
**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): **May 10, 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	OCUL	The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2019, Ocular Therapeutix, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2019. 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 May 10, 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: May 10, 2019

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

Ocular Therapeutix™ Reports First Quarter 2019 Financial Results and Business Update*DEXTENZA® Commercial Launch Scheduled for Mid-Year 2019*

BEDFORD, Mass.—(BUSINESS WIRE)—March 10, 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 first quarter ended March 31, 2019 and provided a business update.

“This is an exciting time at Ocular Therapeutix and it has been a very productive first quarter,” said Antony Mattessich, President and Chief Executive Officer. “We have made tremendous progress with DEXTENZA on a number of fronts and are pleased that the launch is in full roll-out. In addition, we have received a preliminary recommendation from the Center for Medicare and Medicaid Services for our permanent HCPCS J-code for DEXTENZA, and we were given a PDUFA target action date of November 2019 for the expansion of our DEXTENZA label to include the treatment of ocular inflammation following ophthalmic surgery. Beyond DEXTENZA, our pipeline continues to advance and we look forward to announcing results from our first Phase 3 clinical trial of OTX-TP in the next several weeks.”

Key Highlights and Upcoming Events**• *Progressed DEXTENZA (dexamethasone ophthalmic insert):***

- Completed the initial hiring of its sales management, key account managers, medical science liaisons and reimbursement professionals. DEXTENZA is now available at distribution centers with a sampling program targeted at key surgery centers commencing later this month. The formal DEXTENZA commercial launch remains on track for mid-2019 pending the receipt of transitional pass-through payment status (C-code), by the Center for Medicare and Medicaid Services (CMS), anticipated in June for activation July 1, 2019.
 - Announced that CMS has included DEXTENZA 0.4mg for intracanalicular use on its list of products that has been preliminarily recommended for a new dedicated Healthcare Common Procedure Coding System (HCPCS) J-code, effective January 1, 2020.
 - Announced the U.S. Food and Drug Administration (FDA) has accepted for filing the supplemental New Drug Application (sNDA) for DEXTENZA to add the treatment of ocular inflammation following ophthalmic surgery as an additional indication. The FDA has set a PDUFA target action date of November for the completion of its review of the sNDA.
 - Presented data at the recent American Society of Cataract and Refractive Surgery (ASCRS) symposium including pooled Phase 3 safety and efficacy data for DEXTENZA use after cataract surgery and Phase 3 data highlighting DEXTENZA's benefit in treating symptoms of allergic conjunctivitis using a modified conjunctival allergen challenge (CAC) model. The Company
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believes DEXTENZA has potential to be used in multiple ocular indications and is also pursuing preclinical work in post-operation pain, inflammation, antibiotics, dry eye and additional formulations for allergic conjunctivitis.

- **Topline efficacy data from the Phase 3 clinical trial of OTX-TP (travoprost ophthalmic insert) for the treatment of glaucoma expected in the second quarter 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. While not a primary endpoint, the Company will also analyze IOP reduction for clinical meaningfulness as we expect the FDA will require it for regulatory approval. The Company continues to enroll an open-label, one-year safety extension study with OTX-TP to provide additional long-term safety data with repeat administration of OTX-TP.
- **Reported interim results of the Phase 1 clinical trial of OTX-TIC (travoprost intracameral implant) at the Association for Research in Vision and Ophthalmology (ARVO) and ASCRS Annual Meetings.** OTX-TIC is a bioresorbable, travoprost-containing hydrogel intracameral implant to treat patients with primary open-angle glaucoma or ocular hypertension. Interim data showed subjects achieved IOP lowering as good as topical travoprost in the non-study eye for a period of up to 9 months with a single insert. While there were no adverse changes to the cornea, as measured by endothelial cell evaluation and corneal pachymetry, the Company saw several subjects with low-grade inflammation and mild peripheral anterior synechiae, both of which it believes may be addressable with modifications to the implants.
- **Continued dosing of patients in the Phase 1 clinical trial of OTX-TKI (tyrosine kinase inhibitor intravitreal 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 age-related macular degeneration (AMD) for an extended duration. The Phase 1 clinical trial being conducted in Australia is a multi-center, open-label study testing the safety, durability, and tolerability of OTX-TKI. The Data and Safety Monitoring Committee met and agreed with the Company's recommendation to dose the next cohort of subjects at a higher dose.
- **Provided an update on the partnership with Regeneron.** OTX-IVT is a sustained release formulation of the VEGF trap aflibercept, or EYLEA[®], for the treatment of retinal diseases such as wet AMD that is being developed in partnership with Regeneron. The Company has recently agreed with Regeneron to cease development of the current formulation and is currently in discussions regarding the development of an alternative formulation.

First Quarter Ended March 31, 2019 Financial Results

- The Company had \$76.3 million in cash and cash equivalents at March 31, 2019 versus \$54.1 million at year end December 31, 2018. Both of these cash amounts exclude \$6.6 million of restricted cash as required by the Company's existing senior debt facility and letters of credit for our property leases. The cash balance benefited during the first quarter from our \$37.5 million subordinated convertible
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debt offering and \$5.0 million in net proceeds generated from the sale of common stock under the Company's 2016 Sales Agreement, or 2016 Sales Agreement. 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 the second quarter of 2020.

- The Company exhausted the 2016 Sales Agreement with the first quarter sales of common stock and cancelled the facility. On April 5, 2019, the Company entered into an Open Market Sale Agreement, or the 2019 Sales Agreement with Jefferies LLC, under which the Company may offer and sell our common stock having aggregate proceeds of up to \$50 million from time to time. Through May 9, 2019, the Company has not sold any shares of common stock under the 2019 Sales Agreement.
- Research and development expenses for the first quarter were \$11.3 million versus \$8.2 million for the comparable period in 2018 and reflect an increase in unallocated costs, primarily personnel costs associated with additional hiring, and costs associated with the Company's pipeline programs as well as preclinical programs.
- Selling and marketing expenses for the first quarter were \$3.3 million as compared to \$0.7 million for the same quarter in 2018. This increase relates primarily to DEXTENZA pre-commercial launch activities including the hiring of additional personnel and increased spending on consulting, conferences and related costs.
- General and Administrative expenses were \$5.4 million for the first quarter versus \$4.8 million in the comparable quarter of 2018. The increase in expenses stemmed primarily from increased personnel and facilities costs.
- Revenues for the first quarter were driven exclusively by ReSure Sealant and totaled approximately \$0.5 million vs. \$0.3 million in the comparable quarter of 2018. As noted in the past, the Company does not currently provide promotional support to ReSure and does not expect ReSure product revenues to be material in 2019.
- The Company reported a net loss of \$(17.1) million in the first quarter of 2019, or basic net loss of \$(0.41) per share. This compares to a net loss of \$(13.8) million, or basic net loss of \$(0.40) per share, for the same period in 2018. The net loss for the quarter included \$2.5 million in non-cash charges for stock-based compensation and depreciation compared to \$2.4 million for the same quarter in 2018.
- The Company had approximately 42.8 million shares issued and outstanding as of May 9, 2019.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am 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 9580369. An archive of the webcast will be available until August 12, 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	
	March 31,	
	2019	2018
Revenue:		
Product revenue	\$ 492	\$ 340
Total revenue	492	340
Costs and operating expenses:		
Cost of product revenue	128	80
Research and development	11,317	8,227
Selling and marketing	3,347	717
General and administrative	5,358	4,771
Total costs and operating expenses	20,150	13,795
Loss from operations	(19,658)	(13,455)
Other income (expense):		
Interest income	329	176
Interest expense	(1,018)	(486)
Change in fair value of derivative liability	3,223	—
Total other income (expense), net	2,534	(310)
Net loss and comprehensive loss	\$ (17,124)	\$ (13,765)
Net loss per share, basic	\$ (0.41)	\$ (0.40)
Weighted average common shares outstanding, basic	42,251,292	34,792,848
Net loss per share, diluted	\$ (0.45)	\$ (0.40)
Weighted average common shares outstanding, diluted	44,174,369	34,792,848

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 76,251	\$ 54,062
Accounts receivable	276	201
Inventory	265	217
Prepaid expenses and other current assets	2,380	1,713
Total current assets	79,172	56,193
Property and equipment, net	10,548	10,236
Restricted cash	6,614	6,614
Operating lease assets	5,156	—
Total assets	<u>\$ 101,490</u>	<u>\$ 73,043</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,902	\$ 2,965
Accrued expenses and other current liabilities	4,037	6,194
Operating lease liability	675	—
Total current liabilities	8,614	9,159
Other liabilities	—	3,221
Operating lease liabilities, net of current portion	7,909	—
Derivative liability	11,462	—
Notes payable, net of discount	24,843	24,788
2026 convertible notes, net	23,014	—
Total liabilities	75,842	37,168
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 42,836,978 and 41,518,091 shares issued and outstanding at March 31, 2019 and December 31, 2018	4	4
Additional paid-in capital	340,011	333,114
Accumulated deficit	(314,367)	(297,243)
Total stockholders' equity	25,648	35,875
Total liabilities and stockholders' equity	<u>\$ 101,490</u>	<u>\$ 73,043</u>