

# **RBC Capital Markets**

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November 12, 2014

# Ocular Therapeutix, Inc.

# On track for pivotal and other key data starting 1Q:15

**Our view:** Pipeline progress is on track with Phase III OTX-DP inflammation/pain data in 1Q:15 and Phase II OTX-TP glaucoma data in 3Q:15. Results are meaningful because the former leads to commercialization in 2016 and the latter represents a large market. Whether or not long-term delivery of an anti-VEGF is feasible appears to be a 1Q:15 update which could be upside to expectations.

### **Key points:**

- **3Q:14 results vs. expectations.** Revenues missed consensus and expenses were in-line. Sep. end cash was ~\$81M (~\$3/ share).
- 2014 guidance vs. consensus. ReSure sales are expected to be limited as OCUL will not launch its own sales force until OTX-DP approval likely in 20:16.
- Changes to our estimates. We have lowered ReSure estimates going forward.

### Key updates from the conference call:

- OTX-DP Phase III post-surgical ocular inflammation and pain study on track for 1Q:15 read out. Enrollment is complete and along with sustained release efficacy differences in safety vs. steroid eye drops seen historically, such as IOP spikes which were not seen in the Phase II, could create a meaningful differentiation. An NDA is expected in 2Q:15.
- OTX-TP Phase II glaucoma data in 3Q:15. Study is powered for noninferiority vs. timolol. Other metrics to watch are 2- and 3-month plug retention and repeat administration, which is allowed in this study.
- OTX-DP allergic conjunctivitis pivotal 'go/ no-go' plans in 1H:15. The Phase II study (N=68) demonstrated a reduction in itching and redness and met the primary endpoint at day 14. However, the difference of at least 0.5 units, which was stat sig at 3 time points on days 14, 28 and 42, did not cross the 1.0 unit threshold historically used for eye drops. OCUL plans to meet with the FDA to discuss the meaningfulness of its data, where we think efficacy out to 30+ days is meaningful, and what the appropriate endpoints for a pivotal or next study could be given differences in administration (i.e., pulse therapy with eye drops vs. sustained, stable delivery with OTX-DP).
- Sustained release anti-VEGF feasibility data in 1Q:15. Though not in our model, this program has upside potential for OCUL, which appears to be able to deliver the protein, with activity retained, over a long period. However, the challenge seems to be tolerability. A decision on whether or not these objectives can be met is expected in 1Q:15 which could be followed by a partnership with one commercial anti-VEGF partner.

### **Upcoming news flow:**

- Sustained release intravitreal anti-VEGF feasibility in 1Q:15.
- OTX-DP Phase III post-surgical inflammation and pain data in 1Q:15.
- OTX-TP Phase IIb glaucoma data in 3Q:15.

# **Outperform**

**Speculative Risk** 

NASDAQ: OCUL; USD 15.81

### Price Target USD 21.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☑ Est. Change
Preview	☐ News Analysis

### Scenario Analysis\*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	6.00	15.81	21.00	29.00	<b>—</b>
	<b>↓</b> 62%		<b>↑</b> 33%	<b>↑</b> 83%	

\*Implied Total Returns

### **Key Statistics**

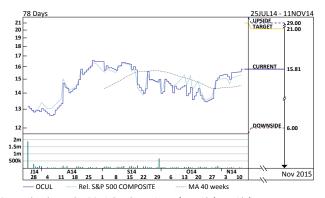
Shares O/S (MM):	21.2	Market Cap (MM):	335
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	77.655

#### **RBC Estimates**

FY Dec	2013A	2014E	2015E	
Revenue	0.0	0.5	2.3	
Prev.		1.6	8.5	
EPS, Ops Diluted	(5.10)	(2.68)	(1.76)	
Prev.		(2.28)	(1.49)	
P/E	NM	NM	NM	
Revenue	Q1	Q2	Q3	Q4
Revenue 2014	<b>Q1</b> 0.0A	<b>Q2</b> 0.1A	<b>Q3</b> 0.1A	<b>Q4</b> 0.2E
	•	•	•	•
2014	•	•	0.1A	0.2E
2014 Prev.	•	•	0.1A	0.2E
2014 Prev. EPS, Ops Diluted	0.0A	0.1A	0.1A 0.5E	0.2E 1.0E

### **Target/Upside/Downside Scenarios**

### Exhibit 1: Ocular Therapeutix, Inc.



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

### Target price/base case

We value OCUL at \$21, which includes US and EU sales with a probability of success of 85% to ReSure (~\$5/share), 75% to OTX-DP inflammation (~\$2/share), 60% to OTX-DP allergy (~\$2/share), and 60% to OTX-TP glaucoma for (~\$12/share). We forecast US and ex-US combined peak sales of ReSure, OTX-DP inflammation, OTX-DP allergic conjunctivitis and OTX-TP glaucoma at ~\$1B and ~\$0.8B respectively. We currently assign no additional value to the earlier stage pipeline.

### **Upside scenario**

Our upside scenario at \$29 per share includes US and EU sales with a probability of regulatory and commercial success of 75% to ReSure (~\$6/share), 65% to OTX-DP inflammation (~\$5/share), 50% to OTX-DP allergy (~\$3/share), and 45% to OTX-TP glaucoma for (~\$15/share). We forecast US and ex-US combined peak sales of ReSure, OTX-DP inflammation, OTX-DP allergic conjunctivitis and OTX-TP glaucoma at ~\$1.4B+ and ~\$1.2B+ respectively. Further upside would come from the advancement of earlier stage pipeline as we currently assign no additional value.

### **Downside scenario**

Our downside scenario at \$6 per share includes US and EU sales with a probability of success of 85% to ReSure (~\$2/share), 80% to OTX-DP inflammation (-\$2/share), 70% to OTX-DP allergy (~\$0/share), and 70% to OTX-TP glaucoma for (~\$5/share). We forecast US and ex-US combined product peak sales at ~\$470MM and ~\$420MM, respectively. The value of OTX-DP inflammation is negative and OTX-DP allergic conjunctivitis is zero because these products are launched first and it is assumed that their sales ramps alone are not high enough to support the R&D and SG&A infrastructure profitably.

### **Investment summary**

We believe OCUL shares offer the potential for upside as the hydrogel, sustained technology platform lowers clinical and development risk, allows multiple shots at success and the pipeline to be diversified, and increases the chances of a candidate making it through the clinic and onto the market. OTX-DP is in Phase III studies for inflammation and pain, and in Phase II studies for allergic conjunctivitis. OTX-TP is in a Phase IIb study for glaucoma, having posted promising Phase IIa, and earlier stage compounds represent upside optionality. Results from these studies are expected in 2014 and 2015, assuming progress going forward through 2017. Target markets represent millions of patients worldwide, and we forecast peak sales of OCUL's products totaling ~\$1.7B.

OCUL owns 100% of the rights to its pipeline, and patent protection extends into 2030, meaning the company is free to commercialize itself, partner, or to be acquired. Because ophthalmology remains an attractive therapeutic area and OCUL's product candidates have potential for improved dosing, convenience as well as safety advantages, progress through clinical and regulatory milestones, and any partnerships could be value-enhancing.

### **Potential Catalysts for OCUL Shares**

- Phase III data for OTX-DP Inflammation and pain in 1Q:15.

  Positive data could lead to an NDA and MAA
- Phase IIb data for OTX-TP in 3Q:15. Potential to show efficacy and 3-month plug retention for glaucoma
- Potential partnership for OTX-DP and OTX-DP. OCUL has the rights to both products, and a partnership is possible.
- Potential OTX-DP approvals and launches in 2016/2017 in the US and EU.
- ReSure sales could be higher than expectation

### **Potential Risks for OCUL Shares**

- Pivotal Phase III and earlier stage studies could fail. Phase II and Phase III data for OTX-DP are expected in 2014-2017 and one or more products could fail
- Sales ramp of punctum plug technology could be slow as clinicians fail to adopt, payers put up hurdles for reimbursing branded drugs, and cheaper generics hamper market penetration.
- Sales of ReSure Sealant could lag sales expectations as surgeons maintain current practices.
- OCUL could fail to find a partner for product commercialization outside the US.
- Other sustained release technologies could preempt
   OCUL's platform, thereby leading to a move away from hydrogel based products.

Exhibit 2: 3Q:14 Actuals vs. RBC estimates

	3Q:14				
(\$ in millions, except per share)	Actual Est. Diff.				
Revenue					
ReSure	0.1	0.5	(0.3)		
OTX-DP Inflammation	-	-	-		
OTX-DP allergy	-	-	-		
OTX-TP glaucoma	-	-	-		
ROW Royalties	-	-	-		
Total Revenue	0.1	. 0.5	(0.3)		
Operating expenses					
Royalty expense	-	0.0	(0.0)		
COGS	0.0	0.1	(0.0)		
R&D	4.5	5.0	(0.5)		
SG&A	2.4	2.0	0.4		
Total operating expenses	6.9	7.1	(0.2)		
Operating Income (Loss)	(6.8)	(6.6)	(0.1)		
Interest income	0.0	0.0	0.0		
Interest expense	(0.4)	(0.1)	(0.4)		
Other income (expense)	(0.1)	(0.1)	(0.0)		
Total other income	(0.5)	(0.1)	(0.4)		
Pretax Income	(7.3)	(6.8)	(0.5)		
Income tax expense		-	-		
Net income (loss)	(7.3)	(6.8)	(0.5)		
EPS - Basic (GAAP)	(\$0.48)	(\$0.32)	(\$0.16)		
EPS - Diluted (GAAP)	(\$0.48)	(\$0.32)	(\$0.16)		
Shares (basic)	15.2	21.2	-6.1		
Shares (diluted)	16.9	22.8	-5.9		

Source: Company reports and RBC Capital Market estimates

Exhibit 3: News flow

Timing	Expected News Flow	Program
1Q:15	Potential feasibility data	IHD-VEGF
1Q:15	Phase III results in post cataract inflammation and pain	OTX-DP
2Q:15	Submit NDA/ MAA for post cataract inflammation and pain	OTX-DP
1H:15	Initiate pivotal, Phase II/ III in allergic conjunctiviits	OTX-DP
1H:15	Go/ no-go Phase III decision in allergic conjunctivitis	OTX-DP
3Q:15	Phase IIb data in glaucoma	OTX-TP
4Q:15	Initiate Phase III study in glaucoma	OTX-TP
2015	Update on clinical program	IHD-VEGF
2015	Potential pipeline update on additional programs	
2015	Potential partnership(s) or business development	
1H:16	Phase III results in allergic conjunctivitis	OTX-DP
2Q/3Q:16	File NDA/ MAA in allergic conjunctivitis	OTX-DP
1H:16	Potential NDA approval for post cataract inflammation and pain	OTX-DP
3Q/4Q:17	Potential NDA approval for allergic conjunctivitis	OTX-DP
4Q:16/ 1H:17	Phase III results in glaucoma	OTX-TP
2H:17	File NDA/ MAA in glaucoma	OTX-TP
2H:18	Potential NDA approval for glaucoma	OTX-TP

Source: Company reports and RBC Capital Market estimates

# Exhibit 4: Pipeline

Product	Mechanism	Stage	Indication
ReSure	Ocular sealant	FDA approved	Sealant post cataract surgery
OTX-DP	Dexamethasone plug	Phase III	Post-cataract surgery for inflammation and pain
OTX-DP	Dexamethasone plug	Phase II	Allergic conjunctivitis
OTX-TP	Travoprost plug	Phase II	Glaucoma
OTX-MP	Moxifloxacin plug	Phase I	Bacterial conjunctivitis
Intravitreal Hydrogel Depot	Sustained release anti-VEGF depot	Pre-clinical	Wet AMD/ RVO/ DME

Source: Company reports and RBC Capital Markets estimates

## Valuation

We arrive at our \$21 per share price target using a sum-of-the parts analysis for OCUL shares. The primary components of our valuation include OCUL's ReSure sealant, OTX-DP for inflammation, OTX-DP for allergy, and OTX-TP for glaucoma product sales in the US and royalty revenues from sales in ROW. Our base, upside and downside scenarios use a discount rate of 15% to reflect potential clinical and commercial risk and assign a probability of success of the clinical and commercial roll out of ReSure, OTX-DP for inflammation, OTX-DP for allergic conjunctivitis, and OTX-TP for glaucoma.

# **Price target impediments**

Our price target is dependent on the clinical, regulatory and commercial success of the ReSure sealant, OTX-DP inflammation, OTX-DP allergy, and OTX-TP glaucoma. A Phase IIIb study for OTX-DP inflammation has been initiated and data is expected in 1Q:15. The phase II clinical trial for OTX-DP allergic conjunctivitis has been initiated and data is expected to report in 4Q:14 The phase IIa clinical trial for OTX-TP has been completed and a Phase IIb clinical trial in OTX-TP is expected in 2Q:15. Failure to demonstrate efficacy or safety in any of these studies would be a significant setback. Furthermore, any setbacks in regulatory approvals in the US or EU, delay in launch, failure to secure a partnership outside the US, increased competition or other limitations to the market potential of these products either due to better efficacy and/ or safety outcomes or pricing pressure due to the availability of generic drugs for glaucoma, could negatively affect our valuation.

# **Company description**

Ocular Therapeutix (OCUL) is developing sustained-release drugs that target ophthalmic disorders by using its proprietary hydrogel technology as a platform. The approach has low clinical and regulatory risks as the drugs OCUL is encapsulating within its proprietary microspheres are either off-patent or about to go off-patent. Since OCUL is able to turn a number of already approved drugs typically administered as eye drops into sustained-release, long-acting products, the hydrogel technology also represents a leverageable platform and a lower risk approach for creating multiple product candidates. OCUL also markets ReSure Sealant, which was recently approved for sealing corneal incisions after cataract surgery. OTX-DP for the treatment of post-surgical ocular inflammation and pain is in Phase III trials. Product candidates undergoing Phase II testing include OTX-DP for allergic conjunctivitis and OTX-TP for glaucoma.



(\$ in millions, except per share)																
Fiscal Year Ends December	2012A	2013A	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014A	2015A	2016A	2017A	2018A	2019A	2020A	2021A	2022A	2023A
Revenue																
ReSure	-	-	-	0.1	0.1	0.2	0.4	2.3	10.8	20.6	39.0	58.2	68.8	76.5	87.8	96.2
OTX-DP Inflammation	-	-	-	-	-	-	-	-	1.5	17.9	30.4	46.5	63.2	80.6	95.9	111.7
OTX-DP allergy	-	-	-	-	-	-	-	-	-	1.9	9.8	16.5	26.6	43.7	54.3	68.5
OTX-TP glaucoma	-	-	-	-	-	-	-	-	-	-	2.3	11.9	72.5	147.6	225.5	306.1
ROW Royalties	-	-	-	-	-	-	-	-	-	0.3	2.8	7.3	14.1	34.5	59.1	81.5
Total Revenue	0.0	-	0.0	0.1	0.1	0.2	0.5	2.3	12.3	40.7	84.4	140.3	245.1	382.9	522.4	664.0
Operating expenses																
Royalty expense	-	-	-	-	-	0.0	0.0	0.1	0.5	1.6	3.3	5.3	9.2	13.9	18.5	23.3
COGS	0.0	-	0.0	0.0	0.0	0.0	0.1	0.3	1.8	6.1	12.2	19.9	34.7	52.2	69.5	87.4
R&D	11.5	10.5	5.0	4.3	4.5	5.3	19.0	24.8	31.0	35.0	37.5	40.0	42.5	45.0	47.5	50.0
SG&A	2.1	2.4	1.9	1.7	2.4	2.5	8.5	14.9	38.0	52.5	65.0	70.0	75.0	80.0	104.5	132.8
Total operating expenses	13.7	12.9	6.9	6.0	6.9	7.8	27.6	40.1	71.3	95.2	118.0	135.3	161.4	191.2	240.0	293.5
Operating Income (Loss)	(13.7)	(12.9)	(6.8)	(5.9)	(6.8)	(7.6)	(27.1)	(37.8)	(59.0)	(54.5)	(33.6)	5.1	83.7	191.7	282.4	370.5
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2
Interest expense	(0.4)	(0.4)	(0.0)	(0.3)	(0.4)	(0.1)	(0.8)	(0.2)	(0.2)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Other income (expense)	(0.0)	0.0	(0.1)	(0.2)	(0.1)	(0.1)	(0.5)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Total other income	(0.4)	(0.4)	(0.2)	(0.5)	(0.5)	(0.1)	(1.3)	(0.6)	(0.5)	(0.8)	(0.8)	(0.8)	(0.8)	(0.7)	(0.7)	(0.7)
Pretax Income	(14.1)	(13.3)	(7.0)	(6.4)	(7.3)	(7.7)	(28.4)	(38.4)	(59.6)	(55.3)	(34.4)	4.3	83.0	191.0	281.7	369.9
Income tax expense	-	-	-	-	-	-	_	_	-	_	-	1.5	29.0	66.8	98.6	129.5
Net income (loss)	(14.1)	(13.3)	(7.0)	(6.4)	(7.3)	(7.7)	(28.4)	(38.4)	(59.6)	(55.3)	(34.4)	2.8	53.9	124.1	183.1	240.4
EPS - Basic (GAAP)	(\$5.59)	(\$5.10)	(\$2.45)	(\$2.10)	(\$0.48)	(\$0.36)	(\$2.68)	(\$1.76)	(\$2.18)	(\$1.65)	(\$1.02)	\$0.08	\$1.56	\$3.55	\$5.19	\$6.75
EPS - Diluted (GAAP)	(\$5.59)	(\$5.10)	(\$2.45)	(\$2.10)	(\$0.48)	(\$0.36)	(\$2.68)	(\$1.76)	(\$2.18)	(\$1.65)	(\$1.02)	\$0.08	\$1.43	\$3.24	\$4.69	\$6.05
Shares (basic)	2.5	2.6	2.9	3.0	15.2	21.3	10.6	21.9	27.3	33.6	33.9	34.2	34.6	34.9	35.3	35.6
Shares (diluted)	13.5	14.6	15.3	15.5	16.9	23.1	12.4	23.8	29.5	35.9	36.5	37.1	37.7	38.3	39.0	39.7
Operations Ratios	2012A	2013A	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014A	2015A	2016A	2017A	2018A	2019A	2020A	2021A	2022A	2023A
Margin Analysis					·											
cogs		-	-	21%	22%	15%	21%	15%	15%	15%	15%	15%	15%	15%	15%	15%
R&D		-	-	4425%	3134%	2582%	4034%	1093%	252%	86%	44%	29%	17%	12%	9%	8%
SG&A		-	6981%	1785%	1682%	1215%	1805%	658%	309%	129%	77%	50%	31%	21%	20%	20%
Operating Margin		-	NM	4%	34%	50%	54%	56%								
Income Tax rate		_	NM	35%	35%	35%	35%	35%								
Net Margin		-	NM	2%	22%	32%	35%	36%								
Source: Company Reports and RBC Capi	tal Markets est	timates														

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# **Required disclosures**

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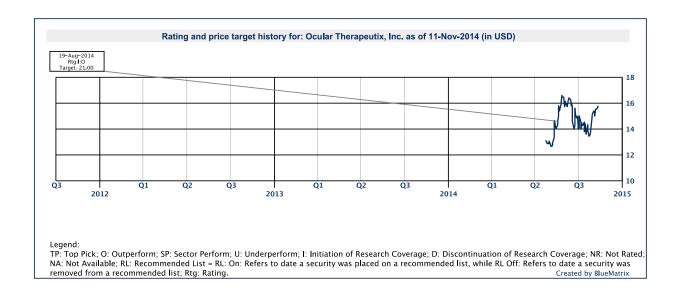
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	Distribution	n of ratings			
	RBC Capital Market	ts, Equity Research			
	As of 30-5	Sep-2014			
			Investment Bank	ing	
			Serv./Past 12 Mos.		
Rating	Count	Percent	Count	Percent	
BUY [Top Pick & Outperform]	858	52.35	308	35.90	
HOLD [Sector Perform]	683	41.67	151	22.11	
SELL [Underperform]	98	5.98	8	8.16	



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