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 7, 2018**

OCULAR THERAPEUTIX, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 November 7, 2018, Ocular Therapeutix, Inc. (the "Company") announced its financial results for the quarter ended September 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 November 7, 2018

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 7, 2018

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

Exhibit 99.1

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

DEXTENZA® NDA Target PDUFA Action Date of December 28, 2018

BEDFORD, Mass.—(BUSINESS WIRE)—November 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 third quarter ended September 30, 2018 and provided a business update.

"It has been another busy quarter highlighted by continued progress on DEXTENZA® as well as the rest of our deep product pipeline," said Antony Mattessich, President and Chief Executive Officer. "Our highest priority remains DEXTENZA and in the quarter we have moved this filing forward with the completion of a Pre-Approval Inspection (PAI). We anticipate the U.S. Food and Drug Administration (FDA) to take action under the Prescription Drug User Fee Act (PDUFA) by December 28th of this year. Moving to our pipeline, we continue to advance our product candidates and have recently reached target enrollment of our Phase 3 clinical trial for OTX-TP in glaucoma and we look forward to reporting topline data in the first half of 2019."

Key Highlights and Upcoming Events

- ***Pre-Approval Inspection of DEXTENZA completed; PDUFA target action date remains December 28, 2018.*** Following an inspection of its manufacturing facility in Bedford, Massachusetts, the Company confirms no repeat 483 observations were made, however, additional observations were identified. The Company is in the process of fully responding to those observations and continues to anticipate a decision from the FDA by the original PDUFA date of December 28, 2018.

- ***Preparations for commercial launch of DEXTENZA continue.*** The Company is actively recruiting for its field organization and is continuing the process of executing its commercial strategy. Ocular intends to launch DEXTENZA, if approved, with a specialty sales team that will initially target high-volume surgery centers.

- ***Positive data from Phase 3 clinical trial of DEXTENZA published in the Journal of Cataract & Refractive Surgery in October.*** The publication included data from a 400-patient, prospective, multicenter, randomized, controlled, phase 3 study, demonstrating statistical significance ($p < .0001$) in treatment of both post-operative ocular inflammation and pain.

- ***Target enrollment reached in Phase 3 clinical trial of OTX-TP (travoprost insert) for the treatment of glaucoma - Topline efficacy data expected in the first half of 2019.*** As target

enrollment for the OTX-TP Phase 3 trial was reached, no additional subjects will be screened. There are still a few subjects in wash-out that may be randomized in the next several days. In parallel, the Company continues dosing 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.

- ***Enrollment in the Phase 1 clinical trial of OTX-TIC (travoprost implant) for the treatment of glaucoma continues with data expected to be presented in the first half of 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 six months with a single insert.

- ***Dosing of initial subject in the Phase 1 clinical trial of OTX-TKI (tyrosine kinase inhibitor implant) anticipated in the fourth quarter of 2018.*** 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 VEGF-induced retinal leakage for an extended duration of up to twelve months. The Phase 1 trial is a multi-center, open-label, study testing the safety, durability, and tolerability of OTX-TKI.

- ***Regeneron is evaluating the final formulation of OTX-IVT (aflibercept implant).*** In December of 2017, the Company delivered to Regeneron a final formulation of OTX-IVT as a product candidate in accordance with a collaboration agreement. 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 Age-related Macular Degeneration (AMD). Regeneron has been evaluating the formulation in preclinical trials and analyzing data generated using the formulation and has not informed the Company of its decision whether to exercise the option to enter into an exclusive, worldwide license.

Third Quarter 2018 Financial Results

- As of the quarter ended September 30, 2018, the Company had $56.9 million in cash and cash equivalents versus $56.8 million at the end of the second quarter of 2018. The cash balance benefited from $12.9 million in net proceeds generated from the sale of common stock under the Company's 2016 Sales Agreement, or ATM, during the third quarter of 2018. Offsetting the ATM inflows during the quarter were a net loss of $15.0 million, principal debt payments of $1.5 million, and capital expenditures of $0.5 million.

- 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.

- Research and development expenses for the third quarter of 2018 were $9.7 million versus $8.1 million for the third quarter of 2017 and reflect increased unallocated other costs, primarily in consulting services, outside testing expenses, facilities expenses associated with additional laboratory space at our corporate headquarters and slightly increased compensation costs associated with additional hiring - primarily in the technical operations and quality departments.

- Selling and marketing expenses for the third quarter of 2018 were $1.1 million as compared to $3.2 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 planned 2017 launch of DEXTENZA.

- General and Administrative expenses were $4.4 million for the third quarter of 2018 versus $4.2 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.

- Revenues for the third quarter of 2018 were driven exclusively by ReSure® Sealant and totaled approximately $0.5 million during each of the three-month periods. As previously disclosed, the Company recently received a warning letter from the FDA regarding ReSure due to a perceived lack of progress with the enrollment and related data collection and information reporting obligations for a required post-approval trial. The Company has appealed the warning letter and will continue to work with the FDA to resolve the issue.

- The Company reported a net loss of $(15.0) million, or a loss of $(0.38) per share. This compares to a net loss of $(15.6) million, or a loss of $(0.54) per share, for the same period in 2017. The net loss for the third quarter of 2018 included $2.4 million in non-cash charges for stock-based compensation and depreciation compared to $2.2 million for the same quarter in 2017.

- The Company had approximately 41.1 million shares issued and outstanding as of November 1, 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 March 8, 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 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 Company's post-approval studies of ReSure® Sealant and the Company's expectations regarding its appeal of the warning letter regarding ReSure Sealant; 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, including the conduct of post-approval studies, the ability to retain regulatory approval of 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product revenue	$ 498	$ 523	$ 1,486	$ 1,436
Total revenue	498	523	1,486	1,436
Costs and operating expenses:				
Cost of product revenue	115	125	348	344
Research and development	9,685	8,126	26,657	22,972
Selling and marketing	1,067	3,238	2,651	16,097
General and administrative	4,447	4,230	13,665	11,230
Total costs and operating expenses	15,314	15,719	43,321	50,643
Loss from operations	(14,816)	(15,196)	(41,835)	(49,207)
Other income (expense):				
Interest income	230	115	621	320
Interest expense	(424)	(491)	(1,365)	(1,402)
Other income (expense), net	—	5	—	5
Total other expense, net	(194)	(371)	(744)	(1,077)
Net loss	$ (15,010)	$ (15,567)	$ (42,579)	$ (50,284)
Net loss per share, basic and diluted	$ (0.38)	$ (0.54)	$ (1.15)	$ (1.76)
Weighted average common shares outstanding, basic and diluted	39,017,922	29,087,654	37,111,200	28,601,179
Comprehensive loss:				
Net loss	$ (15,010)	$ (15,567)	$ (42,579)	$ (50,284)
Other comprehensive loss:				
Unrealized gain on marketable securities	—	—	—	5
Total other comprehensive income	—	—	—	5
Total comprehensive loss	$ (15,010)	$ (15,567)	$ (42,579)	$ (50,279)

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 56,861	$ 41,538
Accounts receivable	240	226
Inventory	102	122
Prepaid expenses and other current assets	1,071	1,453
Total current assets	58,274	43,339
Property and equipment, net	10,382	10,478
Restricted cash	1,614	1,614
Total assets	$ 70,270	$ 55,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,777	$ 3,571
Accrued expenses and deferred rent	4,535	4,310
Notes payable, net of discount, current	6,094	5,545
Total current liabilities	13,406	13,426
Deferred rent, long-term	3,274	3,387
Notes payable, net of discount, long-term	8,073	12,471
Total liabilities	24,753	29,284
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 40,524,335 and 29,658,202 shares issued and outstanding at September 30, 2018 and December 31, 2017	4	3
Additional paid-in capital	325,357	263,409
Accumulated deficit	(279,844)	(237,265)
Total stockholders' equity	45,517	26,147
Total liabilities and stockholders' equity	$ 70,270	$ 55,431