

Equity Research

November 12, 2014

Price: \$15.81 (11/11/2014)

Price Target: \$40.00

OUTPERFORM (1)

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Key Data

Symbol [NASDAQ: OCUL](#)

Market Cap (MM) [\\$337.1](#)

Company Quick Take

Clinical Programs On-Track For A Catalyst-Rich 2015

The Cowen Insight

Ocular reported Q3 results and also provided updates on several key programs. Numerous milestones for Ocular's clinical programs 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 from these levels and is primarily predicated on the success of OTX-TP in glaucoma alone.

First Patient Enrolled In OTX-TP Phase IIb Glaucoma Trial; Data Expected By Q3:2015

Ocular Therapeutix reported Q3 results and also provided updates on several key programs – with a particular focus on the announcement of enrollment of the first patient in the Phase IIb glaucoma and ocular hypertension trial with OTX-TP and the reporting of topline Phase II results for OTX-DP in allergic conjunctivitis (see details below). 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 inflammation and pain and also in Phase II for allergic conjunctivitis. Additionally, the company is in collaboration with 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. Looking forward, we expect the following milestones: (1) Phase III data for OTX-DP in both post-surgical ocular inflammation and pain studies in the first quarter of next year. If the results are good, the NDA could be submitted in Q2, with a potential launch of the Company's first sustained-release product in 2016; (2) feasibility studies for the anti-VEGF hydrogel depot should also be complete in the first quarter of next year; (3) data from OTX-TP in glaucoma is expected in Q3 of next year; and (4) we should hear about a potential path forward with OTX-DP in allergic conjunctivitis in the coming months following an expected meeting with the FDA to discuss the recent results. The bottom line is that all programs continue to progress as expected and 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 into its target market. Meaningful success in the other programs – especially the Company's 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

Regarding OTX-TP, 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. **Please see addendum of this report for important disclosures.**

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.

For OTX-DP, Ocular has just 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 III studies are expected in Q1:15, and if favorable, a NDA filing could occur in Q2:15.

Regarding the secondary indication for allergic conjunctivitis, Ocular announced topline data from a Phase II study of OTX-DP. 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 tailored towards topical eye drop treatments specifically. 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 that 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 conjunctivitis 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).

Finally, Ocular continues to make progress with its sustained-release **Anti-VEGF hydrogel**. The company is working with three confidential partners on feasibility studies, which are expected to be completed in Q1:15. 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. Ocular also recently signed an early-stage agreement with another partner and is getting additional interest from other companies. Given the

nature of the development timeline for a duration-based product, if the data is positive in Q1, the Company would expect to begin clinical trials in the beginning of 2016.

Several Opportunities For Value Creation Exist

Ocular reported a cash balance of \$81MM which should provide sufficient funding for the company through H1:16. 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

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

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

Cowen Securities, formerly known as Dahlgren Rose & Company, Rating System until May 25, 2013

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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Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

Cowen And Company Rating Definitions

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

Ocular Therapeutix Rating History as of 11/11/2014

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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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