

RBC Capital Markets

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Sector: Biotechnology

June 8, 2015

Ocular Therapeutix, Inc.

Updating the long thesis: Funded through product approvals and key catalysts

Our view: We believe near-term clinical drivers and long-term fundamentals support both stand-alone status or takeout potential. Five items underpin value: 1) Leading drug delivery platform, 2) Ability to rejuvenate pipelines, 3) High potential proprietary programs, including those targeting the back of the eye, 4) Several paths to product approvals, launches and profitability, and 5) Likelihood of a take-out given the platform and pipeline.

Key points:

- Capital raise provides several things, including funding through potential launch and several catalysts. We estimate ~\$66-76M raised, which is sufficient to fund operations into 2017. This includes the first commercial launch of Dextenza in post cataract/ surgical pain and inflammation and possibly allergic conjunctivitis too. A direct sales force could also help ReSure sales. Though we had previously assumed an offering in 2Q:16, ahead of Dextenza launch, our target is unchanged as the increased share count is offset with an increased contribution from the back-of-the-eye programs and minor adjustments elsewhere.
- Technology platform has potential to create value multiple ways: 1)
 Proprietary, 2) Partnering, or 3) M&A. With 3-4 active programs (and
 the ability to initiate even more) across 7 different indications spread
 from pre-clinical to pre-NDA stages, all of which are fully owned, OCUL
 has several paths to value. These include the ability to launch drugs
 itself with a focused sales force, partner opportunistically, or have the
 company acquired given the ability to extend product life cycles.
- Catalytic news flow in 2015, 2016 and 2017 for three Dextenza programs; target market opportunity is \$4-5B+. OCUL could file an NDA for Dextenza (OTX-DP) for post-cataract/ surgical pain in 2015, and sNDAs for post-cataract/ surgical inflammation and allergic conjunctivitis in 2016, which means a product launch by YE:16/ 1H:17. Clinical read outs include Phase III data in allergic conjunctivitis in 2015/ 2016 and post-cataract/ surgical inflammation in 2016, and Phase II data in inflam. dry eye in 2015.
- OTX-TP Phase II glaucoma data also coming; could be another sizable market opportunity. This study is not powered for stat sig differences but to guide Phase III design, especially given the new plug (not used in this study) could have 90%+ retention at three months.
- Anti-VEGF/ back-of-the-eye program holds big potential with or without a partner. The conundrum is delivering sufficient anti-VEGF to maintain vision improvement with the longest treatment interval feasible, which we think is 4-6 months for commercial viability. Data at ARVO (see noted dated May 4th) showed long anti-VEGF release is possible, though in vivo data extends to one-month only at this time. OCUL is pursuing a proprietary program with a small molecule TKI and possibly an anti-VEGF biologic. However, partnering remains a possibility but likely only if terms are favorable.

Outperform

Speculative Risk

NASDAQ: OCUL; USD 21.52

Price Target USD 48.00

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	
•	11.00	21.52	48.00	74.00	
	↓ 49%		1 23%	1 244%	

*Implied Total Returns

Kev Statistics

, , ,				
Shares O/S (MI	M):	21.2	Market Cap (MM):	456
Dividend:		0.00	Yield:	0.0%
Downside Valu	e:	11.00	Avg. Daily Volume:	156,639
Upside Value:		74.00		
Implied	Downside	(49)%		
Return:				

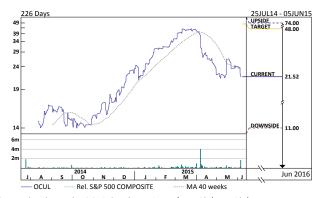
244%

Implied Upside Return: RBC Estimates

FY Dec	2014A	2015E	2016E	2017E
Revenue	0.8	2.3	4.3	19.4
Prev.				14.6
EPS, Ops Diluted	(2.69)	(1.50)	(2.65)	(2.47)
Prev.		(1.65)	(2.66)	(3.06)
P/E	NM	NM	NM	NM
Revenue	Q1	Q2	Q3	Q4
2014	0.0A	0.1A	0.1A	0.5A
2015	0.4A	0.4E	0.6E	0.9E
EPS, Ops Diluted				
2014	(2.45)A	(2.10)A	(0.48)A	(0.37)A
2015	(0.35)A	(0.38)E	(0.37)E	(0.39)E
Prev.		(0.40)E	(0.43)E	(0.46)E
All values in USD unless of	therwise noted	l.		

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 \$48, which includes US and EU sales with a probability of success of 85% to ReSure (~\$3/share), 75% to OTX-DP inflammation (~\$3/share), 60% to OTX-DP allergy (~\$4/share), 55% to OTX-DP dry eye (~\$8/share), 60% to OTX-TP glaucoma for (~\$15/share) and 25% (prev. 20%) to Anti-VEGF hydrogel (~\$16/share). We forecast US and ex-US combined peak sales of ReSure, OTX-DP inflammation, OTX-DP allergic conjunctivitis, OTX-DP dry eye, OTX-TP glaucoma, and anti-VEGF hydrogel at ~\$8B and ~\$10B, respectively.

Upside scenario

Our upside scenario at \$74 per share includes US and EU sales with a probability of regulatory and commercial success of 70% to ReSure (~\$4/share), 60% to OTX-DP inflammation (~\$5/share), 55% to OTX-DP allergy (~\$5/share), 30% to OTX-DP dry eye (~9/share), 45% to OTX-TP glaucoma for (~\$19/share), and 50% to anti-VEGF hydrogel (~\$32/share). We forecast US and ex-US combined peak sales of ReSure, OTX-DP inflammation, OTX-DP allergic conjunctivitis, OTX-DP dry eye, OTX-TP glaucoma, and anti-VEGF hydrogel at ~\$9B+ and ~\$11B+, respectively.

Downside scenario

Our downside scenario at \$11 per share includes US and EU sales with a probability of success of 75% to ReSure (~\$1/share), 70% to OTX-DP inflammation (\$0 share), 70% to OTX-DP allergy (~\$1 share), 60% to OTX-DP dry eye (\$1 share) and 65% to OTX-TP glaucoma for (~\$7 share). We forecast US and ex-US combined product peak sales at ~\$950MM and ~\$700MM, respectively. The value of OTX-DP inflammation is negative because the product is 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 and dry eye. 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 2015 and 2016, assuming progress going forward through 2017. Target markets represent millions of patients worldwide, and we forecast peak sales of OCUL's products totaling ~\$18B.

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 IIb data for OTX-TP in 3Q/ 4Q:15. Potential to show efficacy and 3-month plug retention for glaucoma.
- Phase III data for OTX-DP by YE:15/ 1Q:16. Prior Phase II data in allergic conjunctivitis mixed.
- Phase II data for OTX-DP in 3Q/4Q:15. First look at activity in inflammatory dry eye.
- 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 2015-2017 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: Forecast news flow

Timing	Expected News Flow	Program
Mid-/ 2H:15	Initiate Phase III study in allergic conjunctivitis	Dextenza (OTX-DP)
3Q/4Q:15	File NDA in post-cataract pain	Dextenza (OTX-DP)
4Q:15	Phase IIb data in glaucoma	OTX-TP
2H:15	Initiate 3rd Phase III in cataract pain/ inflamm.	Dextenza (OTX-DP)
2015/ 2016	Update on clinical program or partnership(s)	IHD-VEGF
4Q:15/1Q:16	Potential Phase II data in dry eye	Dextenza (OTX-DP)
2H:15	Initiate 2nd Phase III trial in allergic conjunctivitis	Dextenza (OTX-DP)
YE:15/ 1Q:16	Phase III results in allergic conjunctivitis (1st Phase III)	Dextenza (OTX-DP)
1H:16	Initiate Phase III study in glaucoma	OTX-TP
1H:16	Phase III 'go/ no-go' decision in dry eye	Dextenza (OTX-DP)
1H/ Mid-2016	Second Phase III results in allergic conjunctivitis (2nd Phase III)	Dextenza (OTX-DP)
Mid-/ 3Q:16	Phase III data in cataract pain/inflamm. (3rd Phase III)	Dextenza (OTX-DP)
Mid-/ 3Q:16	File sNDA/ MAA in allergic conjunctivitis	Dextenza (OTX-DP)
3Q/4Q:16	FDA decision on NDA in cataract pain	Dextenza (OTX-DP)
YE:16/1Q:17	US launch in post-cataract/ surgical pain	Dextenza (OTX-DP)
2016	Update on pre-clinical back-of-the-eye program	Anti-VEGF/ TKI
1H/ Mid-2017	Potential sNDA approval for cataract pain/ inflammation and conjunctivitis	Dextenza (OTX-DP)
1H:17	Phase III results in glaucoma	OTX-TP
2H:17/1Q:18	File NDA/ MAA in glaucoma	OTX-TP
2017/ 2018	Potential Phase I data in wAMD	Anti-VEGF/ TKI
2017/ 2018	Update on clinical program or partnership(s)	IHD-VEGF
2H:18/1Q:19	Potential NDA approval for glaucoma	OTX-TP

Source: Company reports and RBC Capital Markets estimates.

Exhibit 3: Pipeline

Product	Mechanism	Stage	Indication
ReSure	Ocular sealant	FDA approved	Sealant post cataract surgery
Dextenza (OTX-DP)	Dexamethasone plug	Pre-NDA (pain)	Post-cataract/ surgical inflammation and pain
		3rd Phase III planned	
		Phase III planned	Allergic conjunctivitis
		Phase II	Inflammatory dry eye
OTX-TP	Travoprost plug	Phase II	Glaucoma
OTX-MP	Moxifloxacin plug	Phase I	Bacterial conjunctivitis
Intravitreal Hydrogel Depot (anti-VEGF)	Sustained release anti- VEGF depot	Pre-clinical	Wet AMD/ RVO/ DME
Intravitreal Hydrogel Depot (TKI)	Sustained release TKI	Pre-clinical planned	Wet AMD/ RVO/ DME

 ${\color{red} \textbf{Source: Company reports and RBC Capital Markets.}}$

Valuation

We arrive at our \$48 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, OTX-DP for dry eye, anti-VEGF hydrogel, 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, OTX-DP dry eye, anti-VEGF hydrogel, and OTX-TP glaucoma. 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.



Ocular Therapeutix Income Statement Adnan Butt (415) 633 - 8588 adnan.butt@rbccm.com

(\$ in millions, except per share)																
Fiscal Year Ends December	2012A	2013A	2014A	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue																
ReSure	-	_	0.4	0.2	0.4	0.6	0.9	2.1	4.3	11.0	21.0	39.8	59.4	70.1	78.0	89.5
OTX-DP Inflammation	-	_	_		_	_	_	-	_	5.0	20.2	41.3	63.2	80.6	93.1	106.2
OTX-DP allergy	-	_	_	-	-	-	_	-	-	3.3	13.6	27.7	56.4	86.4	102.8	119.8
OTX-DP dry eye	-	_	-	-	-	-	_	-	-	_	_	-	23.4	83.7	146.3	211.4
OTX-TP glaucoma	-	_	-	-	-	-	_	-	-	_	2.7	14.4	91.7	194.3	308.6	435.7
ROW Royalties	-	_	-	-	-	-	_	-	-	0.1	1.3	5.2	12.6	33.7	59.4	83.8
Other	0.0	-	0.3	0.2	-	-	-	0.2	-	-	-	-	-	-	-	-
Total Revenue	0.0	-	0.8	0.4	0.4	0.6	0.9	2.3	4.3	19.4	58.9	128.4	306.7	548.7	788.1	1046.4
Operating expenses																
Royalty expense	-	-	-	-	0.0	0.0	0.0	0.1	0.2	0.8	2.3	4.9	10.8	17.3	23.3	30.0
COGS	0.0	-	0.1	0.1	0.1	0.1	0.1	0.3	0.6	2.9	8.6	18.5	44.1	77.2	109.3	144.4
R&D	11.5	10.5	18.9	4.7	5.8	6.3	6.8	23.6	35.0	40.0	50.0	52.5	55.0	57.5	60.0	62.5
SG&A	2.1	2.4	8.9	2.8	3.1	3.5	3.9	13.3	38.0	52.5	65.0	70.0	75.0	80.0	157.6	209.3
Total operating expenses	13.7	12.9	27.9	7.5	9.0	9.9	10.9	37.3	73.8	96.2	125.9	145.9	185.0	232.0	350.2	446.2
Operating Income (Loss)	(13.7)	(12.9)	(27.1)	(7.1)	(8.6)	(9.3)	(10.0)	(35.0)	(69.5)	(76.8)	(67.0)	(17.5)	121.8	316.7	437.9	600.2
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2
Interest expense	(0.4)	(0.4)	(1.1)	(0.5)	(0.1)	(0.1)	(0.1)	(0.7)	(0.2)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Other income (expense)	(0.0)	0.0	(0.4)	-	(0.1)	(0.1)	(0.1)	(0.3)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Total other income	(0.4)	(0.4)	(1.6)	(0.5)	(0.1)	(0.1)	(0.1)	(0.9)	(0.5)	(0.8)	(0.8)	(0.8)	(0.8)	(0.7)	(0.7)	(0.7)
Pretax Income	(14.1)	(13.3)	(28.7)	(7.6)	(8.7)	(9.5)	(10.1)	(35.9)	(70.0)	(77.6)	(67.8)	(18.3)	121.0	316.0	437.2	599.5
Income tax expense	-	-	-	-	-	-	-	-	-	-	-	-	42.4	110.6	153.0	209.8
Net income (loss)	(14.1)	(13.3)	(28.7)	(7.6)	(8.7)	(9.5)	(10.1)	(35.9)	(70.0)	(77.6)	(67.8)	(18.3)	78.7	205.4	284.2	389.7
EPS - Basic (GAAP)	(\$5.59)	(\$5.10)	(\$2.69)	(\$0.35)	(\$0.38)	(\$0.37)	(\$0.39)	(\$1.50)	(\$2.65)	(\$2.47)	(\$2.14)	(\$0.52)	\$2.21	\$5.70	\$7.81	\$10.61
EPS - Diluted (GAAP)	(\$5.59)	(\$5.10)	(\$2.69)	(\$0.35)	(\$0.38)	(\$0.37)	(\$0.39)	(\$1.50)	(\$2.65)	(\$2.47)	(\$2.14)	(\$0.52)	\$2.03	\$5.21	\$7.09	\$9.55
Shares (basic)	2.5	2.6	10.7	21.4	22.8	25.5	25.8	23.9	26.4	31.4	31.7	35.3	35.7	36.0	36.4	36.7
Shares (diluted)	13.5	14.6	12.5	23.2	24.7	27.4	27.7	25.8	28.6	33.8	34.3	38.1	38.8	39.4	40.1	40.8
Operations Ratios	2012A	2013A	2014A	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Margin Analysis																
COGS		-	21%	24%	15%	15%	15%	16%	15%	15%	15%	15%	16%	18%	19%	19%
R&D		-	2446%	1108%	1450%	1050%	768%	1022%	808%	206%	85%	41%	18%	10%	8%	6%
SG&A		-	1152%	649%	775%	583%	441%	574%	877%	270%	110%	55%	24%	15%	20%	20%
Operating Margin		-	NM	40%	58%	56%	57%									
Income Tax rate		-	NM	35%	35%	35%	35%									
Net Margin		-	NM	26%	37%	36%	37%									

Source: Company reports and RBC Capital Markets estimates



Required disclosures

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Top Pick (TP): Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

Outperform (O): Expected to materially outperform sector average over 12 months.

Sector Perform (SP): Returns expected to be in line with sector average over 12 months.

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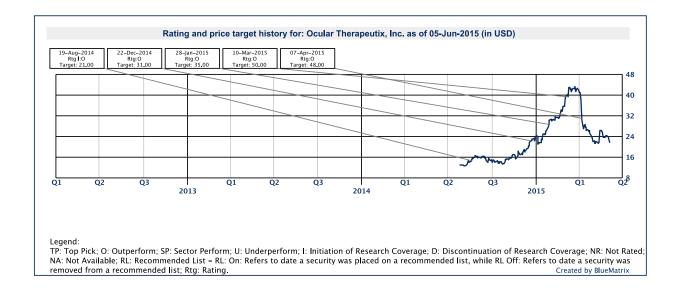
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	Distribution	n of ratings				
	RBC Capital Market	s, Equity Research				
	As of 31-N	/lar-2015				
			Investment Bank	ing		
			Serv./Past 12 Mos.			
Rating	Count	Percent	Count	Percent		
BUY [Top Pick & Outperform]	909	52.33	280	30.80		
HOLD [Sector Perform]	713	41.05	125	17.53		
SELL [Underperform]	115	6.62	5	4.35		



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