# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 10, 2015

# **OCULAR THERAPEUTIX, INC.**

(Exact Name of Company as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-36554 (Commission File Number) 20-5560161 (IRS Employer Identification No.)

36 Crosby Drive, Suite 101 Bedford, MA 01730 (Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: (781) 357-4000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On March 10, 2015, Ocular Therapeutix, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2014. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release of Ocular Therapeutix, Inc., dated March 10, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 10, 2015

#### OCULAR THERAPEUTIX, INC.

By: /s/ Bradford Smith

Bradford Smith Chief Financial Officer

#### Exhibit No. Description

99.1 Press Release of Ocular Therapeutix, Inc., dated March 10, 2015.

#### Ocular Therapeutix™ Reports Fourth Quarter and Full Year 2014 Financial Results

Both primary efficacy measures successfully achieved in the first of two Phase 3 clinical trials of OTX-DP for the treatment of post-surgical ocular inflammation and pain

NDA submission for OTX-DP for the treatment of post-surgical ocular inflammation and pain expected in 2Q 2015

Initiation of Phase 3 clinical trials of OTX-DP for the treatment of allergic conjunctivitis expected in the middle of 2015

Phase 2b clinical data on OTX-TP for glaucoma and ocular hypertension anticipated in 4Q 2015

Conference Call Today at 8:00 am Eastern Time

**BEDFORD, MA, March 10, 2015 (BUSINESS WIRE):** Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the fourth quarter and twelve months ended December 31, 2014.

"2014 was an exceptional year for Ocular Therapeutix, with accelerated advancement of our sustained release drug delivery product candidates, and this momentum is continuing into 2015," said Amar Sawhney, Ph.D., President and Chief Executive Officer. "Earlier this morning, we announced that we successfully achieved both primary efficacy measures in our Phase 3a clinical trial evaluating OTX-DP for the treatment of post-surgical ocular inflammation and pain. This is the first of our two Phase 3 clinical trials of OTX-DP for this indication, and we believe that this product candidate has the potential to meaningfully improve upon the treatment modalities available to patients today. We are advancing our business on multiple fronts and expect to be reporting on a number of important milestones in 2015, the most imminent being Phase 3b clinical trial results and an NDA submission for OTX-DP for the treatment of post-surgical ocular inflammation and pain. We also anticipate the initiation of Phase 3 clinical trials of OTX-DP for allergic conjunctivitis, results from our Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease, and results of a Phase 2b clinical trial of our OTX-TP product candidate for glaucoma and ocular hypertension in 2015. Additionally, we will continue to advance our preclinical development efforts for sustained-release delivery of anti-VEGF drugs for the treatment of wet AMD using our hydrogel depot, which we believe has potential to reduce the number of annual intravitreal injections patients receive for their condition."

#### **Clinical Milestones and Corporate Developments**

• Earlier today, Ocular Therapeutix reported positive topline Phase 3a clinical trial data of its Sustained Release Dexamethasone (OTX-DP) for the treatment of ocular inflammation and pain following cataract surgery in 247 patients, achieving statistically significant improvement both in pain and in the reduction of inflammatory cells. Statistically significant differences were shown in both primary efficacy measures between treatment and control groups, the absence of inflammatory cells at day 14 and the absence of pain at day 8. 33.7% of OTX-DP treated patients showed an absence of inflammatory cells in the anterior chamber of the eye on day 14 compared to 14.6% of those receiving placebo (p=0.0015). In addition, 76.1% of patients receiving OTX-DP reported absence of pain in the study eye at day 8 compared to 36.1% of those patients in the placebo group (p<0.0001).

- In January 2015, the Company initiated patient enrollment in a Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease, expanding the clinical program for its hydrogel technology into a new indication.
- In November 2014, the Company announced results from a Phase 2 clinical trial for OTX-DP for the treatment of allergic conjunctivitis, achieving a statistically significant therapeutic effect for ocular itching and conjunctival redness at multiple time points with a single dose.
- In November 2014, the Company initiated patient enrollment in a Phase 2b clinical trial of its Sustained Release Travoprost (OTX-TP) for the treatment of glaucoma and ocular hypertension. The prospective, multicenter, randomized, double-masked, parallel-arm, active controlled study is designed to evaluate 80 patients at 10 clinical sites in the U.S. for the safety and efficacy of OTX-TP as compared to timolol eye drops. Fifty patients have been enrolled thus far, and the Company is on track to complete the trial in the fourth quarter of 2015.
- In October 2014, the Company signed an early stage feasibility agreement with a fourth biopharmaceutical company to evaluate an oncology drug for ophthalmic indications.
- In July and August 2014, the Company raised net proceeds of approximately \$66.4 million in its IPO of 5,000,000 shares of its common stock and the full exercise of the underwriters' option on an additional 750,000 shares. On July 25, 2014, the Company's shares began trading on the NASDAQ Global Market under the symbol "OCUL".
- In January 2014, the Company received approval from the U.S. Food and Drug Administration (FDA) to commercialize the ReSure<sup>®</sup> Sealant in the United States, with an indication for prevention of postoperative fluid egress from incisions with a demonstrated wound leak following cataract surgery. The ReSure<sup>®</sup> Sealant is the first and only sealant that is FDA-approved for ophthalmic use.

#### **Anticipated Clinical and Regulatory Milestones**

- Completion of the Phase 3b clinical trial of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery, with topline results expected by the end March. This is the second of two Phase 3 clinical trials of OTX-DP for this indication.
- Submission of a New Drug Application (NDA) for OTX-DP for the treatment of post-surgical ocular inflammation and pain anticipated in the second quarter of 2015.
- Advancement of feasibility work on the sustained delivery of anti-VEGF drugs in a hydrogel depot for the treatment of back-of-the-eye diseases, including wet age-related macular degeneration, expected in the first half of 2015.
- Completion of enrollment in the Phase 2b clinical trial evaluating OTX-TP for the treatment of glaucoma and ocular hypertension, with data expected in the fourth quarter of 2015.
- Initiation of Phase 3 clinical trials of OTX-DP for the treatment of allergic conjunctivitis expected in the middle of 2015.
- Completion of a Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease, with data expected in the fourth quarter of 2015.

#### Fourth Quarter and Year Ended December 31, 2014 Financial Results

As of December 31, 2014, cash, cash equivalents and marketable securities totaled \$74.8 million. Cash used in operating activities was \$5.6 million in the fourth quarter of 2014 and \$20.5 million for the year ended December 2014. There was \$15.0 million in outstanding debt as of December 31, 2014, with an interest only period through September 30, 2015. The Company expects that cash, cash equivalents and marketable securities will be sufficient to fund operating expenses, debt service obligations and capital expenditures at least through the first half of 2016.

Ocular Therapeutix reported a net loss of approximately \$8.0 million, or \$(0.37) per share, for the quarter ended December 31, 2014, compared to a net loss of \$3.5 million, or \$(1.32) per share, for the quarter ended December 31, 2013. The fourth quarter 2014 results include \$1.0 million in non-cash charges for stock-based compensation compared to \$0.1 million in such non-cash charges in the fourth quarter of 2013. The Company reported a net loss of approximately \$28.7 million, or \$(2.69) per share, for the year ended December 31, 2014, compared to a net loss of \$1.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to a net loss of \$13.3 million, or \$(5.11) per share, for the year ended December 31, 2014, compared to \$0.5 million in such non-cash charges in 2013.

Total operating expenses for the quarter ended December 31, 2014 were \$8.0 million as compared to \$3.4 million for the quarter ended December 31, 2013. Research and development (R&D) expenses for the quarter ended December 31, 2014 were \$5.1 million, compared to \$2.8 million for the quarter ended December 31, 2013. This increase in operating expenses is primarily related to clinical trial activities, the expansion of the Company's product development programs and costs incurred in connection with operating as a public company.

The Company generated \$0.5 million in revenue during the three months ended December 31, 2014, including collaboration revenue from feasibility agreements with pharmaceutical company partners and revenue from sales of ReSure® Sealant. Sales of ReSure Sealant commenced in the first quarter of 2014, and limited sales are anticipated in 2015 as the Company expects to defer the hiring of a direct sales force until the potential launch of its first sustained release drug delivery product, OTX-DP for the treatment of post-surgical inflammation and pain.

As of December 31, 2014, there were approximately 21.3 million shares outstanding.

#### **Conference Call & Webcast Information**

Members of the Ocular Therapeutix management team will host a live conference call and webcast at 8:00 am **Eastern Time on March 10, 2014** to discuss the Company's financial results and provide a general business update.

The live webcast and a replay may be accessed by visiting Ocular's website at <u>investors.ocutx.com</u>. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (international) to listen to the live conference call. The conference ID number for the live call is 98833560. Please dial in approximately 10 minutes prior to the call. Following the webcast, an archived version of the call will be available for three months.

#### About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidates are in Phase 3 clinical development for post-surgical ocular inflammation and pain, and Phase 2 clinical development for glaucoma, allergic conjunctivitis, and inflammatory dry eye disease. The Company is also evaluating sustained-release injectable anti-VEGF drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure<sup>®</sup> Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

#### **Forward Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development of the Company's product candidates, such as the timing and conduct of the Company's Phase 3 clinical trials of OTX-DP for the treatment of post-surgical ocular inflammation and pain, the potential submission of an NDA for OTX-DP for this indication, the timing and conduct of the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension, the Company's Phase 3 clinical trials of OTX-DP for allergic conjunctivitis and the Company's Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease, pre-commercial activities, the advancement of the Company's earlier stage pipeline, including the timing and conduct of feasibility studies for the Company's hydrogel depot delivering anti-VEGF drugs. future sales of ReSure Sealant and other statements containing the words "anticipate," "believe," "expect," "intend", "aoal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause Ocular Therapeutix' clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions, the timing and costs involved in commercializing ReSure® Sealant and other factors discussed in the "Risk Factors" section contained in the Company's most recent Quarterly Report on Form 10-Q on file with the

Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

#### Investors:

Ocular Therapeutix, Inc. Brad Smith Chief Financial Officer bsmith@ocutx.com or Burns McClellan on behalf of Ocular Therapeutix Kimberly Minarovich, 212-213-0006 kminarovich@burnsmc.com or

#### Media:

Scott Corning Vice President of Sales and Marketing scorning@ocutx.com

### Ocular Therapeutix, Inc. Statement of Operations and Comprehensive Loss (In thousands, except share and per share data)

	Three Months ended December 31,				Year ended December 31,			
		2014		2013	_	2014		2013
Product revenue	\$	193	\$		\$	460	\$	
Collaboration revenue		312		—		312		—
Total revenue		505				772		
Operating Expenses:								
Cost of product revenue		30				91		
Research and development		5,148		2,842		18,880		10,517
Selling and marketing		658		197		1,982		625
General and administrative		2,216		380		6,913		1,761
Total operating expenses		8,052		3,419		27,866		12,903
Loss from operations		(7,547)		(3,419)		(27,094)		(12,903)
Other income (expense):								
Interest income				2		7		13
Interest expense		(407)		(91)		(1,119)		(441)
Other (expense) income, net		—		3		(442)		14
Total other expense, net		(407)		(86)		(1,554)		(414)
Net loss and comprehensive loss		(7,954)		(3,505)		(28,648)		(13,317)
Accretion of redeemable convertible preferred stock to redemption value		—		(5)		(11)		(27)
Net loss attributable to common stockholders	\$	(7,954)	\$	(3,510)	\$	(28,659)	\$	(13,344)
Net loss per share attributable to common stockholders per share, basic and diluted	\$	(0.37)	\$	(1.32)	\$	(2.69)	\$	(5.11)
Weighted average shares outstanding, basic and diluted	21,	289,378	2	,659,726	10	),652,865	_2	,609,020

## OCULAR THERAPEUTIX, INC.

### **BALANCE SHEETS**

(In thousands, except share and per share data)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,393	\$ 17,505
Marketable securities	37,435	—
Accounts receivable from related party		19
Accounts receivable	329	250
Inventory	133	—
Prepaid expenses and other current assets	893	240
Total current assets	76,183	18,014
Property and equipment, net	1,782	904
Restricted cash	228	228
Total assets	\$ 78,193	\$ 19,146
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,316	\$ 545
Accrued expenses	3,016	741
Deferred revenue	188	250
Notes payable, net of discount, current	1,354	1,806
Total current liabilities	5,874	3,342
Preferred stock warrants		254
Deferred rent, long-term	112	27
Notes payable, net of discount, long-term	13,511	651
Total liabilities	19,497	4,274
Commitments and contingencies		
Redeemable convertible preferred stock (Series A, B, C, D and D-1), \$0.001 par value; no shares and 33,979,025 shares		
authorized at December 31, 2014 and 2013, respectively; no shares and 32,842,187 shares issued and outstanding at		
December 31, 2014 and 2013, respectively	_	74,344
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 5,000,000 and no shares authorized at December 31, 2014 and 2013, respectively; no		
shares issued or outstanding at December 31, 2014 and 2013		
Common stock, \$0.0001 par value; 100,000,000 and 45,000,000 shares authorized at December 31, 2014 and 2013,		
respectively; 21,333,507 and 2,676,648 shares issued and outstanding at December 31, 2014 and 2013, respectively	2	
Additional paid-in capital	148,122	1,308
Accumulated deficit	(89,428)	(60,780)
Total stockholders' equity (deficit)	58,696	(59,472)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 78,193	\$ 19,146
	\$ 70,133	φ 1 <i>3</i> ,140