
**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 7, 2019**

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.)

15 Crosby Drive
Bedford, MA 01730
(Address of Principal Executive Offices) (Zip Code)

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 7, 2019, Ocular Therapeutix, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2018. 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 7, 2019](#)

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.

OCULAR THERAPEUTIX, INC.

Date: March 7, 2019

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer

Ocular Therapeutix™ Reports Fourth Quarter and Year End 2018 Financial Results and Business Update*DEXTENZA® Commercial Launch Planned for Mid-Year 2019**OTX-TP Phase 3 Data Expected in the First Half of 2019**Strengthened Cash Position with Closing of \$37.5 Million Financing*

BEDFORD, Mass.—(BUSINESS WIRE)—March 7, 2019— Ocular Therapeutix™, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the fourth quarter and year ended December 31, 2018 and provided a business update.

“2018 was a transformational year for Ocular highlighted by the U.S. Food and Drug Administration’s approval of DEXTENZA®, our dexamethasone intracanalicular insert for the treatment of post-surgical ocular pain,” said Antony Mattessich, President and Chief Executive Officer. “This accomplishment brings us one step closer to realizing the significant potential of our hydrogel drug-delivery platform. We are at a critical moment for the company as we are on the cusp of becoming a fully-integrated, commercial-stage biopharmaceutical company. We remain on track to launch DEXTENZA by mid-year. We are also pleased with the early momentum we are seeing as we enter 2019, having filed a supplemental New Drug Application to expand the DEXTENZA label for the treatment of ocular inflammation and recently closing a \$37.5 million convertible debt financing which strengthens our cash position and extends our runway into early 2020. Lastly, our pipeline continues to progress and we remain on track to present top-line data from our first Phase 3 pivotal trial of OTX-TP in the first half of this year. Our two Phase 1 programs are also progressing well with the dosing of our second patient in the OTX-TKI trial in wet Age-Related Macular Degeneration (wet AMD) and the continuing enrollment of patients in our second cohort in our OTX-TIC program in glaucoma.”

Key Highlights and Upcoming Events

- ***DEXTENZA commercial launch planned for mid-year 2019.*** Ocular remains on track to begin sampling DEXTENZA in May 2019 with a formal launch planned by July 2019, upon receipt of pass-through payment status, when the Center for Medicare and Medicaid Services (CMS) is expected to issue a C-Code. As of today, applications for both transitional C-Code and permanent J-Code reimbursement are submitted and pending with CMS.
 - ***Preparations for commercial launch of DEXTENZA continue.*** The Company has completed
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the hiring of its sales management team and is actively recruiting for the rest of its field organization. Ocular plans to launch with an initial sales force of approximately 20 key account managers plus a field reimbursement team with the goal of being at approximately 40 key account managers by the end of the year. Additionally, the distribution network is in place, a reimbursement services hub is in progress, and the Company expects to schedule meetings with payers in the near term.

- ***Topline efficacy data for the Phase 3 clinical trial of OTX-TP (travoprost insert) for the treatment of glaucoma expected in the first half of 2019.*** The Phase 3 clinical trial enrolled 550 subjects with the primary efficacy endpoint being a statistically superior mean reduction of intraocular pressure (IOP) from baseline for OTX-TP treated subjects compared with placebo insert treated subjects at three diurnal time points at each of three measurement dates of 2, 6, and 12 weeks following insertion. In addition, while not a primary endpoint, the Company expects that the IOP reduction will also need to be clinically meaningful for regulatory approval. The Company continues to enroll an open-label, one-year safety extension study with OTX-TP. This study is designed to provide additional long-term safety data with repeat administration of OTX-TP.
- ***Initial results of the Phase 1 clinical trial of OTX-TIC (travoprost implant) for the treatment of glaucoma are anticipated in first half 2019.*** OTX-TIC is a bioresorbable, travoprost-containing hydrogel intracameral implant. The U.S. Phase 1 trial is a multi-center, open-label, prospective, dose escalation clinical trial to evaluate the safety, efficacy, durability, and tolerability of OTX-TIC in patients with primary open-angle glaucoma or ocular hypertension. The first subject has been treated for 9 months with a single insert.
- ***Commenced dosing of patients in the Phase 1 clinical trial of OTX-TKI (intravitreal tyrosine kinase inhibitor implant).*** OTX-TKI is a bioresorbable, hydrogel fiber implant with anti-angiogenic properties delivered by intravitreal injection to the posterior segment of the eye for the treatment of wet AMD for an extended duration of up to nine months. The Phase 1 trial is being conducted in Australia and is a multi-center, open-label study testing the safety, durability, and tolerability of OTX-TKI.
- ***Regeneron continues evaluating the final formulation of OTX-IVT (aflibercept implant).*** OTX-IVT is an extended-delivery formulation of the VEGF trap aflibercept (EYLEA®), delivered by intravitreal injection, for the treatment of retinal diseases such as wet AMD.

Fourth Quarter and Year Ended December 31, 2018 Financial Results

- The Company augmented cash and cash equivalents of \$54.1 million at December 31, 2018 during the first two months of 2019 with proceeds from \$37.5 million in senior subordinated convertible notes and \$5.0 million of net proceeds raised under the Company's 2016 Sales
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Agreement (ATM) during the first two months of 2019. Based on the Company's current plans and forecasted expenses, Ocular Therapeutix believes that existing cash and cash equivalents will fund operating expenses, debt service obligations, and capital expenditures into early 2020.

- As of the quarter and year ended December 31, 2018, the Company had \$54.1 million in cash and cash equivalents versus \$56.9 million at the end of the third quarter of 2018. The year end cash balance benefited from \$5.6 million in net proceeds generated from the sale of common stock under the ATM during the fourth quarter of 2018 as well as \$12.0 million of net proceeds from an expansion and extension of the Company's existing five-year term loan facility. Offsetting these inflows during the quarter were a net loss of \$17.4 million and principal debt and interest payments of \$1.5 million.
- Research and development expenses for the fourth quarter were \$10.3 million versus \$7.9 million for the fourth quarter of 2017 and reflect increased unallocated other costs, primarily in personnel costs, consulting services, outside testing expenses, and costs associated with additional hiring.
- Selling and marketing expenses for the fourth quarter were \$2.3 million as compared to \$0.9 million for the same quarter in 2017. This increase relates to initial scale-up in pre-commercial activities as a result of the early approval of DEXTENZA on November 30, 2018.
- General and Administrative expenses were \$5.1 million for the fourth quarter of 2018 versus \$4.3 million in the comparable quarter of 2017. The increase in expenses stemmed primarily from increases in legal costs related to the defense of the Company in ongoing legal proceedings.
- The Company reported a fourth quarter net loss of \$(17.4) million, or a loss of \$(0.42) per share. This compares to a net loss of \$(13.1) million, or a loss of \$(0.44) per share, for the same period in 2017. The net loss for the fourth quarter of 2018 included \$2.5 million in non-cash charges for stock-based compensation and depreciation compared to \$2.6 million for the same quarter in 2017.
- The Company had approximately 42.8 million shares issued and outstanding as of March 1, 2019.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 4:30 pm Eastern Time to review the Company's financial results and provide a general business update. The live webcast can be accessed by visiting the Investors section of the

Company's website at investors.ocutx.com. Please connect 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 will be 6599787. An archive of the webcast will be available until June 7, 2019 on the Company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's first commercial drug product, DEXTENZA®, is FDA-approved for the treatment of ocular pain following ophthalmic surgery. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in Phase 3 clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company's earlier stage assets include OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. Ocular Therapeutix's first product, ReSure® 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 the commercialization of DEXTENZA®, ReSure Sealant, or any of the Company's product candidates, including the anticipated commercial launch of, and receipt of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and the prospects for approvability of DEXTENZA for post-surgical ocular inflammation or any other indications, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder; the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "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 the Company's 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 timing and costs involved in commercializing DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to obtain reimbursement codes for DEXTENZA, the initiation, timing and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and 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, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the outcome of the Company's ongoing legal proceedings and need for additional financing or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports 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 except as required by law. 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.

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Ocular Therapeutix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue:				
Product revenue	\$ 504	\$ 487	\$ 1,990	\$ 1,923
Total revenue	<u>504</u>	<u>487</u>	<u>1,990</u>	<u>1,923</u>
Costs and operating expenses:				
Cost of product revenue	117	113	465	457
Research and development	10,258	7,908	36,915	30,880
Selling and marketing	2,291	903	4,942	17,000
General and administrative	5,121	4,279	18,786	15,509
Total costs and operating expenses	<u>17,787</u>	<u>13,203</u>	<u>61,108</u>	<u>63,846</u>
Loss from operations	<u>(17,283)</u>	<u>(12,716)</u>	<u>(59,118)</u>	<u>(61,923)</u>
Other income (expense):				
Interest income	258	104	879	424
Interest expense	(374)	(490)	(1,739)	(1,892)
Other income (expense), net	—	—	—	5
Total other expense, net	<u>(116)</u>	<u>(386)</u>	<u>(860)</u>	<u>(1,463)</u>
Net loss	<u>\$ (17,399)</u>	<u>\$ (13,102)</u>	<u>\$ (59,978)</u>	<u>\$ (63,386)</u>
Net loss per share, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (0.44)</u>	<u>\$ (1.57)</u>	<u>\$ (2.20)</u>
Weighted average common shares outstanding, basic and diluted	<u>41,094,230</u>	<u>29,448,993</u>	<u>38,115,142</u>	<u>28,818,196</u>
Comprehensive loss:				
Net loss	<u>\$ (17,399)</u>	<u>\$ (13,102)</u>	<u>\$ (59,978)</u>	<u>\$ (63,386)</u>
Other comprehensive loss:				
Unrealized gain on marketable securities	—	—	—	5
Total other comprehensive income	<u>—</u>	<u>—</u>	<u>—</u>	<u>5</u>
Total comprehensive loss	<u>\$ (17,399)</u>	<u>\$ (13,102)</u>	<u>\$ (59,978)</u>	<u>\$ (63,381)</u>

OCULAR THERAPEUTIX, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 54,062	\$ 41,538
Accounts receivable	201	226
Inventory	217	122
Prepaid expenses and other current assets	1,713	1,453
Total current assets	56,193	43,339
Property and equipment, net	10,236	10,478
Restricted cash	6,614	1,614
Total assets	<u>\$ 73,043</u>	<u>\$ 55,431</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,965	\$ 3,571
Accrued expenses and deferred rent	6,194	4,310
Notes payable, net of discount, current	—	5,545
Total current liabilities	9,159	13,426
Deferred rent, long-term	3,221	3,387
Notes payable, net of discount, long-term	24,788	12,471
Total liabilities	<u>37,168</u>	<u>29,284</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 41,518,091 and 29,658,202 shares issued and outstanding at December 31, 2018 and December 31, 2017	4	3
Additional paid-in capital	333,114	263,409
Accumulated deficit	(297,243)	(237,265)
Total stockholders' equity	35,875	26,147
Total liabilities and stockholders' equity	<u>\$ 73,043</u>	<u>\$ 55,431</u>