

**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, 2018**

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 August 7, 2018, Ocular Therapeutix, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 August 7, 2018](#)

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, 2018

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

Ocular Therapeutix™ Reports Second Quarter 2018 Financial Results and Business Update

DEXTENZA® NDA Resubmission Submitted and Accepted by the U.S. Food and Drug Administration

DEXTENZA Given December 28, 2018 Target PDUFA Date

BEDFORD, Mass.—(BUSINESS WIRE)—August 7, 2018— 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, 2018 and provided a business update.

“We are encouraged with our progress through the first half of 2018,” said Antony Mattessich, President and Chief Executive Officer. “The on-time resubmission and establishment of a December 28th PDUFA date for DEXTENZA® were critical achievements and we are pleased to have accomplished them. Clearly, we need to demonstrate that the transformation we have experienced internally translates to externally-validated results. While the team understands the approval of DEXTENZA is our top priority, we will continue to drive our pipeline forward which should be increasingly appreciated as we demonstrate our ability to execute.”

Key Highlights and Upcoming Events

- **DEXTENZA® New Drug Application (NDA) resubmission completed and accepted by the U.S. Food and Drug Administration (FDA).** Ocular resubmitted the NDA to the FDA on June 28th and announced the acceptance of the filing on July 19th. As expected the resubmission will be treated as a Class 2 response with a six-month review period. The target action date under the Prescription Drug User Fee Act, or PDUFA, is December 28, 2018.
- **Initiated commercialization planning for DEXTENZA.** If DEXTENZA is approved, Ocular intends to launch it with a specialty sales team and has begun executing on the commercial build-out.
- **OTX-TP (travoprost insert) Phase 3 topline efficacy data for the treatment of glaucoma expected in the first half of 2019.** Enrollment in the 550 patient Phase 3 trial remains steady and the Company continues to anticipate topline data in the first half of 2019. The Company has also dosed the first patient in the third quarter in an open-label, one-year safety extension study that will be included as part of the current pivotal program. This study will provide additional long-term safety data with repeat administration of OTX-TP.
- **Dosed first patient in Phase 1 clinical trial of OTX-TIC (travoprost implant).** OTX-TIC, Ocular Therapeutix’s second glaucoma product candidate, 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 and ocular hypertension.

- **Initiated OTX-TKI (tyrosine kinase inhibitor implant) ex-U.S. Phase 1 clinical trial; the first patient is expected to be dosed in the third quarter.** OTX-TKI is a bioresorbable, hydrogel fiber implant with anti-angiogenic properties delivered by intravitreal injection being developed to treat patients with wet Age-related Macular Degeneration (AMD) and other retinal diseases. Preclinical data have demonstrated the ability to deliver an efficacious dose of OTX-TKI to the posterior segment of the eye for the treatment of VEGF-induced retinal leakage for an extended duration of up to twelve months. The Phase 1 trial is a multi-center, open-label, dose escalation study testing the safety, durability, and tolerability of OTX-TKI.
- **Regeneron collaboration continues for the development of OTX-IVT (aflibercept implant).** The Company, along with Regeneron, continues the pre-clinical development of an extended-delivery formulation of the VEGF trap aflibercept (EYLEA®), delivered by intravitreal injection, for the treatment of retinal diseases such as wet AMD. The Company remains pleased with the state of the collaboration and the teams have been working well together.

Second Quarter 2018 Financial Results

- As of the quarter-ended June 30, 2018, the Company had \$56.8 million in cash and cash equivalents versus \$62.9 million at the end of the first quarter of 2018. The cash balance benefited from \$8.4 million in net proceeds generated from the sale of common stock under the Company’s 2016 Sales Agreement, or ATM, during the second quarter of 2018. Offsetting the ATM inflows during the quarter were a net loss of \$13.8 million, principal debt payments of \$1.6 million, and capital expenditures of \$0.6 million. At the end of Q2 2018, \$24.1 million remained available to be sold under the 2016 Sales Agreement and the Company will continue to monitor the opportunity to sell additional common stock as appropriate under the facility.
- 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 2019, exclusive of the potential \$10 million option payment from our Regeneron partnership.
- Research and development expenses for the second quarter were \$8.7 million versus \$8.1 million for the second quarter of 2017 and reflect an increase in compensation costs associated with additional hiring primarily in the technical operations and quality

departments, as well as an increase in facilities expenses associated with additional lab space at corporate headquarters.

- Selling and marketing expenses for the second quarter were \$0.9 million as compared to \$6.8 million for the same quarter in 2017. This decrease relates to a significant reduction in pre-commercial activities as a result of the delay in the launch of DEXTENZA.
- General and Administrative expenses were \$4.4 million for the second quarter versus \$3.7 million in the comparable quarter of 2017. The increase in expenses stemmed primarily from increases in legal costs related to the defense of ongoing legal proceedings.

- Revenues for the second quarter of 2018 were driven exclusively by ReSure Sealant and totaled approximately \$0.6 million compared with \$0.4 million in the same period for 2017, reflecting principally an increased number of units sold.
- The Company reported a net loss of \$(13.8) million, or a loss of \$(0.37) per share for the second quarter of 2018. This compares to a net loss of \$(18.7) million, or a loss of \$(0.64) per share, for the same period in 2017. The net loss for the second quarter of 2018 included \$2.4 million in non-cash charges for stock-based compensation and depreciation compared to \$2.1 million for the same quarter in 2017.
- The Company had approximately 38.5 million shares issued and outstanding as of June 30, 2018 compared to 37.3 million shares issued and outstanding as of March 31, 2018.

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 7875199. An archive of the webcast will be available until November 7, 2018 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 lead product candidate, DEXTENZA® (dexamethasone insert), has completed Phase 3 clinical development for the treatment of ocular pain and inflammation following ophthalmic

surgery. OTX-TP (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 travoprost intracameral 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 the development of OTX-TKI, 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 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 pain and inflammation, including with respect to manufacturing deficiencies identified by the FDA, the Company's expectations regarding the NDA filed with the FDA, the FDA's response to the resubmitted NDA and the prospects for approvability of DEXTENZA for these 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; potential commercialization 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 ReSure® Sealant or any product candidate that receives regulatory approval, 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 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. 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.
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,	
	2018	2017	2018	2017
Revenue:				
Product revenue	\$ 648	\$ 438	\$ 988	\$ 913
Total revenue	648	438	988	913
Costs and operating expenses:				
Cost of product revenue	153	104	233	219
Research and development	8,745	8,117	16,972	14,846
Selling and marketing	867	6,832	1,584	12,859
General and administrative	4,447	3,724	9,218	7,000
Total costs and operating expenses	14,212	18,777	28,007	34,924
Loss from operations	(13,564)	(18,339)	(27,019)	(34,011)
Other income (expense):				
Interest income	215	113	391	205
Interest expense	(455)	(468)	(941)	(911)
Total other expense, net	(240)	(355)	(550)	(706)
Net loss	(13,804)	(18,694)	\$ (27,569)	\$ (34,717)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.64)	\$ (0.76)	\$ (1.22)
Weighted average common shares outstanding, basic and diluted	37,524,512	29,026,259	36,160,251	28,352,348
Comprehensive loss:				
Net loss	\$ (13,804)	\$ (18,694)	\$ (27,569)	\$ (34,717)
Other comprehensive loss:				
Unrealized gain on marketable securities	—	9	—	5
Total other comprehensive income	—	9	—	5
Total comprehensive loss	\$ (13,804)	\$ (18,685)	\$ (27,569)	\$ (34,712)

Ocular Therapeutix, Inc.
Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 56,834	\$ 41,538
Accounts receivable	285	226
Inventory	131	122
Prepaid expenses and other current assets	1,222	1,453
Total current assets	58,472	43,339
Property and equipment, net	10,373	10,478
Restricted cash	1,614	1,614
Total assets	\$ 70,459	\$ 55,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,137	\$ 3,571
Accrued expenses and deferred rent	3,680	4,310
Notes payable, net of discount, current	6,082	5,545
Total current liabilities	11,899	13,426
Deferred rent, long-term	3,283	3,387
Notes payable, net of discount, long-term	9,548	12,471
Total liabilities	24,730	29,284
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, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 38,476,937 and 29,658,202 shares issued and outstanding at June 30, 2018 and December 31, 2017	4	3
Additional paid-in capital	310,559	263,409
Accumulated deficit	(264,834)	(237,265)
Total stockholders' equity	45,729	26,147
Total liabilities and stockholders' equity	<u>\$ 70,459</u>	<u>\$ 55,431</u>
