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, 2020**

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.)

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:

☐ 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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**OCUL**	**The Nasdaq Global 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, 2020, Ocular Therapeutix, Inc. announced its financial results for the quarter ended June 30, 2020. 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, 2020

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, 2020

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

Exhibit 99.1

Ocular Therapeutix™ Reports Second Quarter 2020 Financial Results and Business Update

Newly Published Physician Fee Schedules for 0356T for the Administration of Intracanalicular Inserts to Support Ongoing DEXTENZA® Launch

May Financing Yields $48.3 Million in Net Proceeds

DEXTENZA Net Product Revenue in Second Quarter of $1.4 million; Billable In-Market Sales Record Achieved in June

BEDFORD, Mass. —(BUSINESS WIRE)—August 7, 2020—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, 2020 and provided a business update.

“Despite the challenges caused by the global pandemic, it has been a very productive quarter for Ocular Therapeutix,” said Antony Mattessich, President and CEO. “Our clinical programs continue to support potential product profiles that, if approved, we believe could become the standards-of-care in the treatment of Wet AMD, glaucoma and ocular surface diseases including dry-eye disease and allergic conjunctivitis. We also added a new program for the treatment of episodic dry eye. We have positioned ourselves to potentially enter Phase 2 trials on four major programs within the next 12 months that could, if approved, compete in some of the largest global ophthalmology markets. On the sales side, despite the global COVID-19 pandemic, we saw a welcome bounce back in DEXTENZA® sales with nearly 2,300 in-market units sold in June, exceeding our previous monthly record by 40% and eclipsing $1 million of in-market sales in a calendar month for the first time. With a new rebate program and the establishment of physician reimbursement fee schedules for the insertion of DEXTENZA at two Medicare Administrative Contractors that cover approximately 30% of the Medicare population, we expect, subject to the potential impact of the pandemic, adoption trends to accelerate in the second half of the year.”

Recent Highlights

Announced published physician fee schedules for the administration of intracanalicular inserts. In July, the Company announced that Novitas Solutions and First Coast, two of seven Medicare Administrative Contractors (MACs) representing approximately 30% of all Medicare beneficiaries, established physician fee schedules for procedure code 0356T for the administration of drug-eluting intracanalicular inserts, including DEXTENZA (dexamethasone ophthalmic insert) 0.4mg, effective July 1, 2020. Physicians in these geographies seeking reimbursement for the administration of DEXTENZA are now eligible to be paid per the established local fee schedule. In addition, four of the remaining five MACs have retired their non-coverage policies for 0356T, and the Company believes that these MACs may publish fee schedules in the near future.

Announced new product candidate (OTX-DED) to treat episodic dry eye disease. There are approximately 8.6 million patients diagnosed with episodic dry eye disease in the United States, according to Market Scope (2019 report). Many of these dry eye patients experience episodic flares of their signs and symptoms which the Company believes are likely related to inflammation. Currently available topical steroids may lead to adverse events such as elevated intraocular pressure (IOP) or cataracts if used chronically and all contain preservatives which can cause ocular surface toxicity, resulting in itching and burning. OTX-DED, a new product candidate with a lower dose of dexamethasone and a smaller insert size than DEXTENZA, is designed to offer these patients the opportunity, if approved, to be treated with a non-abusable, physician-administered, preservative-free and hands-free steroid therapy. Since OTX-DED has a lower concentration of dexamethasone compared with DEXTENZA, the Company is able to leverage the DEXTENZA safety package generated to date and plans to file a Phase 2-enabling Investigative New Drug (IND) Application with the U.S. Food and Drug Administration (FDA) by the end of 2020.

Amended collaboration with Regeneron for the development of a suprachoroidal injection formulation of the FDA-approved VEGF trap aflibercept. In May, the Company amended its existing collaboration with Regeneron to develop an extended-delivery, suprachoroidal injection formulation of the FDA-approved VEGF trap aflibercept. Under the new amendment, Regeneron has agreed to compensate Ocular Therapeutix on a cost-plus basis for all work performed under the pre-clinical portion of the collaboration. The back-end economics of the original agreement remain the same with the potential for option exercise fees and milestone payments of $305 million and tiered, escalating royalties from the high single digits into the low-to-mid teens.

Completed common stock financing. In May, the Company raised $48.3 million, net of fees, from a public offering of stock. Cash and cash equivalents as of June 30, 2020 was $84.3 million and is expected to provide funding for at least the next twelve months.

Key Program Updates

OTX-TKI (axitinib intravitreal implant)
OTX-TKI is a bioresorbable, hydrogel implant incorporating axitinib, a small molecule tyrosine kinase inhibitor with anti-angiogenic properties for the potential treatment of wet age-related macular degeneration (wet AMD) and other retinal diseases. The Company is conducting a Phase 1, prospective, multi-center, open-label, dose-escalation clinical trial in Australia intended to evaluate the safety, durability, tolerability, and biological activity of OTX-TKI for the treatment of wet AMD. Two cohorts of six subjects each have been enrolled, a lower-dose cohort of 200 µg and a higher-dose cohort of 400 µg.

- In the 200 µg cohort, certain patients who had required frequent anti-VEGF dosing prior to enrollment were shown to not need rescue therapy for as long as 10 months after being treated with OTX-TKI.
- In the 400 µg cohort, two subjects have demonstrated reduction of intraretinal and/or subretinal fluid with durability out to at least 4.5 and 7.5 months, respectively.
- The Company is enrolling a third cohort of patients where half the subjects will be dosed at 600 µg (cohort 3a = 6 patients) and half the subjects will receive a 400 µg dose and an anti-VEGF induction injection (cohort 3b = 6 patients).
- The Company plans to provide a Phase 1 update in the fall and is on track to submit an exploratory IND to the FDA for the U.S. by the end of 2020.

OTX-TIC (travoprost intracameral implant)
OTX-TIC is a long-acting travoprost intracameral implant for the treatment of patients with primary open angle glaucoma or ocular hypertension. The Company is conducting a Phase 1, prospective, multi-center, open-label, dose-escalation clinical trial which is intended to evaluate the safety, biological activity, durability and tolerability of OTX-TIC for the reduction of elevated IOP in patients with primary open angle glaucoma or ocular hypertension.

- Data from the first two fully enrolled cohorts (cohort 1 = 5 patients, cohort 2 = 4 patients) have indicated a clinically meaningful reduction in mean IOP values in patients receiving OTX-TIC out to six months with durability demonstrated in one patient out to 21 months.
- The third patient cohort (faster-degrading implant, equivalent dose to cohort 1) is now fully enrolled and the fourth patient cohort (smaller implant, lower dose) is enrolling.
- The Company plans to initiate a Phase 2 clinical trial for OTX-TIC in the first half of 2021.

OTX-CSI (cyclosporine intracanalicular insert)
OTX-CSI is a long-acting cyclosporine intracanalicular insert for the treatment of chronic dry eye disease. The Company has recently initiated a Phase 1, open-label, single-center clinical trial in the United States to evaluate the safety, biological activity, durability, and tolerability of OTX-CSI for the treatment of dry eye disease.

- The five patient cohort for the Phase 1 trial has been enrolled.
- The safety committee has met and is supportive of moving forward with a double masked, randomized, placebo-controlled, multi-center Phase 2 trial.
- The Company anticipates initiating a 105 patient Phase 2 clinical trial by year end.

***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.

- ***U.S. Commercial Launch of DEXTENZA.*** The Company reported net product revenue of DEXTENZA in the second quarter ended June 30, 2020 of $1.4 million, after a temporary shutdown in elective surgeries resulting from the COVID-19 pandemic. Despite the ongoing market challenges amid the pandemic, the Company reported its strongest month to date of DEXTENZA in-market sales in June, as Ambulatory Surgery Centers (ASCs) and hospital outpatient departments (HOPDs) purchased 2,294 billable inserts, breaking the million dollar threshold for in-market sales in a calendar month for the first time, a threshold that the Company cleared again in July. DEXTENZA has shown a steady and robust rebound with the sales of billable inserts in-market of 64, 790 and 2,294 in April, May and June, respectively, reflecting the reopening of some ASCs and HOPDs. The Company believes the market views its hands-free alternative to drops as compelling and expects to see this momentum carry over into the third quarter.

- ***DEXTENZA in Allergic Conjunctivitis.*** The Company remains on track to meet with the FDA and plans to submit an sNDA by the end of 2020.

- ***DEXTENZA for use in other ocular surface indications.*** There remains significant interest and excitement in evaluating DEXTENZA in many areas of unmet need with over 70 Investigator Initiated Trial (IIT) requests submitted and 14 IIT studies that are actively enrolling, including two that have completed enrollment.

Second Quarter Ended June 30, 2020 Financial Results

- Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $1.6 million for the three months ended June 30, 2020. Net product revenue of DEXTENZA and ReSure® Sealant in the second quarter was $1.4 million and $0.2 million, respectively.

- Research and development expenses for the second quarter were $8.0 million versus $9.4 million for the comparable period in 2019 and primarily reflect a decrease in personnel and unallocated costs due the organizational restructuring announced in November 2019.

- Selling and Marketing expenses for the second quarter were $6.2 million as compared to $7.2 million for the same quarter in 2019, stemming primarily from a decrease in travel, consulting, marketing and conference expenses as a result of the COVID-related slowdown in the commercialization of DEXTENZA.

- General and Administrative expenses were $5.1 million in the second quarter of both 2020 and 2019, with a modest increase in facilities expenses being offset by decreased professional fees in Q2 2020.

- The Company reported a net loss of $(36.6) million, or a loss of $(0.64) per share on a basic and diluted basis. This compares to a net loss of $(24.5) million, or a loss of $(0.57) per share on a basic and diluted basis, for the same period in 2019. The net loss for the second quarter included $2.5 million in non-cash charges for stock-based compensation and depreciation compared to $2.3 million for the same quarter in 2019. The net loss for the quarter includes a non-cash charge of $17.0 million related to the change in the fair value of the derivative liability associated with the Company's convertible notes, resulting primarily from the significant increase in the share price of the Company's common stock as compared to the prior quarter.

- As of August 1, 2020, the Company had approximately 63.0 million shares outstanding.

- As of the June 30, 2020, the Company had $84.3 million in cash and cash equivalents versus $48.2 million at the end of Q1 2020. The cash balance at June 30, 2020 reflects the addition of $48.3 million in net proceeds generated from a public offering of stock in May and net proceeds of $1.7 million from the sale of common stock under the Company's 2019 Sales Agreement under which the Company may offer and sell its common stock having aggregate proceeds of up to $50.0 million from time-to-time. Approximately $1.3 million of common stock remains available to be sold under the 2019 Sales Agreement.

  The Company believes that its existing cash and cash equivalents of $84.3 million as of June 30, 2020 will enable the Company to fund its planned operating expenses, debt service obligations and capital expenditure requirements for at least the next twelve months. This estimate is based on the Company's currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, a continuing expected rebound in cataract surgeries in the third quarter of 2020 and beyond, the revenues and expenses associated with the commercialization of DEXTENZA, variable expense reductions, the pace of the Company's research and clinical development programs, and other aspects of the Company's business. We have based our estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly.

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 6937647. An archive of the webcast will be available until September 21, 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 in the lacrimal punctum and 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%).

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 recently completed a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. The Company's earlier stage development assets currently in Phase 1 trials include OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension, OTX-CSI (cyclosporine intracanalicular insert) for the treatment of the signs and symptoms of dry eye disease and OTX-TKI (axitinib intravitreal implant) for the treatment of retinal diseases. Also, Ocular Therapeutix is currently developing OTX-DED (dexamethasone intracanalicular insert) for the treatment of episodic dry eye and, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) for an extended-delivery formulation of aflibercept for the treatment of retinal diseases. 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; 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-DED for the treatment of episodic dry eye disease, OTX-CSI for the treatment of dry eye disease, 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-AFS 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 size of potential markets for our product candidates; 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; projected net product revenue and other financial metrics of DEXTENZA; the expected impact of the COVID-19 pandemic on the Company and its operations; 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, 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 Company's ability to generate its projected net product revenue on the timeline expected, if at all, 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, the severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, the 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 press 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 press 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Product revenue, net	$ 1,569	$ 650	$ 4,178	$ 1,142
Total revenue, net	1,569	650	4,178	1,142
Costs and operating expenses:				
Cost of product revenue	134	552	953	680
Research and development	8,021	9,414	14,119	20,731
Selling and marketing	6,153	7,225	13,283	10,572
General and administrative	5,145	5,058	10,321	10,416
Total costs and operating expenses	19,453	22,249	38,676	42,399
Loss from operations	(17,884)	(21,599)	(34,498)	(41,257)
Other income (expense):				
Interest income	17	379	156	708
Interest expense	(1,694)	(1,627)	(3,327)	(2,645)
Change in fair value of derivative liability	(17,007)	(1,606)	(20,411)	1,617
Total other income (expense), net	(18,684)	(2,854)	(23,582)	(320)
Net loss and comprehensive loss	$ (36,568)	$ (24,453)	$ (58,080)	$ (41,577)
Net loss per share, basic and diluted	$ (0.64)	$ (0.57)	$ (1.06)	$ (0.98)
Weighted average common shares outstanding, basic and diluted	57,368,292	42,910,084	54,634,572	42,582,501

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 84,294	$ 54,437
Accounts receivable, net	2,874	2,548
Inventory	1,067	954
Prepaid expenses and other current assets	2,058	2,231
Total current assets	90,293	60,170
Property and equipment, net	8,934	10,151
Restricted cash	1,764	1,764
Operating lease assets	6,269	6,655
Total assets	$ 107,260	$ 78,740
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,650	$ 3,268
Accrued expenses and other current liabilities	5,769	7,635
Operating lease liabilities	1,238	1,126
Notes payable, net of discount, current	4,146	—
Total current liabilities	13,803	12,029
Operating lease liabilities, net of current portion	8,256	8,905
Derivative liability	32,535	12,124
Notes payable, net of discount	20,970	25,007
2026 convertible notes, net	26,352	24,305
Total liabilities	101,916	82,370
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 62,953,793 and 50,333,559 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	447,033	379,980
Accumulated deficit	(441,695)	(383,615)
Total stockholders' equity (deficit)	5,344	(3,630)
Total liabilities and stockholders' equity (deficit)	$ 107,260	$ 78,740