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Ocata Therapeutics

Pharma & biotech

17 April 2015

An eye on commercialisation

Ocata has completed enrolment and published encouraging results in its Phase I/II trial of stem cell therapy in both dry age-related macular degeneration (AMD) and Stargardt's macular degeneration (SMD). It is pursuing the quicker orphan drug approval process of SMD and the large potential market of AMD by beginning an AMD Phase II trial and a pivotal trial in SMD. It has also secured a licensing agreement to use induced pluripotent stem cells (iPSC) as a platform for differentiating ocular tissue for other diseases. In spite of this recent clinical momentum, a weak capital position will require additional funding to reach clinical approval.

Encouraging Phase I/II trial builds momentum

Ocata dosed the final patient and reported interim follow-up of initial patients in its Phase I/II trial with retinal pigment epithelial (RPE) cells derived from human embryonic stem cells (hESC). This data shows that the hESC grafts appeared to be safe and possibly viable 22 months after treatment. Of the 18 patients treated, 10 had improved vision. These results have led to Advanced Therapy Medicinal Product (ATMP) designation providing momentum.

Two paths forward to market entry

Ocata is targeting both the 27 million patient dry AMD market and the orphan disease market of SMD. Currently there are no approved treatments for either disorder; however, there is intense competition in this segment. There are plans to follow the current trial with Phase II trials for AMD and a pivotal trial for SMD. With the ATMP designation and the SMD pivotal trial status, positive results may lead to regulatory approval.

Recent deal enhances stem cell platform

As Ocata matures its pipeline, it has announced a licensing agreement to use iPSCs in addition to hESCs. iPSCs will complement the current pipeline and expand the platform as it explores differentiating and implanting other tissues in the eye. So far the iPSCs have scant data, but company releases are encouraging.

Valuation: Weak capitalisation dampens momentum

Ocata ended FY14 with $4m in cash and a burn rate of $35.29m, causing concern regarding capital structure and the potential need for further debt or equity financing. With a discount reflecting these concerns, the EV of $241m only partially captures the potential of its stem cell therapies in dry AMD and SMD markets.

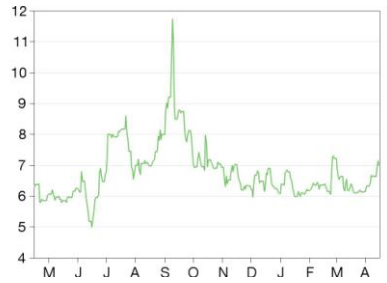
Consensus estimates

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/13	0.2	(31.0)	(1.34)	0.0	N/A	N/A
12/14	0.2	(34.7)	(1.17)	0.0	N/A	N/A
12/15e	10.2	(9.8)	(0.26)	0.0	N/A	N/A

Source: Bloomberg

Price	$7.00
Market cap	$245m

Share price graph



Share details

Code	OCAT
Listing	NASDAQ
Shares in issue	35.04m

Business description

Ocata Therapeutics is a clinical-stage biotechnology company specialising in regenerative ophthalmology using stem cells. It is currently in Phase I trials for dry macular degeneration, Stargardt's disease and myopic macular degeneration. They are in preclinical studies outside ophthalmology.

Bull

- Potential market of 27 million patients for dry AMD.
- Phase I/II trials encouraging with Advanced Therapy Medicinal Product designation granted.
- iPSC licensing agreement expands technology platform to other ocular tissues.

Bear

- Only just beginning Phase II trials.
- Weak capitalisation structure.
- Intense competition in dry AMD market.

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