COWEN
AND COMPANY

Pharmaceuticals/Specialty

# Ocular Therapeutix

Equity Research

Quick Take: Company Update

January 29, 2015

**Price: $28.83** (01/28/2015)

**Price Target: $40.00**

**OUTPERFORM (1)**


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**Key Data**

| | |
|---|---|
| Symbol | NASDAQ: OCUL |
| Market Cap (MM) | $614.7 |

# *Clinical Programs Continue To Progress For A Catalyst-Rich 2015*

## The Cowen Insight

Numerous milestones are approaching in 2015 and our consultants continue to suggest these candidates serve a real unmet need in the targeted markets. Our valuation work suggests significant potential and is primarily predicated on the success of OTX-TP in glaucoma alone. Disclosures from other key development programs (such as long-acting anti-VEGF) could drive even more rapid value creation.

## We Continue To Believe There Is An Under-appreciation Of The Depth And Breadth Of The Ocular Development Portfolio

As a reminder, Ocular's lead development candidates are OTX-TP and OTX-DP. OTX-TP is a travoprost punctum plug in Phase II development for glaucoma and ocular hypertension and OTX-DP is a dexamethasone punctum plug in Phase III clinical development for post-surgical ocular pain and inflammation, and also has completed Phase II studies for allergic conjunctivitis. Additionally, the company is in collaboration with four undisclosed partners to develop a long-acting anti-VEGF hydrogel depot that has successfully demonstrated a duration of 4-6 months during in vitro studies. While this program is admittedly very early, we view it as having tremendous valuation optionality given its potential blockbuster status, and disclosures about potential licensing candidates could occur within the next 3-6 months. We do not believe the Street appreciates this potential disclosure. Looking forward, we expect the following milestones in 2015: (1) Phase IIIa and IIIb data for OTX-DP in post-surgical ocular inflammation and pain studies in Q1. If the results are positive, the NDA will be submitted in Q2, with a potential launch of the Company's first sustained-release punctum plug product in 2016; (2) OTX-DP has also been evaluated in Phase II studies for allergic conjunctivitis, and the decision to move that program into Phase III will be made in the first half of this year following an expected meeting with the FDA to discuss the recent results; (3) feasibility studies with biopharmaceutical partners for the long-acting anti-VEGF hydrogel depot should also be complete in H1:2015 with potential for a licensing agreement soon thereafter; (4) importantly, data from the OTX-TP Phase IIb study in glaucoma is expected in H2:2015; and finally (5) Ocular recently provided new details on the use OTX-DP for the treatment of dry eye, with Phase II data expected by year-end.

The bottom-line is that all programs continue to progress as expected and the upcoming year contains a series critical milestones. Our consultants continue to reiterate that Ocular's innovative drug delivery technology has the potential to serve a real unmet need of compliance in the markets that the Company is targeting. Our price target of $40 per share is almost entirely predicated on OTX-TP in glaucoma alone with reasonable penetration rates. Meaningful success in the other programs – especially the Company's long-acting anti-VEGF hydrogel depot – could more than double our target valuation. We would add heading into a catalyst-rich 2015 with significant potential for value creation.

## Specifics On Clinical Program Updates

**OTX-TP:** in November of last year Ocular announced the enrollment of its first patient in a randomized, blinded, active-controlled Phase IIb study comparing the product to timolol. The study will evaluate 80 patients across 10 clinical sites with topline results expected in Q3:15. Recall, the Phase IIa data for OTX-TP looked promising as efficacy was comparable to twice-daily timolol with a duration of 2-3 months. The poor compliance for topical glaucoma eye drops is well understood by the physician community and the improvement in compliance seen with once-daily PGAs relative to treatments that require multiple daily drops suggests that a product that only requires administration every 2-3 months could have a profound impact on compliance. Despite our initial concerns about plug retention, our consultants noted that a treatment option that lasted anywhere between 60 and 90 days would be a "game changer" and that the 2-3 month duration of the product would fit well into the currently established glaucoma treatment protocol. The next generation NSR3 plug design will be used in the Phase IIb study and we believe retention can continue to be improved. Consolidating all of the feedback from our clinicians, we believe OTX-TP could be at least a $450MM product in the U.S. and approval in the E.U. and Japan, could provide additional upside.

**OTX-DP:** Ocular has completed enrollment for the Phase III pivotal trials for post-operative ocular inflammation and pain. As previously disclosed, Phase II findings for OTX-DP were promising for both primary endpoints including a statistically significant reduction in anterior chamber inflammatory cells at days 14 and 30 and absence of pain in the eye on all measured days. A secondary endpoint measuring absence of anterior chamber flare was also statistically significant on all measured days. Results from the Phase IIIa and IIIb studies are expected in Q1:15, and if favorable, an NDA will be filed in Q2:2015.

Earlier this month, Ocular announced the enrollment of the first patient in a Phase II study evaluating OTX-DP for the treatment of dry eye. The randomized, double-blinded, vehicle-controlled study will evaluate 40 patients (up to 80 eyes) exhibiting signs and symptoms of dry eye disease. Clinical endpoints will 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. Patients will be enrolled at two U.S. sites, and in order to establish a baseline level of disease, they will initially be administered a placebo vehicle plug for 30 days. Patients who respond to the placebo plug in treatment of their dry eye will be excluded from the study, while those who continue to exhibit symptoms during the initial 30 days will continue into the treatment phase. Patients will then be randomized to receive either OTX-DP or a placebo vehicle plug. Topline data from the Phase II dry eye study should be available by year-end.

Regarding the OTX-DP indication for allergic conjunctivitis, Ocular announced topline data from a Phase II study of OTX-DP in November of last year. The randomized, blinded, placebo-controlled study evaluated 68 patients across two clinical sites. The primary endpoints for the study were ocular itching and conjunctival redness at 14 days using a modified Conjunctival Allergen Challenge (CAC) model. OTX-DP demonstrated a statistically significant reduction in ocular itching and conjunctival redness at all measured days (14, 28, and 42). Using a 5-point scale, a mean difference greater than 0.5 units was seen at day 14, but a mean difference of 1.0 units was not seen at any of the measured days. Our consultants note that for currently approved topical treatments (emphasis on topical) for allergic conjunctivitis, a difference of 1.0 units is generally observed, but is not an absolute requirement as products have been approved by the FDA without meeting this criteria. Additionally, the previous FDA guidance of a treatment difference of 1.0 units is specifically

tailored towards topical eye drop treatments. Ocular is using a new, sustained-release approach with OTX-DP that does not achieve the same peaks seen with topical agents. As a result, the findings from the Phase II study are not surprising and we believe it's important to remember that OTX-DP is providing a similar treatment effect over 42 days, compared to the meager 8-16 hours experienced with eye drops. Our consultants agree that the findings support continued development for the allergic conjuctivitis indication and the Company will be meeting with the FDA to discuss the study findings in greater detail and to determine the appropriate design and endpoints moving forward for this novel treatment approach (sustained-release vs. topical eye drops). A decision on the next steps for OTX-DP in allergic conjunctivitis will be made during the first half of this year, with a likely plan to begin Phase III studies in H2:2015.

**Long-Acting Anti-VEGF Hydrogel Depot:** Finally, Ocular continues to make progress with its long-acting anti-VEGF hydrogel depot. The Company is working with four confidential biopharmaceutical partners on feasibility studies, which are expected to be completed in H1:2015. Initial findings suggest a duration toward the high-end of the 4-6 month range. The product is well-tolerated in animal models and importantly, the hydrogel appears to be delivering a meaningful amount of drug in the eye. Given the nature of the development timeline for a duration-based product, if the data is positive in H1, the Company would expect to begin clinical trials in 12-18 months.

## Several Opportunities For Value Creation Exist

During its Q3:14 earnings call, Ocular reported a cash balance of $81MM, which should provide sufficient funding for the company through H1:2016. Our base case valuation model for Ocular assumes approval for OTX-TP in 2017, and U.S. peak sales eventually reaching approximately $450MM, which is a conservative penetration of roughly 5% of total U.S. glaucoma prescriptions by 2020. We also assume modest ex-U.S. sales for OTX-TP with a peak sales value of ~$150MM. For OTX-DP, we assume a successful approval in post-operative pain and inflammation, with steady growth and total peak sales of $300MM across all potential indications. We also expect growth for ReSure to be stable with total worldwide peak sales of approximately $150MM. Finally, we assume Ocular moves forward with OTX-MP and the product is launched in 2018/2019. Our peak sales estimate for the product is slightly above $100MM. We would note, our valuation does not attribute any value to the long-duration anti-VEGF hydrogel, which has the greatest potential upside of any of Ocular's products. If the company successfully enters the $3B+ and growing wet AMD market, with a transformational duration product, our valuation could inflect to 2-3x our base case $40 per share valuation.

# Valuation Methodology And Risks

## Valuation Methodology

### Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

## Investment Risks

### Pharmaceuticals/Specialty

**Risks include:** (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

## Risks To The Price Target

Ocular Therapeutix' valuation is primarily based upon its clinical development programs and failure of its late-stage development programs could have a significant negative impact on its valuation.

# *Addendum*

## Stocks Mentioned In Important Disclosures

| Ticker | Company Name |
|---|---|
| OCUL | Ocular Therapeutix |

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**Outperform (1):** The stock is expected to achieve a total positive return of at least 15% over the next 12 months

**Market Perform (2):** The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

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**Assumption:** The expected total return calculation includes anticipated dividend yield

***Cowen and Company Rating System until May 25, 2013***

**Outperform (1):** Stock expected to outperform the S&P 500

**Neutral (2):** Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

**Assumptions:** Time horizon is 12 months; S&P 500 is flat over forecast period

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**Buy** – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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| Rating | Count | Ratings Distribution | Count | IB Services/Past 12 Months |
|---|---|---|---|---|
| Buy (a) | 461 | 60.50% | 109 | 23.64% |
| Hold (b) | 288 | 37.80% | 14 | 4.86% |
| Sell (c) | 13 | 1.71% | 0 | 0.00% |

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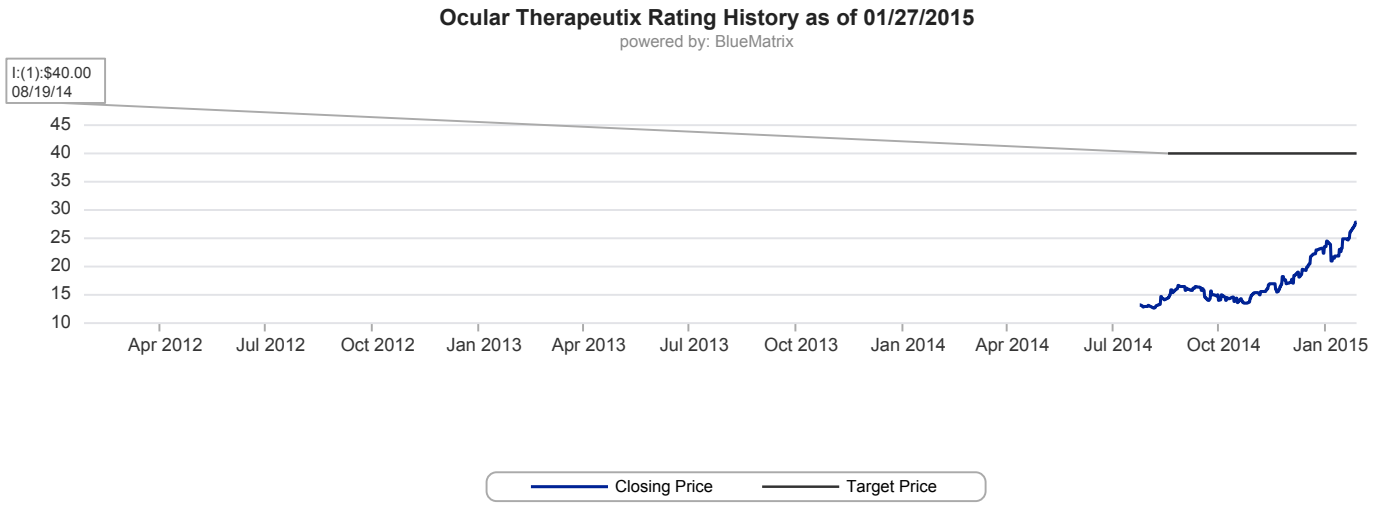


**Legend for Price Chart:**

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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