on the radar of many Japanese companies. Since the Japanese government put in place a favourable regulatory climate in 2014, easing approval rules for stem cell development, making Japan one of the fastest places in the world to get a regenerative medical product on the market, regenerative medicine acquisition activity has accelerated. Recent Japanese stem cell deals include:

- Astellas (Japan) acquired Ocata Inc (Advanced Cell Technology) for USD380 mn in Nov 2015,
- Fujifilm acquired Cellular Dynamics, a manufacturer of induced pluripotent stem cells in 20015 for USD307mn,
- Reprocell (Japan) acquired 3D cell culture company Reinnervate Ltd (UK) and Human Tissue supplier BioServe (USA) to generate a wide range of disease-related iPS cell lines for production of human disease cell models Sept2014, and,

failed steroids. As such if CYP-001 blunts the inflammation it will be clear that CYPs MSCs are responsible, which will be enough to conclude equivalence and that they are good for other indications MSCs are used for.

[11] Fujifilm acquired Cellular Dynamics, a manufacturer of induced pluripotent stem cells in 2015 for $307mn. Essentially Fuji bought technology, scientists, and staff of an established business servicing invitro research. The rationale was to change pharmaceutical industry practice away from predominantly testing with animal cells towards using human iPS cells. However, testing for drug development is a relatively small market with low margins and Fuji has stated it will have to look at leveraging other technologies to scale the business.

- ReproCELL Inc. (Yokohama, Japan) the Scottish life sciences company, Biopta (Glasgow, United Kingdom) in Dec 2015 aimed at strengthening ReproCELL's pharmaceutical industry-targeted drug discovery services.

Acquisitions occurring outside Japan include:

- NeoStem acquired California Stem Cell (CSC) July 2014 for USD124mn – CSC had an autologous melanoma initiating (stem) cell immune based therapy,

- Aastrom Biosciences, Inc. (Nasdaq:ASTM), acquired Sanofi's cell therapy and regenerative medicine business unit in June 2014 for $6.5m which had three marketed autologous cell therapy products, and,

- Ember Therapeutics, Inc. (OTCQB:EMBT), a New York-based targeted therapy developer acquired ICX-RHY/Vavelta™, a regenerative medicine asset, from Intercytex in March 2016.

CYP is on the radar of many of these companies. They all have iPS technology which can be better leveraged through owning Cymerus. Regience a Japanese regenerative medicine company recently offered to take equity in CYP and Dr Paul Wotton, from Ocata, recently joined the CYP board[12] further validating the company's potential.

### CYP is an undervalued target

We believe CYP should have a value in excess of both CDI and Ocata once it has confirmation of the effectiveness of its MSCs in humans. Our concern is that prior to that confirmation CYP could get acquired at a market capitalisation well below that and what its technology is potentially worth.

Since acquiring rights to the Cymerus technology in 2013 significant pre-clinical developments have been achieved, both CYPs own and by external groups (see Appendix 1), which have propelled the technology forward as the only likely MSC solution. This is now being reflected in the commercial deals CYP is starting to secure. We believe securing these deals has been a sensible strategy. They highlight industry acceptance and value without giving away all that the technology can be applied to, ahead of the GvHD proof-of-concept clinical study validating the Cymerus stem cell production platform.

We expect in six months, with the GvHD validation in place, CYP should be in better position to: 1) validate its value and defend against possible acquisition, and 2) partner with more established companies for more substantial therapeutics development.

[12] Following Ocata being sold to Astellas in February 2016 Cynata appointed Paul K Wotton Ph.D. to its Board of Directors in June 2016. Dr Wotton served as CEO and President of Ocata Therapeutics from July 2014 until the completion of the Astellas acquisition.

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## Rating Classification

| | |
|---|---|
| **Buy** | Expected to outperform the overall market |
| **Hold** | Expected to perform in line with the overall market |
| **Sell** | Expected to underperform the overall market |
| **Not Rated** | Shaw has issued a factual note on the company but does not have a recommendation |

## Risk Rating

| | |
|---|---|
| **High** | Higher risk than the overall market – investors should be aware this stock may be speculative |
| **Medium** | Risk broadly in line with the overall market |
| **Low** | Lower risk than the overall market |

**RISK STATEMENT:** Where a company is designated as 'High' risk, this means that the analyst has determined that the risk profile for this company is significantly higher than for the market as a whole, and so may not suit all investors. Clients should make an assessment as to whether this stock and its potential price volatility is compatible with their financial objectives. Clients should discuss this stock with their Shaw adviser before making any investment decision.

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