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 8, 2023**

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 8, 2023, Ocular Therapeutix, Inc. announced its financial results for the quarter ended March 31, 2023. 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 8, 2023

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 8, 2023

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

Exhibit 99.1

Ocular Therapeutix™ Provides First Quarter 2023 Financial Results and Corporate Update

12-month Top-Line Data from the U.S.-based Phase 1 Clinical Trial of OTX-TKI (axitinib intravitreal implant) for the Treatment of Wet AMD to be Presented in June at the Clinical Trials at the Summit 2023 Meeting

Presented Pre-Clinical and Clinical Data on Three Pipeline Programs at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held April 23rd to 27th

DEXTENZA® Net Product Revenue in the First Quarter of 2023 was $13.2 million, Representing Growth of Approximately 6% Over the First Quarter of 2022

Reiterated DEXTENZA Net Product Revenue for the Year Ending 2023 is Estimated to be between $55 and $60 million, Representing Anticipated Growth of Approximately 10% to 20% Over 2022

BEDFORD, Mass.–(BUSINESS WIRE)— May 8, 2023 – 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 first quarter ended March 31, 2023, and provided updates on its ophthalmology pipeline.

“The strong start to the year has continued through the end of the first quarter,” said Antony Mattessich, President and CEO. “We have been in productive conversations with the FDA and believe we have a pivotal design for OTX-TKI in diabetic retinopathy and two potential designs in wet AMD. While we are eager to advance both of these programs, we look forward to sharing top-line 12-month data from our U.S.-based Phase 1 trial for OTX-TKI in wet AMD at the Clinic Trials at the Summit meeting being held in June. We are also making excellent progress advancing our next late-stage program, the Phase 2 trial of OTX-TIC for the treatment of glaucoma. This trial continues to enroll well, and we continue to anticipate providing top-line data from this trial in the fourth quarter of 2023. Glaucoma represents another large potential ophthalmology market where we believe our hydrogel technology, which we have branded as Elutyx™, has the potential to redefine the current standard of care. On the commercial side, DEXTENZA finished with a strong quarter. In-market billable unit volumes were approximately 8% ahead of fourth quarter volumes, and we continue to guide towards a full year 2023 net product revenue of $55 to $60 million. Overall, I am pleased with our continued progress in building a mid-tier strategic within ophthalmology.”

Business Updates

Presented Pre-Clinical and Clinical Data at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held April 23rd to 27th

- Data presented included clinical and preclinical updates on OTX-TKI, OTX-TIC, and gene delivery programs that demonstrate the depth of the ELUTYX technology and its potential to provide solutions to improve efficacy and reduce the complexity and burden of the current standard of care for a number of diseases in both the front and back of the eye.

- Access to the presentations made at ARVO are available on the Company’s investor website.

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

- The Company plans to present top-line 12-month data from its U.S.-based Phase 1 clinical trial of OTX-TKI for the treatment of wet AMD at the Clinical Trials at the Summit 2023 meeting being held June 10th 2023 in Park City, Utah.

- The Company has been in discussions with the FDA for the clinical development of OTX-TKI in the treatment of wet AMD and has two potential pivotal designs. Subject to obtaining the necessary financing, the Company plans to be prepared to initiate the first pivotal trial for OTX-TKI for the treatment of wet AMD as early as Q3 2023.

OTX-TKI (axitinib intravitreal implant) for the treatment of diabetic retinopathy

- The Company is currently enrolling patients in a U.S.-based, randomized, masked Phase 1 clinical trial in approximately 21 patients randomized 2:1 to either a 600 µg OTX-TKI single implant containing axitinib or a sham control.

- The Company has been in discussions with the FDA for the clinical development of OTX-TKI in the treatment of diabetic retinopathy and has a potential pivotal design. Subject to receiving favorable top-line data from the ongoing Phase 1 trial and obtaining the necessary financing to fund the trial, the Company plans to be prepared to initiate a Phase 3 clinical trial as early as Q1 2024.

OTX-TIC (travoprost intracameral implant) for the treatment of primary open-angle glaucoma or ocular hypertension.

- The Company continues to enroll 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 compared to DURYSTA®. The trial is designed to evaluate whether OTX-TIC can demonstrate a clinically meaningful decrease in intraocular pressure while preserving endothelial cell health.

- The Company continues to enroll patients in the Phase 2 trial and plans to provide top-line data in Q4 2023.

OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease and OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease

- The Company has initiated a small study in the second quarter of 2023 to evaluate the performance of OTX-DED versus fast-dissolving collagen plugs and no inserts at all in order to identify a proper placebo control for any future trials of these product candidates.

- The Company plans to use the results of this study to inform the next steps for both the OTX-DED and OTX-CSI programs.

DEXTENZA (dexamethasone ophthalmic insert) 0.4mg approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis.

- Net product revenue of DEXTENZA for the first quarter of 2023 was $13.2 million, slightly ahead of first quarter 2022 net product revenue of $12.5 million and slightly behind fourth quarter net product revenue of $13.9 million.

- In-market unit volume—units sold to ambulatory surgery centers (ASCs) and hospital outpatient departments (HOPDs)—was 34,491 for the first quarter of 2023, an approximate 8% increase in unit volume over the fourth quarter of 2022.

- The Company is reiterating its guidance of DEXTENZA net product revenue for the full year 2023 to be between $55 and $60 million, which would represent potential growth of approximately 10% to 20% over 2022. The Company believes that DEXTENZA is currently used in less than 5% of cataract procedures and that growth in 2023 will be driven by: continued separate reimbursement now available under the non-opioid pain management drug as a surgical supply provision in ASCs; a renewed focus on sales to ASCs and specifically strategic accounts that own and control multiple ASCs; the continuing success of the revised pricing and discounting strategy that was implemented in the third quarter of 2022; and the introduction of a Commercial Assurance Program. The Company believes the momentum with ASCs will more than offset the impact of the loss of separate drug reimbursement in the HOPD setting in 2023.

First Quarter Ended March 31, 2023 Financial Results

Total net revenue, which includes both gross DEXTENZA product revenue net of discounts, rebates, and returns, which the Company refers to as net product revenue, and collaboration revenue was $13.4 million for the first quarter of 2023, slightly ahead of first quarter 2022 net revenues of $13.2 million and slightly behind fourth quarter net revenue of $14.1 million. DEXTENZA net product revenue grew from $12.5 million to $13.2 million over the comparable period in 2022 while collaboration revenue declined from $0.7 million to $0.2 million.

Research and development expenses for the first quarter of 2023 were $14.7 million versus $13.1 million for the comparable period in 2022, driven primarily by an increase in expenses associated with clinical and preclinical programs.

Selling and marketing expenses in the first quarter of 2023 were $10.8 million as compared to $9.1 million for the comparable quarter of 2022, reflecting primarily an increase field force personnel.

General and administrative expenses were $9.1 million for the first quarter of 2023 versus $7.6 million in the comparable quarter of 2022, primarily due to an increase in personnel-related costs, including stock-based compensation, and professional fees.

The Company reported a net loss for the first quarter of 2023 of $(30.3) million, or a loss of $(0.39) per share on both a basic basis and diluted basis, compared to a net loss of $(12.5) million, or a net loss of $(0.16) per share on a basic basis and a loss of $(0.22) per share on a diluted basis for the comparable period in 2022. Net loss in the first quarter of 2023 included a $6.6 million non-cash item attributable to a change in the fair value of the derivative liability associated with the Company’s convertible notes, increasing total other expenses as the price of the Company’s common stock increased during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $5.1 million in the first quarter of 2023 versus $4.8 million for the comparable quarter in 2022.

As of May 4, 2023, the Company had approximately 77.5 million shares outstanding.

2023 Financial Guidance

- Net product revenue in 2023 is expected to be in the range of $55 to $60 million, representing anticipated growth of approximately 10% to 20% over 2022. The growth is anticipated to be driven by sales of DEXTENZA for the treatment of post-surgical inflammation and pain in the ASC setting.

- As of March 31, 2023, the Company had $79.0 million in cash and cash equivalents versus $102.3 million as of December 31, 2022. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and anticipated cash outflows from operating expenses, the Company believes that its existing cash and cash equivalents are sufficient to enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements to the middle of 2024. This cash guidance is subject to a number of assumptions including the revenues, expenses and reimbursement associated with DEXTENZA, and the pace of research and clinical development programs, among other aspects of the business, and excludes expenses related to the Company's planned clinical trials for OTX-TKI for the treatment of wet AMD and for the treatment of diabetic retinopathy.

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. A live audio webcast will be available at www.ocutx.com. Interested parties may also register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 include: OTX-TKI (axitinib intravitreal implant), currently in Phase 1 clinical trials for the treatment of wet AMD and diabetic retinopathy; OTX-TIC (travoprost intracameral implant), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension; and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease; and OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease, both of which have completed Phase 2 clinical trials.

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® or any of the Company's products or product candidates; the development and regulatory status of the Company's product candidates, such as the Company's development of, timing of, and prospects for approvability of OTX-TKI for the treatment of retinal diseases including wet AMD and diabetic retinopathy including the timing of planned pivotal clinical trials, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, and OTX-CSI for the chronic treatment of dry eye disease; the Company's plans to advance the development of its product candidates or preclinical programs; the Company's ability to fund the planned and future development of its product candidates, whether through strategic alliances or other fundraising; the potential utility of any of the Company's product candidates; the size of potential markets for the Company's product candidates; 2023 financial guidance, including estimated 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 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 or any product or product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA or any product or 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 will be indicative of the results of subsequent clinical trials in the same or other indications or that interim data will be indicative of the full data from a clinical trial, uncertainties as to the timing and 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, any additional financing needs, the Company's ability to recruit and retain key personnel, 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.

Investors
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Ocular Therapeutix, Inc.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Product revenue, net	$ 13,214	$ 12,498
Collaboration revenue	160	689
Total revenue, net	13,374	13,187
Costs and operating expenses:		
Cost of product revenue	1,214	1,300
Research and development	14,747	13,100
Selling and marketing	10,835	9,063
General and administrative	9,127	7,557
Total costs and operating expenses	35,923	31,020
Loss from operations	(22,549)	(17,833)
Other income (expense):		
Interest income	563	18
Interest expense	(1,768)	(1,683)
Change in fair value of derivative liability	(6,563)	6,958
Other expense, net	(1)	(2)
Total other (expense) income, net	(7,769)	5,291
Net loss	$ (30,318)	$ (12,542)
Net loss per share, basic	$ (0.39)	$ (0.16)
Weighted average common shares outstanding, basic	77,386,287	76,745,663
Net loss per share, diluted	$ (0.39)	$ (0.22)
Weighted average common shares outstanding, diluted	77,386,287	82,514,895

Ocular Therapeutix, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 79,026	$ 102,300
Accounts receivable, net	21,124	21,325
Inventory	2,266	1,974
Prepaid expenses and other current assets	4,746	4,028
Total current assets	107,162	129,627
Property and equipment, net	12,022	9,856
Restricted cash	1,764	1,764
Operating lease assets	7,625	8,042
Total assets	$ 128,573	$ 149,289
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,441	$ 5,123
Accrued expenses and other current liabilities	21,993	24,097
Deferred revenue	463	576
Operating lease liabilities	1,818	1,599
Total current liabilities	29,715	31,395
Other liabilities:		
Operating lease liabilities, net of current portion	8,114	8,678
Derivative liability	12,914	6,351
Deferred revenue, net of current portion	13,340	13,387
Notes payable, net of discount	25,321	25,257
Other non-current liabilities	100	93
2026 convertible notes, net	29,358	28,749
Total liabilities	118,862	113,910
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, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 77,516,638 and 77,201,819 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8	8
Additional paid-in capital	656,863	652,213
Accumulated deficit	(647,160)	(616,842)
Total stockholders' equity	9,711	35,379
Total liabilities and stockholders' equity	$ 128,573	$ 149,289