
**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): **August 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))

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

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

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 August 7, 2019, Ocular Therapeutix, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 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 August 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: August 7, 2019

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

Ocular Therapeutix™ Reports Second Quarter 2019 Financial Results and Business Update

Commenced U.S. Launch of DEXTENZA® with Broad Reimbursement Status and Differentiated Product Label

BEDFORD, Mass. —(BUSINESS WIRE)—August 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 second quarter ended June 30, 2019 and provided a business update.

“It has been a great quarter and productive July for Ocular Therapeutix,” said Antony Mattessich, President and Chief Executive Officer. “We received both our DEXTENZA® label expansion and our J-code a quarter earlier than we had expected. Also, through disciplined expense management, elimination of the restricted cash covenant under our senior credit agreement, and additional cash raised through our 2019 Open Market Sales Agreement, we believe that we have extended our cash runway into the third quarter of 2020. We are in great shape to begin the hard work of establishing DEXTENZA as the new dropless standard of care for the prevention of post-surgical inflammation and pain.”

Key Highlights and Upcoming Events

- **Announced CMS Approval of C-code and J-code for the Reimbursement of DEXTENZA (dexamethasone ophthalmic insert).** In May 2019, the Company received C-code approval, effective July 1st, from the Centers for Medicare and Medicaid Services (CMS) for transitional pass-through payment status enabling DEXTENZA full reimbursement for patients covered under Medicare Part B in the surgical setting. In July 2019, the Company received J-code approval from CMS, establishing a specific and permanent reimbursement for DEXTENZA. The J-code, which is scheduled to become effective October 1st, institutes a broader reimbursement status than a C-code and has the potential to expand use of DEXTENZA into the office setting and across payer types.
 - **Commenced the Launch of DEXTENZA in the U.S.** The Company launched DEXTENZA with a sampling program that began in May 2019 supported by a direct, initial sales force of 21 Key Account Managers (KAMs) who are supported by five Field Reimbursement Managers (FRMs) and five Medical Science (MSLs) Liaisons. The Company’s initial commercial efforts are focused on the two million cataract procedures performed annually under Medicare Part B.
 - **Received sNDA Approval from the FDA expanding DEXTENZA’s Label to Include the Treatment of Ocular Inflammation Following Ophthalmic Surgery.** Following the approval of the NDA supplement, DEXTENZA is now approved for the treatment of both ocular inflammation and pain following ophthalmic surgery. The expanded label further differentiates DEXTENZA by making it the only dropless product indicated for the treatment of both post-surgical inflammation and pain.
 - **Expanded Leadership Team.** In July 2019, the Company announced two important senior management hires — Patricia Kitchen as Chief Operations Officer who will oversee the Company’s manufacturing and quality functions and Chris White as Senior Vice President of Business and
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Corporate Development who will head up business and corporate development efforts. Each brings to the Company over 20 years of experience in the biopharmaceutical industry.

- **Extended Cash Runway into the Third Quarter of 2020.** Since the end of the second quarter, the Company raised an aggregate of approximately \$14.8 million in net proceeds under the Company's 2019 Open Market Sales Agreement. In addition, the Company also entered into an amendment of its credit agreement with the lenders of its \$25.0 million term loan agreement to eliminate the liquidity covenant requiring that the Company maintain \$5.0 million in a restricted cash account. The net impact is that nearly \$20 million has been added to cash and cash equivalents since the end of the second quarter. Based on the Company's current plans and forecasted expenses, the Company believes that existing cash and cash equivalents will fund operating expenses, debt service obligations, and capital expenditures into the third quarter of 2020, providing an additional quarter of cash runway since the Company's last earnings update.
 - **Pipeline Update**
 - DEXTENZA (dexamethasone ophthalmic insert) for the treatment of allergic conjunctivitis: The Company has initiated an 80 subject pivotal Phase 3 clinical trial for ocular itching associated with allergic conjunctivitis. Subject to obtaining favorable results in this clinical trial, the Company plans to submit an NDA supplement to the FDA for the treatment of ocular itching associated with allergic conjunctivitis as DEXTENZA's first non-surgical indication.
 - OTX-TP (travoprost ophthalmic insert) for the reduction of elevated intraocular pressure in patients with glaucoma: The Company plans to meet with the FDA in the second half of 2019 to discuss results from its Phase 3 clinical trial and determine appropriate steps forward. In May 2019, the Company reported topline results that it did not achieve the primary endpoint, despite results which showed statistically significant superiority in reduction of intraocular pressure (IOP) for subjects receiving OTX-TP inserts compared with placebo at eight of nine diurnal time points. The trial demonstrated OTX-TP's ability to lower IOP out to 12 weeks with a single insert using this novel dosage form.
 - OTX-TIC (travoprost intracameral implant) for the reduction of elevated intraocular pressure in patients with glaucoma: The Company continues to enroll patients in a Phase 1, prospective, multi-center, open-label, dose escalation clinical trial to evaluate the safety, efficacy, durability, and tolerability of OTX-TIC. With data from one patient now out to 13 months, interim data continues to show comparable IOP lowering versus topical travoprost drops with a single insert. The study continues to evaluate the safety profile. The Company is also evaluating two new formulations of OTX-TIC that will be dosed in patients in the upcoming months.
 - OTX-TKI (tyrosine kinase inhibitor intravitreal implant) for the treatment of wet age-related macular degeneration (AMD): OTX-TKI is a bioresorbable, hydrogel fiber implant with anti-angiogenic properties delivered by intravitreal injection to the posterior segment of the eye for an extended duration. Following a review of the data by The Data and Safety Monitoring Committee, the Company will initiate dosing of the second patient cohort in the Phase 1, multi-center, open-label study using a higher dose of OTX-TKI in the upcoming weeks.
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Second Quarter Ended June 30, 2019 Financial Results

- The Company had \$61.8 million in cash and cash equivalents, inclusive of approximately \$5.1 million raised under the Company's 2019 Open Market Sales Agreement, versus \$76.3 million at the end of the first quarter 2019.
- Research and development expenses for the second quarter were \$9.4 million versus \$8.7 million for the comparable period in 2018 and reflect an increase in unallocated costs, primarily costs associated with pipeline and preclinical programs.
- Selling and marketing expenses for the second quarter were \$7.2 million as compared to \$0.9 million for the same quarter in 2018. This increase relates almost entirely to preparations for the commercial launch of DEXTENZA, driven primarily by the hiring of new members of the commercial team, including KAMs, FRMs and MSLs, as well as increased spending on consulting, trade shows, conferences and related costs.
- General and administrative expenses were \$5.1 million for the second quarter versus \$4.4 million in the comparable quarter of 2018. The increase in expenses for the second quarter stemmed primarily from increased personnel, professional and facilities costs.
- Revenues for the second quarter totaled \$0.6 million and included both ReSure® Sealant and early DEXTENZA revenues. This compared to \$0.6 million in revenues for the same quarter in 2018. As noted in the past, the Company is not currently providing promotional support to ReSure and does not expect product revenues related to ReSure to be material in 2019.
- The Company reported a net loss of \$(24.5) million, or a loss of \$(0.57) per share on a basic and diluted basis. This compares to a net loss of \$(13.8) million, or a loss of \$(0.37) per share on a basic and diluted basis, for the same period in 2018. The net loss for the second quarter included \$2.3 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 47.2 million shares issued and outstanding as of August 5, 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 9968447. An archive of the webcast will be available until November 7, 2019 on the Company's website.

About DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg

DEXTENZA is an FDA-approved corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery. DEXTENZA is inserted into the lower lacrimal punctum into the canaliculus by the physician following ophthalmic surgery. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion. DEXTENZA is preservative free, resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert, if

necessary.

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during the course of the treatment. Corticosteroids may suppress the host response to, and increase the hazard for and severity of, secondary bacterial, viral, or fungal infections. The use of steroids after cataract surgery may delay wound healing and increase the incidence of bleb formation.

The most commonly reported ocular adverse reactions that occurred in patients treated with DEXTENZA were anterior chamber inflammation including iritis and iridocyclitis (10%) and elevations in intraocular pressure (6%). The most common non-ocular adverse reaction was headache (1%).

[Click here for the full Prescribing Information.](#)

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 inflammation and 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 commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's prospects for approvability of DEXTENZA for additional 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 maintain 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.

Contacts:

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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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue, net	\$ 650	\$ 648	\$ 1,142	\$ 988
Total revenue, net	<u>650</u>	<u>648</u>	<u>1,142</u>	<u>988</u>
Costs and operating expenses:				
Cost of product revenue	552	153	680	233
Research and development	9,414	8,745	20,731	16,972
Selling and marketing	7,225	867	10,572	1,584
General and administrative	5,058	4,447	10,416	9,218
Total costs and operating expenses	<u>22,249</u>	<u>14,212</u>	<u>42,399</u>	<u>28,007</u>
Loss from operations	<u>(21,599)</u>	<u>(13,564)</u>	<u>(41,257)</u>	<u>(27,019)</u>
Other income (expense):				
Interest income	379	215	708	391
Interest expense	(1,627)	(455)	(2,645)	(941)
Change in fair value of derivative liability	(1,606)	—	1,617	—
Total other income (expense), net	<u>(2,854)</u>	<u>(240)</u>	<u>(320)</u>	<u>(550)</u>
Net loss and comprehensive loss	<u>\$ (24,453)</u>	<u>\$ (13,804)</u>	<u>\$ (41,577)</u>	<u>\$ (27,569)</u>
Net loss per share, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.37)</u>	<u>\$ (0.98)</u>	<u>\$ (0.76)</u>
Weighted average common shares outstanding, basic and diluted	<u>42,910,084</u>	<u>37,524,512</u>	<u>42,582,501</u>	<u>36,160,251</u>

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 61,765	\$ 54,062
Accounts receivable	615	201
Inventory	762	217
Prepaid expenses and other current assets	2,294	1,713
Total current assets	65,436	56,193
Property and equipment, net	10,532	10,236
Restricted cash	6,764	6,614
Operating lease assets	7,010	—
Total assets	<u>\$ 89,742</u>	<u>\$ 73,043</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,044	\$ 2,965
Accrued expenses and other current liabilities	5,059	6,194
Operating lease liabilities	1,024	—
Total current liabilities	10,127	9,159
Other liabilities	—	3,221
Operating lease liabilities, net of current portion	9,493	—
Derivative liability	13,068	—
Notes payable, net of discount	24,898	24,788
2026 convertible notes, net	23,898	—
Total liabilities	81,484	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 June 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 44,101,583 and 41,518,091 shares issued and outstanding at June 30, 2019 and December 31, 2018	4	4
Additional paid-in capital	347,074	333,114
Accumulated deficit	(338,820)	(297,243)
Total stockholders' equity	8,258	35,875
Total liabilities and stockholders' equity	<u>\$ 89,742</u>	<u>\$ 73,043</u>