


RBC Capital Markets
RBC Capital Markets, LLC
Adnan Butt (Analyst)

(415) 633-8588

adnan.butt@rbccm.com

Jeffrey Takimoto (Associate)

(415) 633-8538

jeffrey.takimoto@rbccm.com

John Chung (Associate)

(415) 633-8620

john.chung@rbccm.com

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Ocular Therapeutix, Inc.

Phase II dry eye study all upside; not in our model

Impact: Positive

Given that OCUL had not telegraphed a dry eye program, the exploratory study should be upside upon progress.

First Impression

The start of a OTX-DP Phase II trial for dry eye adds further optionality and news flow to an already catalyst-rich pipeline. Since dry eye is not an indication included in our estimates, progress would be upside. Next up are OTX-DP inflammation/pain data in 1Q:15, OTX-TP glaucoma data in 3Q:15, and partnering/ business development updates, including anti-VEGF IHD in 2015.

Phase II dry eye study initiated, data possible 4Q:15/1Q:16. The Phase II for dry eye study will compare OTX-DP to placebo for 30-day activity. This follows a 30-day run-in period to identify more difficult to treat dry eye patients. Since the trial is small and the primary endpoint evaluated at day 30 once the right patients are enrolled, it is possible that data could come in 2015 or early 2016.

Study is designed to be exploratory to identify the right patients and likely endpoints. The Phase II study will enroll 40 patients (up to 80 eyes) with signs and symptoms of dry eye, evaluate them on placebo plugs for 30 days, and only include those who have ongoing symptoms of dry eye disease. Presumably these could be harder to treat patients who are less likely to respond to over-the-counter medication. These patients will be randomized to receive a placebo plug or an OTX-DP plug for 30 days. Endpoints include corneal and conjunctival staining, tear osmolarity, tear film break-up time, presence of the plug, ease of product use and visualization and resorption of the plug following treatment. Since the FDA typically requires a sign and symptom to improve, OCUL can use this exploratory study to evaluate which endpoints seem most likely for the Phase II/ III study.

Phase III trials for dry eye are notoriously difficult; positive Phase II and path forward could add to value. Treatment for dry eye disease is typically escalated starting with over-the-counter lubricant eye drops, followed by punctum plugs, and then prescription medication. The addressable market is large, with most successful prescription, branded products expected to achieve \$1B in sales. Since the bar is high, i.e., a number of companies have failed to demonstrate efficacy consistently in Phase III and failed to receive FDA approval, positive Phase II data followed by a Phase III trial design that is agreed upon by the FDA, whether as a chronic or acute dry eye treatment, is likely to add optionality.

Outperform

Speculative Risk

NASDAQ: OCUL

Price: USD 25.00

All values in USD unless otherwise noted.



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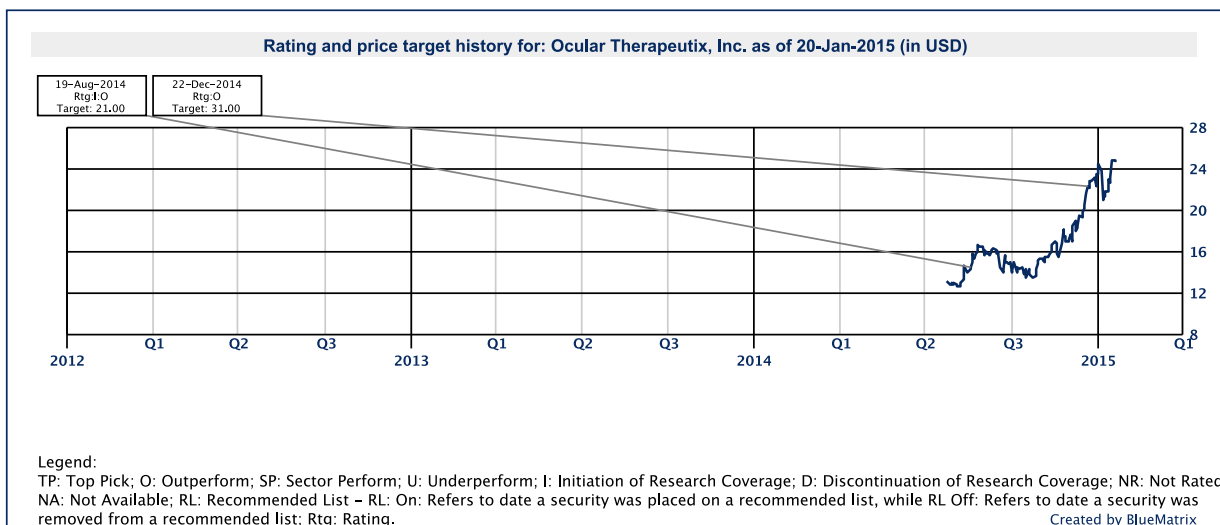
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