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): **March 12, 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 (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 exchange on which registered**
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 March 20, 2020, Ocular Therapeutix, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 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 March 12, 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: March 12, 2020

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

Exhibit 99.1

Ocular Therapeutix™ Reports Fourth Quarter and Year End 2019 Financial Results and Business Update

Fourth Quarter DEXTENZA® Net Product Revenue of $1.6 million, a 433% Sequential Increase; Guiding First Quarter Total Net Product Revenue of $3.0 million to $3.2 million

Presented Interim Clinical Data Releases for OTX-TIC and OTX-TKI Showing Favorable Safety Profile, Tolerability, Durability and Early Biological Activity

BEDFORD, Mass. —(BUSINESS WIRE)—March 12, 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 fourth quarter and year ended December 31, 2019 and provided a business update.

“Ocular Therapeutix has had an impressive final quarter of 2019 and strong start to 2020,” said Antony Mattessich, President and Chief Executive Officer. “Key performance indicators on the launch of DEXTENZA point to a building momentum, most notably in the number of billable inserts ordered by ASC’s and hospitals that show a definitive acceleration. We are equally excited on the product development side by interim results from our two Phase 1 programs: in our OTX-TIC program, signals support the possibility for a product that could have both the magnitude and duration of effect to become a standard of care in the treatment of elevated IOP; and, most encouragingly, in our OTX-TKI program, we have seen a signal of biologic effect, observing a reduction in sub-retinal and intra-retinal fluid in some patients with wet AMD. Both of these early programs have the potential to shift current treatment paradigms.”

Key Program Updates

***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 fourth quarter ended December 31, 2019 of $1.6 million versus $0.3 million in the third quarter ended September 30, 2019, an amount which reflects a 433% sequential increase. DEXTENZA was commercially launched in July 2019 and received its J-code in October of the same year.

    - The Company continues to increase the number of new accounts, including seeing larger accounts adopting DEXTENZA, and the number of existing accounts re-ordering continues to increase.

    - Over the three months ended February 2020, the Company has experienced month-over-month growth in billable units of 9%, 26% and 34%.

    - The Company anticipates net product revenue of DEXTENZA for the first quarter of 2020 will be in the range of $2.4 million to $2.6 million.

- ***DEXTENZA for use in other ocular surface indications***

    - The Company is currently conducting a pivotal Phase 3 clinical trial for the treatment of ocular itching associated with allergic conjunctivitis. The Company has recently completed enrollment and anticipates releasing results in the second quarter 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 expansion of DEXTENZA into the office setting would highlight the versatility of the product and the opportunity for the Company's technology to potentially be used in ocular surface diseases.

OTX-TIC (travoprost implant for intracameral injection)

OTX-TIC is a long-acting travoprost intracameral implant for the treatment of patients with primary open angle glaucoma or ocular hypertension. The Company presented interim data on OTX-TIC at the Glaucoma 360 Conference held in San Francisco, CA in February.

- The Phase 1, prospective, multi-center, open-label, dose escalation clinical trial 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 subjects, cohort 2=4 subjects) indicate a clinically meaningful reduction in mean IOP values in patients receiving OTX-TIC. The data also show that the mean IOP values remained decreased from the baseline values through the six month study period and beyond and, in one patient, for up to eighteen months. This Phase 1 clinical trial is not powered to measure any efficacy endpoints with statistical significance.

- The implant biodegraded consistently in approximately five to seven months and was generally well tolerated and observed to have a favorable safety profile in both cohorts, with no serious ocular adverse events reported.

- Enrollment has begun in the third and fourth cohorts of the trial while continued long-term evaluation remains ongoing in the first two cohorts.

OTX-TKI (tyrosine kinase inhibitor intravitreal implant containing axitinib)

The Company announced interim results last week from a Phase 1 clinical trial for OTX-TKI, a bioresorbable, hydrogel implant with anti-angiogenic properties delivered by intravitreal injection to the posterior segment of the eye for wet age-related macular degeneration (wet AMD) and other retinal diseases.

- The Phase 1, prospective, multi-center, open-label, dose escalation clinical trial is 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 ug and a higher-dose cohort of 400 ug. This Phase 1 clinical trial is not powered to measure any efficacy endpoints with statistical significance.

- In the higher-dose cohort, a decrease in intraretinal and/or subretinal fluid was seen in some subjects treated with OTX-TKI as a monotherapy. In both cohorts, initial data showed that in subjects previously treated with anti-VEGF, OTX-TKI may extend the durability of anti-VEGF injections with no increase or decrease in fluid noted.

- Data from the first two fully enrolled cohorts demonstrated OTX-TKI was generally well tolerated and observed to have a favorable safety profile, with no serious adverse ocular events noted.

- Long-term evaluation of cohorts 1 and 2 will continue and the Company will be amending its current clinical trial protocol to enroll a third, higher-dose cohort.

OTX-CSI (cyclosporine intracanalicular insert)

The Company recently filed an IND and intends to begin a Phase 1 clinical trial by the middle of 2020 for OTX-CSI, a cyclosporine intracanalicular insert targeting dry eye disease.

Fourth Quarter and Year Ended December 31, 2019 Financial Results

- Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $2.3 million for the three months ended December 31, 2019, reflecting a 172% sequential increase over the third quarter ended September 30, 2019. Net product revenue of DEXTENZA® in the fourth quarter 2019 was $1.6 million versus $0.3 million in the third quarter and reflecting a 433% sequential increase. Total net product revenue for the fourth quarter of 2019 also includes net product revenue of $0.7 million from ReSure® Sealant. Overall net product revenue for the year ended December 31, 2019 was $4.2 million versus $2.0 million for 2018 and primarily reflects the addition of DEXTENZA sales beginning in the late second quarter of 2019.

- Research and development expenses for the fourth quarter were $10.1 million versus $10.3 million for the comparable period in 2018 and primarily reflect an increase in unallocated costs and clinical trial costs associated with the Phase 3 DEXTENZA allergic conjunctivitis trial and the Phase 1 trials for OTX-TIC and OTX-TKI offset by a significant reduction of the Phase 3 clinical trial costs associated with OTX-TP. Overall R&D expenses for the full year increased $4.2 million to $41.1 million from $36.9 million in 2018, reflecting increased unallocated costs and the trend in clinical trial expenses mentioned above.

- Selling and marketing expenses for the fourth quarter were $7.1 million as compared to $2.3 million for the same quarter in 2018. This increase relates almost entirely to support of the commercial launch of DEXTENZA, driven primarily by the full impact of the hiring of new members of the commercial team including Key Account Managers, Field Reimbursement Managers and Medical Sales Liaisons beginning in the second quarter of 2019. Overall selling and marketing expenses for the full year increased $19.6 million to $24.5 million from $4.9 million in 2018, driven primarily by the hiring of new members of the commercial team, as highlighted above, as well as increased spending on consulting, conferences and related costs.

- Finally, general and administrative expenses were $5.6 million for the fourth quarter of 2019 versus $5.1 million in the comparable quarter of 2018. The increase in expenses for the fourth quarter stemmed primarily from increased personnel costs. Overall, general and administrative expenses for the full year increased $3.3 million to $22.1 million from $18.8 million in 2018, again reflecting primarily increased personnel costs.

- The Company reported a net loss of $(26.0) million, or a loss of $(0.53) per share on a basic and diluted basis for the fourth quarter of 2019. This compares to a net loss of $(17.4) million, or a loss of $(0.42) per share on a basic and diluted basis, for the same period in 2018. The net loss for the fourth quarter included $2.6 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, includes a non-cash charge of $3.0 million related to the change in the fair value of the derivative liability associated with the Company's convertible notes. Overall, the Company reported a net loss of $86.4 million or a loss of $(1.91) per share on a basic and diluted basis for the full year ended December 31, 2019 versus a net loss of $60.0 million or a loss of $(1.57) per share on a basic and diluted basis in 2018.

- As of March 2, 2020, the Company had 52.6 million shares outstanding.

- As of the full year ended December 31, 2019, the Company had $54.4 million in cash and cash equivalents versus $54.1 million at year end 2018. These cash amounts exclude restricted cash of $1.8 million and $6.6 million, respectively. Restricted cash was reduced by $5.0 million in the third quarter of 2019 as a result of an amendment with the lenders of our $25.0 million term loan facility to eliminate the $5.0 million liquidity covenant. The cash balance benefited during the fourth quarter from $8.9 million in net proceeds generated 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. For the full year ended December 31, 2019, cash balances benefited from total net proceeds from financing activities of $75.3 million, primarily consisting of net proceeds from the 2026 Convertible Notes of $37.3 million, common stock sales under the 2016 Sales Agreement of $4.9 million, and common stock sales under the 2019 Sales Agreement of $32.7 million. For the current calendar year through March 10, 2020, the Company has sold additional common stock under the 2019 Sales Agreement generating net proceeds of $10.7 million; approximately $5.2 million of common stock remains available to be sold under the 2019 Sales Agreement.

- Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and ReSure product sales and cash outflows from operating expenses, the Company believes that existing cash and cash equivalents, as of December 31, 2019, together with the first quarter 2020 net proceeds through March 10th, from sales of common stock pursuant to its 2019 Sales Agreement highlighted previously, will enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2021. This cash guidance is of course subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of research and clinical development programs, and other aspects of the Company's business.

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 9974763. An archive of the webcast will be available until June 10, 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 lower 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 is conducting 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 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; 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; projected net product revenue; 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 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.

Investors
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Ocular Therapeutix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Product revenue, net	$ 2,256	$ 504	$ 4,227	$ 1,990
Total revenue, net	2,256	504	4,227	1,990
Costs and operating expenses:				
Cost of product revenue	839	117	2,325	465
Research and development	10,125	10,258	41,091	36,915
Selling and marketing	7,142	2,291	24,491	4,942
General and administrative	5,551	5,121	22,122	18,786
Total costs and operating expenses	23,657	17,787	90,029	61,108
Loss from operations	(21,401)	(17,283)	(85,802)	(59,118)
Other income (expense):				
Interest income	213	258	1,229	879
Interest expense	(1,805)	(374)	(6,101)	(1,739)
Change in fair value of derivative liability	(3,024)	—	4,310	—
Other income (expense), net	—	—	(8)	—
Total other income (expense), net	(4,616)	(116)	(570)	(860)
Net loss and comprehensive loss	$ (26,017)	$ (17,399)	$ (86,372)	$ (59,978)
Net loss per share, basic	$ (0.53)	$ (0.42)	$ (1.91)	$ (1.57)
Weighted average common shares outstanding, basic and diluted	48,489,846	41,094,230	45,273,231	38,115,142

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 54,437	$ 54,062
Accounts receivable, net	2,548	201
Inventory	954	217
Prepaid expenses and other current assets	2,231	1,713
Total current assets	60,170	56,193
Property and equipment, net	10,151	10,236
Restricted cash	1,764	6,614
Operating lease assets	6,655	—
Total assets	$ 78,740	$ 73,043
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,268	$ 2,965
Accrued expenses and other current liabilities	7,635	6,194
Operating lease liabilities	1,126	—
Total current liabilities	12,029	9,159
Other liabilities	—	3,221
Operating lease liabilities, net of current portion	8,905	—
Derivative liability	12,124	—
Notes payable, net of discount	25,007	24,788
2026 convertible notes, net	24,305	—
Total liabilities	82,370	37,168
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 50,333,559 and 41,518,091 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	5	4
Additional paid-in capital	379,980	333,114
Accumulated deficit	(383,615)	(297,243)
Total stockholders' equity (deficit)	(3,630)	35,875
Total liabilities and stockholders' equity (deficit)	$ 78,740	$ 73,043