

**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): **November 12, 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.)

**24 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>
<b>Common Stock, \$0.0001 par value per share</b>	<b>OCUL</b>	<b>The Nasdaq Global Select Market</b>

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     x

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.     x

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

On November 12, 2019, Ocular Therapeutix, Inc. (the “Company”) announced its financial results for the quarter ended September 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 November 12, 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: November 12, 2019

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

**Ocular Therapeutix™ Reports Third Quarter 2019 Financial Results and Business Update**

*Over 7,000 Patients Treated Since Launch at more than 350 Surgical Sites*

*Expanded the DEXTENZA® Field Team by 50%*

*Implemented Restructuring Plan That Extends Cash Runway Through the Fourth Quarter of 2020*

*Topline data for Phase 3 Clinical Trial of DEXTENZA for Ocular Itching Associated with Allergic Conjunctivitis Anticipated in First Half of 2020*

BEDFORD, Mass. —(BUSINESS WIRE)—November 12, 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 third quarter ended September 30, 2019 and provided a business update.

“We have had very productive quarter,” said Antony Mattessich, President and Chief Executive Officer. “As we had hoped, the first phase of our DEXTENZA launch has given us the confidence to expand our field presence by 50%. Now, with a good understanding of the time and effort it takes to remove the obstacles at the ambulatory surgical centers and Hospital Outpatient Departments, and a J-code in place as of October 1st, we are set to capitalize on our expanded reach. Additionally, we have recently restructured operations in a way that allows us to complete key clinical programs while extending our runway. Overall we are in great shape to deliver in the future.”

**Key Highlights and Upcoming Events**

- **Update on the U.S. Commercial Launch of DEXTENZA.** DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg has been commercially available now since July 2019 and is receiving favorable patient and surgeon feedback. Perhaps most importantly, of the centers who have made initial purchases, as of the end of October half of accounts have re-ordered the product with over a third of accounts having re-ordered three or more times. Based on the recent uptake and comprehensive reimbursement surrounding DEXTENZA, the Company announced the expansion of its field team by 50% with the goal to have a total of 30 Key Account Managers (KAMs) in place by the end of November. The Company’s expanded field team is now in position to reach more of the high-volume centers and gain greater access to the two million cataract procedures performed annually under Medicare Part B. Since the launch, over 7,000 patients have now been treated across more than 350 surgical sites.
  - **Announced CMS Approval of Permanent J-code (J1096) for the Reimbursement of DEXTENZA.** In October 2019, the Company received a permanent product-specific J-code for DEXTENZA (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use. The assignment of permanent J1096 replaces the C-code received in July 2019 and expands the possibility of reimbursement of DEXTENZA beyond the surgical setting and into the office setting. The expanded coverage, along with physician familiarity with J-codes, increases provider confidence of DEXTENZA reimbursement and
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offers the potential to broaden the commercial opportunity of DEXTENZA to the estimated 8.0 million steroid prescriptions written each year in the United States.

· **Implemented Restructuring Plan Designed to Focus on the Commercialization of DEXTENZA and High Priority Pipeline Initiatives.** The restructuring plan is expected to result in an estimated \$11 million in annualized savings and approximately \$14 million in one-time program deferrals. The restructuring represents a strategic realignment and commitment by the Company to allocate capital and resources to prioritize the commercial opportunity of DEXTENZA for the treatment of post-surgical inflammation and pain. Additionally, the restructuring will focus resources on progressing key pipeline assets, including completion of its DEXTENZA Phase 3 trial for ocular itching associated with allergic conjunctivitis and of its Phase 1 trials of OTX-TIC for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension and OTX-TKI for the treatment of wet age-related macular degeneration. Based on its current operating plans and forecast expenses, the Company believes the restructuring, upon completion, will result in an extension of the Company's current cash runway through the end of the fourth quarter of 2020.

· **Pipeline Update**

· **DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg:**

- The Company is currently evaluating patients in a potential, final pivotal Phase 3 clinical trial for the treatment of ocular itching associated with allergic conjunctivitis. The primary efficacy endpoint being evaluated in the study is ocular itching following insertion of DEXTENZA at multiple time points during a 30-day period. The Company anticipates data from the Phase 3 clinical trial in the first half of 2020. 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.
- The ocular community has shown strong interest in DEXTENZA and is actively communicating with the Company on the potential for investigator-initiated trials. The interest points to the versatility of the product and the opportunity to potentially use DEXTENZA in multiple areas beyond post-surgical inflammation and pain to benefit patients.

· **OTX-TP (travoprost ophthalmic insert) for the reduction of elevated intraocular pressure in patients with glaucoma:** The Company recently completed its Type C meeting with the FDA to discuss OTX-TP. While the FDA did not feel that the data from this trial met the standard of clinical meaningfulness in the population studied, there were constructive discussions about potential pathways forward in specific patient populations for whom drops are problematic. Given the feedback, there are no immediate plans to bring this program forward without the assistance of a partner.

· **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 a targeted product profile of 6-12 months of IOP lowering, and current data showing efficacy beyond 16 months and a favorable safety profile in the first subject treated, the Company is focused on optimizing the formulation to achieve the targeted product profile in a smaller intracameral injection.

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- **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. The Company has completed the dosing of the first cohort of subjects in the Phase 1, multi-center, open-label study with no safety concern and has moved to dosing a second cohort with a higher dosage.

### Third Quarter Ended September 30, 2019 Financial Results

- Revenues for the third quarter totaled \$0.8 million consisting of \$0.3 million and \$0.5 million in net revenue from DEXTENZA and ReSure® Sealant, respectively. This compares to \$0.5 million in revenues for the same quarter in 2018, all of which were generated from ReSure. 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.
  - Research and development expenses for the third quarter were \$10.2 million versus \$9.7 million for the comparable period in 2018 and reflect an increase in costs associated with the Phase 1 OTX-TIC trial, the Phase 1 OTX-TKI trial and the start of the Phase 3 DEXTENZA allergic conjunctivitis trial, as well as increases in unallocated costs. These were offset by a significant reduction of the Phase 3 clinic trial costs associated with OTX-TP.
  - Selling and marketing expenses for the third quarter were \$6.8 million as compared to \$1.1 million for the same quarter in 2018. This increase relates almost entirely to support of the commercial launch of DEXTENZA, driven primarily by the hiring of new members of the commercial team in the second quarter of 2019, including KAMs, FRMs and MSLs, as well as increased spending on consulting, trade shows, conferences and related costs.
  - General and administrative expenses were \$6.2 million for the third quarter versus \$4.4 million in the comparable quarter of 2018. The increase in expenses for the third quarter stemmed primarily from increased personnel and facilities costs, offset by decreased professional fees.
  - The Company reported a net loss of \$(18.8) million, or a loss of \$(0.40) per share on a basic basis and \$(0.45) on a diluted basis. This compares to a net loss of \$(15.0) million, or a loss of \$(0.38) per share on a basic and diluted basis, for the same period in 2018. The net loss for the third quarter included \$3.9 million in non-cash charges for stock-based compensation and depreciation compared to \$2.5 million for the same quarter in 2018. In addition, the net loss for the quarter, included a gain in the amount of \$5.7 related to the change in the derivative liability.
  - The Company had approximately 48.1 million shares issued and outstanding as of November 7, 2019.
  - The Company had \$65.4 million in cash and cash equivalents at the end of the third quarter versus \$61.8 million at the end of the second quarter 2019. These cash amounts exclude restricted cash of \$1.8 million and \$6.8 million, respectively. Restricted cash was reduced by \$5 million in the third quarter 2019 as a result of an amendment with the lenders of our \$25 million term loan facility to eliminate the \$5 million liquidity covenant. The cash balance benefited during the third quarter from \$18.6 million in net proceeds generated from the sale of common stock under the Company's 2019
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Sales Agreement, or ATM, under which the Company may offer and sell its common stock having aggregate proceeds of up to \$50.0 million from time to time. The Company has not made any additional sales under the ATM during the fourth quarter of 2019.

## **Conference Call & Webcast Information**

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:00 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](http://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 1450668. An archive of the webcast will be available until March 11, 2020 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 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.

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. Ocular Therapeutix has also begun a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. 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

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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 impact of and restructuring costs and potential future savings associated with the Company's operational restructuring, workforce reduction and development program deferrals; 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 development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, 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 implementation of the operational restructuring, 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.

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**Investors**

Ocular Therapeutix  
Donald Notman  
Chief Financial Officer  
dnotman@ocutx.com

or

Westwicke, an ICR Company  
Chris Brinzey, 339-970-2843  
Managing Director  
chris.brinzey@westwicke.com

**Media**

Ocular Therapeutix  
Scott Corning  
Senior Vice President, Commercial  
sorning@ocutx.com

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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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
<b>Revenue:</b>				
Product revenue, net	\$ 829	\$ 498	\$ 1,971	\$ 1,486
Total revenue, net	829	498	1,971	1,486
<b>Costs and operating expenses:</b>				
Cost of product revenue	806	115	1,486	348
Research and development	10,235	9,685	30,966	26,657
Selling and marketing	6,777	1,067	17,349	2,651
General and administrative	6,155	4,447	16,571	13,665
Total costs and operating expenses	23,973	15,314	66,372	43,321
Loss from operations	(23,144)	(14,816)	(64,401)	(41,835)
<b>Other income (expense):</b>				
Interest income	308	230	1,016	621
Interest expense	(1,651)	(424)	(4,296)	(1,365)
Change in fair value of derivative liability	5,717	—	7,334	—
Other income (expense), net	(8)	—	(8)	—
Total other income (expense), net	4,366	(194)	4,046	(744)
Net loss and comprehensive loss	\$ (18,778)	\$ (15,010)	\$ (60,355)	\$ (42,579)
Net loss per share, basic	\$ (0.40)	\$ (0.38)	\$ (1.37)	\$ (1.15)
Weighted average common shares outstanding, basic	46,944,536	39,017,922	44,052,470	37,111,200
Net loss per share, diluted	\$ (0.45)	\$ (0.38)	\$ (1.37)	\$ (1.15)
Weighted average common shares outstanding, diluted	52,713,768	39,017,922	44,052,470	37,111,200

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

	September 30, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 65,414	\$ 54,062
Accounts receivable	1,114	201
Inventory	895	217
Prepaid expenses and other current assets	2,213	1,713
Total current assets	69,636	56,193
Property and equipment, net	10,474	10,236
Restricted cash	1,764	6,614
Operating lease assets	6,836	—
Total assets	<u>\$ 88,710</u>	<u>\$ 73,043</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,461	\$ 2,965
Accrued expenses and other current liabilities	6,471	6,194
Operating lease liabilities	1,073	—
Total current liabilities	11,005	9,159
Other liabilities	—	3,221
Operating lease liabilities, net of current portion	9,206	—
Derivative liability	9,100	—
Notes payable, net of discount	24,952	24,788
2026 convertible notes, net	23,146	—
Total liabilities	77,409	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 September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 48,079,615 and 41,518,091 shares issued and outstanding at September 30, 2019 and December 31, 2018	5	4
Additional paid-in capital	368,894	333,114
Accumulated deficit	(357,598)	(297,243)
Total stockholders' equity	11,301	35,875
Total liabilities and stockholders' equity	<u>\$ 88,710</u>	<u>\$ 73,043</u>