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): **May 9, 2022**

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 May 9, 2022, Ocular Therapeutix, Inc. announced its financial results for the quarter ended March 31, 2022. 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 May 9, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 9, 2022

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

Exhibit 99.1

Ocular Therapeutix™ Reports First Quarter 2022 Financial Results and Business Update

DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg Recorded Quarterly Net Product Revenue of $12.5 Million, Representing Year-Over-Year Growth of 87%

Guiding DEXTENZA Annual Net Product Revenue for 2022 between $55 to $60 million, Representing Annual Growth of Approximately 26% to 38%

Expanding Commercial Team to Address the Commercial Opportunity for DEXTENZA in the Office Setting

Topline Data from the U.S.-based Clinical Trial for OTX-TKI for the Treatment of Wet AMD Anticipated in the Third Quarter of 2022

Dosing of Subjects in Phase 2 OTX-TIC Clinical Trial for the Treatment of Glaucoma Began in February, Triggering a $2M Milestone Clinical Support Payment from AffaMed Therapeutics

Conference Call to Discuss First Quarter Results to be Held at 4:30 p.m. ET

BEDFORD, Mass.--(BUSINESS WIRE)— May 9, 2022 -- 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 reported financial results for the quarter ended March 31, 2022, and provided updates on its ophthalmology pipeline.

“We have had a solid start to the year,” said Antony Mattessich, President and Chief Executive Officer. “Following a slowdown in cataract surgeries in January due to a spike in COVID-19 infections as a result of the Omicron variant, we saw a rebound in sales as the quarter progressed, culminating in approximately 10,500 billable units sold to ASCs and HOPDs in March—a monthly record by more than 500 units. Overall, net product revenue for DEXTENZA® reached $12.5M, an 87% increase over same quarter of the prior year. In the pipeline, we also saw great progress in the quarter as we completed enrollment of the U.S. Phase 1 clinical trial for OTX-TKI, our treatment for wet-AMD, and began dosing subjects in our Phase 2 clinical trial for OTX-TIC, our glaucoma product candidate. We look forward to announcing data from the OTX-TKI trial in the third quarter and enrolling the OTX-TIC trial as quickly as possible. We have a lot to look forward to over the course of this year from both a commercial and pipeline perspective.”

Recent Business Updates

The U.S. Commercial Uptake of DEXTENZA.

- Net product revenue of DEXTENZA® for the quarter was $12.5 million, an 87% increase over the first quarter of 2021.
- In-market purchases were nearly 28,000 billable units for the quarter, with March accounting for approximately 10,500 billable units, setting a new record for a calendar month.

Expanding Commercial Team and the Addition of Vice President of Sales to Optimize the Commercial Opportunity in the Office Setting.

- In March 2022, the Company expanded its commercial group with the hiring of Steve Meyers as Vice President, Surgical and Office Sales. In addition to overseeing the growing surgical sales force, Mr. Meyers will also be responsible for leading a separate sales team focused on the office setting, starting with four Key Account Managers (KAMs) and supported by the field reimbursement team.
- Mr. Meyers brings to the Company over 20 years of experience with a deep background selling buy-and-bill specialty products in the office setting and leading high-performing sales organizations. Mr. Meyers was most recently Vice President Sales at Flexion Therapeutics and has served in other commercial roles at leading biotechnology and pharmaceuticals companies including Regeneron, AbbVie, and Procter & Gamble.

Presented Data on Ocular Surface and Retinal Programs at ASCRS and ARVO; Presenting New Data at ASGCT.

- At the American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting held on April 22-24, 2022 in Washington D.C., the Company presented fifteen posters and papers from eight investigator-initiated trials and seven papers from Company-sponsored trials on the use of DEXTENZA and pipeline products. Two of these presentations highlighted real world use of DEXTENZA for the first 10,000 plus inserts.
- At the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held on May 1-4, 2022 in Denver, the Company presented six posters from Company-sponsored pre-clinical and clinical trials on our pipeline. Two posters highlighted recent studies of OTX-TKI in non-human primates: a pharmacokinetic and tolerability study and a six-month GLP toxicology study.
- At the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting held on May 16-19 in Washington, D.C., the Company is presenting two posters highlighting pre-clinical studies demonstrating the potential for sustained-release hydrogel implants as a therapeutic and safety benefit for ocular adeno-associated virus (AAV) gene therapy to the eye.
- Company-sponsored papers and posters can be found under the “Events and Presentations” section on the Ocular Therapeutix website.

2022 Financial Guidance

- Total net product revenue in 2022 is expected to be in the range of $55 million to $60 million, representing growth of between 26% to 38% over 2021.
- The growth is anticipated to be almost entirely driven by sales of DEXTENZA for the treatment of post-surgical inflammation and pain.
- Based on current operating plans and related estimates of anticipated cash inflows from product sales, the Company believes that existing cash and cash equivalents, totaling $145.4 million as of March 31, 2022, are sufficient to enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements through 2023.

Key Pipeline Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD and other retinal diseases.***

- At the Angiogenesis, Exudation, and Degeneration Meeting held in February 2022, the Company presented interim data from the ongoing Australia-based Phase 1 clinical trial of OTX-TKI for the treatment of wet AMD demonstrating preliminary evidence of biological activity as observed by a clinically meaningful decrease in intraretinal and/or subretinal fluid in some subjects, and durability of six months or more in over 60% of subjects across all cohorts and over 80% of subjects in cohort 3a (600 µg), the dose being evaluated in the U.S.-based Phase 1 clinical trial.
- The Company continues to follow subjects in the ongoing Australia-based Phase 1 clinical trial.
- The U.S.-based Phase 1 clinical trial is now fully enrolled, and the Company expects to report interim, six-month data in the third quarter of this year.

· ***OTX-TIC (travoprost intracameral implant) for the treatment of patients with primary open-angle glaucoma or ocular hypertension.***
- The Company presented interim Phase 1 data for OTX-TIC at Glaucoma 360 held in February 2022 highlighting the product candidate's ability to cause a clinically meaningful decrease in intraocular pressure (IOP) for six months or longer with a single implant in many subjects while preserving corneal health.
- The Company is actively enrolling its U.S.-based Phase 2 prospective, multi-center, randomized, controlled clinical trial evaluating the safety, tolerability, and efficacy of OTX-TIC for the treatment of patients with primary open-angle glaucoma or ocular hypertension. The trial will enroll approximately 105 subjects in three different arms (~35 subjects per arm; randomized 1:1:1) in which the subjects are to receive a single OTX-TIC implant, containing either a 5 µg or 26 µg dose of travoprost, compared with an injection of Allergan's DURYSTA™. The trial is designed to observe the changes in diurnal IOP from baseline (8 am, 10 am, 4 pm) at 2, 6, and 12 weeks, and follow duration of IOP response over time.
- With the dosing of the first patient in the Phase 2 trial, the Company earned a $2.0 million clinical support payment from AffaMed Therapeutics (AffaMed), under its licensing agreement, to support costs associated with this clinical trial. The Company expects to receive the payment in the second quarter.

· ***OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.***
- The Company has resumed development of OTX-CSI, including formulation work for the insert to allow improved product retention. The Company is also developing an appropriate vehicle comparator that may be used in both the OTX-CSI and OTX-DED programs. Ocular recently received US Patent No. 11,291,627 which covers the formulation under development.

· ***OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.***
- The Company is currently developing an optimized clinical, regulatory and manufacturing plan. This plan is expected to include some additional improvements to the product's formulation and the development of an improved vehicle comparator.

First Quarter Ended March 31, 2022 Financial Results

Net revenue, which includes both gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, and collaboration revenue was $13.2 million for the first quarter and represented an 81% increase over the same period in 2021. Net product revenue of DEXTENZA in the first quarter of 2022 was $12.5 million versus $6.7 million in the comparable quarter of 2021, reflecting an 87% increase. Total net revenue for the first quarter of 2022 also included collaboration revenue of $0.7 million from our licensing agreement with AffaMed.

Research and development expenses for the first quarter were $13.1 million versus $10.9 million for the comparable period in 2021 driven primarily by an increase in unallocated expenses, predominantly unallocated personnel costs, and increased clinical trial costs.

Selling and marketing expenses in the quarter were $9.1 million as compared to $8.1 million for the same quarter in 2021, reflecting increased personnel costs associated primarily with an expansion of the commercial field force.

General and administrative expenses were $7.6 million for the first quarter versus $7.7 million in the comparable quarter of 2021.

The Company reported a net loss of $(12.5) million, or a loss of $(0.16) per share on a basic basis and a loss of $(0.22) per share on a diluted basis for the three months ended March 31, 2022. This compares to a net income of $3.1 million, or income of $0.04 per share on a basic basis and a loss of $(0.24) per share on a diluted basis for the same period in 2021. Net loss in the first quarter of 2022 included a $7.0 million non-cash increase in the fair value of the derivative liability associated with the Company's convertible notes, driven by a decrease in the price of its common stock during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $4.8 million in the first quarter versus $3.7 million for the same quarter in 2021.

As of May 6, 2022, the Company had 76.8 million shares outstanding

As of March 31, 2022, the Company had $145.4 million in cash and cash equivalents versus $164.2 million at December 31, 2021. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and anticipated cash outflows from operating expenses, the Company believes that existing cash and cash equivalents are sufficient to enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements through 2023. This cash guidance is subject to a number of assumptions including the impacts from the ongoing COVID-19 pandemic; the revenues, expenses and reimbursement associated with DEXTENZA; and the pace of research and clinical development programs, among other aspects of the 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 6054473. An archive of the webcast will be available until August 9, 2022 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 first commercial drug product, DEXTENZA®, is an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix's earlier stage development assets includes OTX-TKI (axitinib intravitreal implant), currently in Phase 1 clinical trials for the treatment of wet AMD and other retinal diseases. OTX-TIC (travoprost intracameral implant) recently began a Phase 2 clinical trial to evaluate the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix has also completed Phase 2 clinical trials for OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device to prevent wound leaks in corneal incisions following cataract surgery.

About DEXTENZA

DEXTENZA is FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. DEXTENZA is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA resorbs and exits the nasolacrimal system without the need for removal.

Please see full Prescribing and Safety Information at www. DEXTENZA.com.

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 the effectiveness of and amounts applicable to reimbursement codes for, DEXTENZA; the conduct of post-approval studies of and compliance with related labeling requirements for DEXTENZA and ReSure Sealant; the Company's sales and marketing strategy; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, and OTX-TKI 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 operations of Company collaborations, including any potential future costs or payments thereunder; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA and ReSure Sealant; the Company's participation in scientific conferences; potential market sizes for indications targeted by the Company's product candidates, if approved; 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 preclinical and 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 successfully develop and commercialize products for the ophthalmology office setting, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA, the initiation, timing, conduct and outcomes of clinical trials, whether clinical trial data such as the data reported in this release will be indicative of the results of subsequent clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's ability to enter into and perform its obligations under collaborations and the performance of its collaborators under such collaborations, 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 meet supply demands, the Company's ability to generate its projected net product revenue and in-market sales 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 severity and duration of the COVID-19 pandemic including its effect on the Company's revenues and relevant regulatory authorities' operations, any additional financing needs 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, whether as a result of new information, future events or otherwise, 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.

Ocular Therapeutix, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Product revenue, net	$ 12,498	$ 7,342
Collaboration revenue	689	—
Total revenue, net	13,187	7,342
Costs and operating expenses:		
Cost of product revenue	1,300	892
Research and development	13,100	10,927
Selling and marketing	9,063	8,086
General and administrative	7,557	7,665
Total costs and operating expenses	31,020	27,570
Loss from operations	(17,833)	(20,228)
Other income :		
Interest income	18	12
Interest expense	(1,683)	(1,679)
Change in fair value of derivative liability	6,958	25,016
Other income (expense), net	(2)	—
Total other income, net	5,291	23,349
Net (loss) income attributable to common stockholders	$ (12,542)	$ 3,121
Net (loss) income per share, basic	$ (0.16)	$ 0.04
Weighted average common shares outstanding, basic	76,745,663	76,071,017
Net (loss) income per share, diluted	$ (0.22)	$ (0.24)
Weighted average common shares outstanding, diluted	82,514,895	87,245,706

Ocular Therapeutix, Inc.

Consolidated Balance Sheet
(In thousands, except share and per share data)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 145,417	$ 164,164
Accounts receivable, net	23,207	21,135
Inventory	1,358	1,250
Prepaid expenses and other current assets	4,670	4,751
Total current assets	174,652	191,300
Property and equipment, net	6,614	6,956
Restricted cash	1,764	1,764
Operating lease assets	4,592	4,867
Total assets	$ 187,622	$ 204,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,420	$ 4,592
Accrued expenses and other current liabilities	17,636	20,121
Deferred revenue	1,208	—
Operating lease liabilities	1,696	1,624
Total current liabilities	23,960	26,337
Other liabilities:		
Operating lease liabilities, net of current portion	5,472	5,924
Derivative liability	13,234	20,192
Deferred revenue, net of current portion	13,103	13,000
Notes payable, net of discount	25,063	25,000
2026 convertible notes, net	26,995	26,435
Total liabilities	107,827	116,888
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 76,759,614 and 76,731,940 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	638,133	633,795
Accumulated deficit	(558,346)	(545,804)
Total stockholders' equity	79,795	87,999
Total liabilities and stockholders' equity	$ 187,622	$ 204,887

Investors

Ocular Therapeutix
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or

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