

# Cynata Therapeutics (CYP)

## Shaw and Partners Flashnote

### Progressing Towards being the Only Viable Mesenchymal Stem Cell Solution (Rec: Not rated)

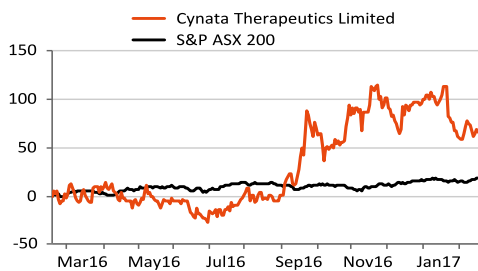
#### Key Information

Price (cps)	61.0
Market Cap (\$M)	55
52 week Hi-Lo (\$)	0.79 - 0.23
Cash (\$m)	14.0
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 successive generations and are infinitely expandable. 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
FUJIFILM Corporation	10.0%
Pershing Nominees	4.0%
Slukvin, Igor	2.6%
John King	2.6%
Celtic Capital	2.6%

#### Directors and Management

Stewart Washers (Ch)  
 Ross Macdonald (MD)  
 Peter Webse (Secretary & Non - Executive Director)  
 John Chiplin (Independent Non - Executive Director)  
 Paul Wotton (Independent Non-exec director)

#### Disclaimer

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#### Event

Over the last couple of months CYP has delivered on a number of initiatives which increasingly make it look to be the only likely viable mesenchymal stem cell (MSC) solution for large scale clinical applications. We look at recent developments and the upcoming Graft V Host Disease (GvHD) clinical trial which will be the basis on which it expects its infinitely expandable iSPC-generated MSCs to be recognized as superior to bone marrow derived MSCs, which are now widely regarded as only having limited expansion capability. Positive results from this trial will potentially compel other industry participants to move towards adopting CYPs MSCs for large scale use and FUJIFILM (Fuji) to move forward towards a more significant relationship.

#### Highlights

- Fuji Development/Commercialisation Agreement & Equity Stake.** In January CYP entered a development and commercialisation partnership with Fuji under which Fuji took a A\$4m strategic equity stake in CYP and entered a strategic relationship to potentially commercialise and manufacture CYP-001 for GvHD and certain rights to other CYP technology. Total potential milestone payments are in excess of A\$60m and double-digit royalties on CYP-001 net sales for GvHD have been put in place. Results from the GvHD clinical trial will be crucial to Fuji taking the program forward.
- Positive Preliminary Data from Preclinical Heart Attack Study with CYP's MSCs.** In February CYP released preliminary results from a proof of concept study in rats suggesting that its MSCs may have potential to restore cardiac function and reduce scar size after a heart attack. The data is not only encouraging for heart applications, but also supports confidence in the quality and likely efficacy of CYPs iSPC-generated MSCs ahead of GvHD clinical results.
- Treatment Benefit Confirmed in Final GvHD Preclinical Study of MSCs.** In February CYP also announced results from an expanded study of its MSCs in mice with induced GvHD. The study of 60 animals confirmed the results of earlier smaller trials showing highly statistically significant evidence of prolonged survival. The trial also produced evidence of mechanism of action.
- Efficacy in Preclinical Asthma Study Further Supports Efficacy.** In October CYP released a compelling data set from its proof of concept study of MSCs in an experimental mouse model of asthma. This is further confirmation that its MSCs work.
- CYPs GvHD Clinical trial is now ready to roll.** CYP's pre-clinical program has demonstrated the sterility, purity, potency, stability, safety and indicative efficacy of its MSCs. Similarly CYPs contract manufacturer, Waisman Biomanufacturing, has established indicative efficacy/potency using assays which helps validate CYP's animal data. Regulators now require CYP to demonstrate that its iPS derived MSCs are safe and effective in humans. This is the key reason for CYP's GvHD trial. 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) possibly a takeover.

#### Recommendation

CYP is not currently rated by Shaw and Partners. The data around CYPs MSCs - both its own and that developed by external groups - and the partnering deals it is putting in place increasingly point towards validation and industry acceptance of CYPs MSCs. CYP still needs to show that its MSCs are at least as safe and effective as harvested MSCs, however it has made significant steps forward towards being the only likely viable MSC solution for large scale clinical applications, which is unrecognised by its market capitalisation of \$45m.

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

## Risk Rating

<b>High</b>	Higher risk than the overall market – investors should be aware this stock may be speculative
<b>Medium</b>	Risk broadly in line with the overall market
<b>Low</b>	Lower risk than the overall market

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