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, 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 August 7, 2023, Ocular Therapeutix, Inc. announced its financial results for the quarter ended June 30, 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 August 7, 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: August 7, 2023

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

Exhibit 99.1

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

DEXTENZA® Net Product Revenue in Q2 2023 was $15.0 million, Representing Growth of Approximately 24% Over Q2 2022

Closed on a New $82.5 million Credit Facility; Cash Runway Now Forecasted into 2025

First of Two Planned Pivotal Clinical Trials for OTX-TKI in Wet AMD Expected to Initiate in Q3 2023

Completed Enrollment of HELIOS U.S.-based OTX-TKI Phase 1 Clinical Trial for Treatment of Non-Proliferative Diabetic Retinopathy; 6-Month Interim Data Anticipated Q1 2024

Completed Enrollment of OTX-TIC Phase 2 Clinical Trial and Began Pilot Repeat-Dose Sub-Study

BEDFORD, Mass.–(BUSINESS WIRE)— August 7, 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 second quarter ended June 30, 2023, and provided updates on its ophthalmology pipeline.

“The progress at Ocular Therapeutix over this last quarter has been significant,” said Antony Mattessich, President and CEO. “We reached the milestone of $15.0 million in DEXTENZA net product revenues for the quarter and achieved revenue growth of 24% over the same quarter prior year and 14% over the previous quarter. This represents the third straight quarter of sequential growth of in-market unit sales and gives us great confidence in DEXTENZA’s ability to augment funding of our fast-developing pipeline. As importantly, we now have a path forward with OTX-TKI in wet AMD and expect to initiate our first pivotal trial in the United States for wet AMD before the end of this quarter. We were also able to secure a credit facility of $82.5M that puts the funding in place to be able to initiate the trial and extends our runway into 2025. We believe that our successes in R&D and improved commercial performance have positioned us well for the future.”

Business Updates

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

- The Company presented positive 12-month top-line data from its 21-subject U.S.-based Phase 1 trial of OTX-TKI for the treatment of wet AMD at the Clinical Trials at the Summit 2023 Meeting held in Park City, Utah in June 2023.
    - An 89% reduction in treatment burden was observed in OTX-TKI treated subjects for up to 12 months.
    - Subjects treated with a single OTX-TKI implant continued to demonstrate sustained BCVA (mean change from baseline of -1.0 letters) and CSFT (mean change from baseline of +20.2 µm) in the OTX-TKI arm at 12 months, which was comparable with the aflibercept arm (mean change from BCVA baseline of +2.0 letters; mean change from CSFT baseline of -2.2 µm).

- 60% of the OTX-TKI subjects were rescue-free up to Month 12. Four subjects received rescue therapy for the first time at Month 12, which reflects the anticipated waning of OTX-TKI's therapeutic effect and potential disease reactivation and helps establish a re-dosing timeline for patients.

- Top-line data showed that a single OTX-TKI implant was well-tolerated by subjects in the trial with no drug-related ocular or systemic serious adverse events (SAEs) observed through Month 12.

- The Company intends to initiate the first of two planned pivotal trials in wet AMD in Q3 2023. This pivotal trial will be a prospective, multi-center, randomized, parallel-group trial that will be run primarily at U.S. sites. This will be a superiority trial that the Company designed after extensive discussions with key opinion leaders and is consistent with the FDA's current wet AMD draft guidelines. The trial is planned to enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye. It will compare a single implant of OTX-TKI to a single injection of aflibercept and assess the safety and efficacy of OTX-TKI in subjects with wet AMD by measuring BCVA and CSFT.

OTX-TKI (axitinib intravitreal implant) for the treatment of non-proliferative diabetic retinopathy (NPDR).

- In June 2023, the Company completed enrollment of the HELIOS trial, a U.S.-based, double-masked Phase 1 clinical trial in 22 subjects randomized 2:1 to either a 600 µg OTX-TKI single implant containing axitinib or a sham control.

- The Company plans to present interim 6-month data from the trial in Q1 2024.

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

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

- The Company has recently completed enrollment of 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 subjects with primary open-angle glaucoma (OAG) or ocular hypertension (OHT) compared to DURYSTA®.

- The Company has designed the Phase 2 clinical trial to evaluate whether OTX-TIC can demonstrate a clinically meaningful decrease in intraocular pressure while preserving endothelial cell health.

- The Company has started a pilot repeat-dose sub-study in the Phase 2 clinical trial that is being run to evaluate the safety of a repeat, sustained release dose of OTX-TIC 26 µg, in a small sub-set of subjects with OAG or OHT. These subjects will be followed for at least 6 months after their enrollment in the sub-study to monitor and evaluate their endothelial cell health.

- The Company plans to report top-line data from the single-dose portion of the Phase 2 clinical trial in Q1 2024.

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

- In Q2 2023, the Company initiated a small study to evaluate the performance of OTX-DED versus fast-dissolving collagen plugs and no inserts at all in order to identify a potential placebo control for 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 Q2 2023 was $15.0 million, approximately 24% ahead of Q2 2022 net product revenue of $12.1 million and approximately 14% ahead of Q1 2023 net product revenue of $13.2 million.

- The Company believes that DEXTENZA is currently used in less than 5% of cataract procedures and that growth will be driven by a continued focus on sales to ASCs, specifically strategic accounts that own and control multiple ASCs, and the revised pricing and discounting strategy that was implemented in Q3 2022.

Expanded Board of Directors

- In July 2023, the Company added Dr. Adrienne Graves to its board of directors. A visual scientist by training and a global industry leader in ophthalmology, Dr. Graves brings extensive experience to her role. As the former CEO of Santen Inc., the US subsidiary of a 130-year-old Japanese pharmaceutical company, she successfully established a strong global presence, bringing multiple ophthalmic products through development to approval and commercialization and leading global teams through successful acquisitions and partnerships.

Closed $82.5 million Credit Facility

- The Company has closed on an $82.5 million credit facility with Barings, LLC. The credit facility was fully funded at close (approximately $80 million after the original issue discount) and, after repayment of the MidCap debt and related fees and expenses, the Company realized net cash proceeds of approximately $51.6 million. The debt has a six-year term and bears interest at the one-month SOFR (secured overnight financing rate) plus 6.75%, with a SOFR floor of not less than 1.5%. The new credit facility requires the Company to make interest payments on a monthly basis until maturity, at which time the Company shall also be required to repay the entirety of the principal in a bullet payment. Additionally, the credit facility carries a royalty fee equal to, in the aggregate, the funded loan amount requiring the Company to pay the lenders installments against the fee equal to 3.5% of U.S. DEXTENZA net revenues until such time as Barings has received total payments (inclusive of interest payments, principal prepayment fees and contingent revenue interest payments) equal to, in the aggregate, the funded loan amount. The royalty fee is reduced to either 20% or 30% of the funded loan amount, depending on the circumstances, if a change of control were to occur within 12 months of the closing. Any balance of the royalty fee is payable in connection with a change of control thereafter. The credit facility includes customary affirmative and negative covenants as well as a $20 million minimum liquidity requirement. Concurrently with the closing, the Company repaid an aggregate of $26.2 million to MidCap Financial Trust and our other lenders to satisfy its obligations under its prior credit facility and the maturity date of the Company’s existing $37.5 million convertible notes was extended to a date three months following the maturity of the new credit facility.

Second Quarter Ended June 30, 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 $15.2 million for the second quarter of 2023, an increase of approximately 24% over second quarter 2022 net revenues of $12.3 million and an increase of approximately 13% over first quarter net revenue of $13.4 million. For the second quarter of 2023, DEXTENZA net product revenue grew to $15.0 million from $12.1 million over the comparable period in 2022 while collaboration revenue grew to $0.2 million from $0.1 million.

Research and development expenses for the second quarter of 2023 were $15.1 million versus $13.1 million for the comparable period in 2022, driven primarily by an increase in expenses associated with clinical trial programs.

Selling and marketing expenses in the second quarter of 2023 were $11.2 million as compared to $10.1 million for the comparable quarter of 2022, reflecting primarily an increase in field force personnel.

General and administrative expenses were $8.2 million for the second quarter of 2023 versus $7.8 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 second quarter of 2023 of $(20.7) million, or a loss of $(0.26) per share on both a basic and diluted basis, compared to a net loss of $(18.8) million, or a net loss of $(0.24) per share on a basic basis and a net loss of $(0.25) per share on a diluted basis for the comparable period in 2022. The net loss in the second quarter of 2023 included a $1.1 million non-cash item attributable to a change in the fair value of the derivative liability associated with the Company's convertible notes, decreasing total other expenses as the price of the Company's common stock decreased during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $5.1 million in the second quarter of 2023 versus $4.8 million for the comparable quarter in 2022.

As of August 3, 2023, the Company had approximately 79.4 million shares outstanding.

2023 Financial Guidance

- The Company anticipates DEXTENZA net product revenue guidance for the full year 2023 to come in at the upper end of the current $55 and $60 million range provided by the Company. The current range represents 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.

- Existing cash and cash equivalents of $66.6 million as of June 30, 2023, plus the net cash received from the borrowing under the Barings Credit Facility after the repayment of the MidCap Credit Facility and reflecting the $20.0 million minimum cash covenant in the Barings Credit Agreement, is expected to fund planned operating expenses, debt service obligations and capital expenditure requirements into 2025. This estimate is based on the Company's current operating plan which includes estimates of anticipated cash inflows from DEXTENZA product sales, and cash outflows from operating expenses, including clinical trials. The Company's planned operating expenses exclude expenses necessary to complete the first of two planned pivotal trials for OTX-TKI for the treatment of wet AMD and expenses to initiate the second of our two planned pivotal clinical trials for OTX-TKI for the treatment of wet AMD or any other pivotal trials for our other product candidates, including OTX-TKI for the treatment of NPDR, which we do not intend to commence unless we obtain additional financing.

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-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, 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, including the timing and design of the Company's planned pivotal trials of OTX-TKI for the treatment of wet AMD; the Company's cash runway and sufficiency of the Company's cash resources; 2023 financial guidance, including estimated net product revenue; 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; availability of data from clinical trials and expectations for regulatory submissions and approvals; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; 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

Ocular Therapeutix
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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 15,029	$ 12,144	$ 28,243	$ 24,642
Collaboration revenue	157	122	318	811
Total revenue, net	15,186	12,266	28,561	25,453
Costs and operating expenses:				
Cost of product revenue	1,304	1,155	2,517	2,454
Research and development	15,094	13,100	29,842	26,200
Selling and marketing	11,153	10,140	21,989	19,203
General and administrative	8,205	7,787	17,332	15,344
Total costs and operating expenses	35,756	32,182	71,680	63,201
Loss from operations	(20,570)	(19,916)	(43,119)	(37,748)
Other income (expense):				
Interest income	748	73	1,312	89
Interest expense	(1,991)	(1,696)	(3,760)	(3,378)
Change in fair value of derivative liability	1,131	2,773	(5,432)	9,731
Other expense, net	—	—	(1)	(2)
Total other (expense) income, net	(112)	1,150	(7,881)	6,440
Net loss	$ (20,682)	$ (18,766)	$ (51,000)	$ (31,308)
Net loss per share, basic	$ (0.26)	$ (0.24)	$ (0.66)	$ (0.41)
Weighted average common shares outstanding, basic	78,047,705	76,764,296	77,718,823	76,755,028
Net loss per share, diluted	$ (0.26)	$ (0.25)	$ (0.66)	$ (0.47)
Weighted average common shares outstanding, diluted	78,047,705	82,533,528	77,718,823	82,524,260

Ocular Therapeutix, Inc.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 66,606	$ 102,300
Accounts receivable, net	27,309	21,325
Inventory	2,204	1,974
Prepaid expenses and other current assets	4,593	4,028
Total current assets	100,712	129,627
Property and equipment, net	12,830	9,856
Restricted cash	1,764	1,764
Operating lease assets	7,252	8,042
Total assets	$ 122,558	$ 149,289
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,572	$ 5,123
Accrued expenses and other current liabilities	24,598	24,097
Deferred revenue	391	576
Operating lease liabilities	1,713	1,599
Notes payable, net of discount, current	2,083	—
Total current liabilities	32,357	31,395
Other liabilities:		
Operating lease liabilities, net of current portion	7,689	8,678
Derivative liability	11,783	6,351
Deferred revenue, net of current portion	14,254	13,387
Notes payable, net of discount, net of current portion	23,303	25,257
Other non-current liabilities	104	93
Convertible Notes, net	29,981	28,749
Total liabilities	119,471	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 June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 79,233,804 and 77,201,819 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	8	8
Additional paid-in capital	670,921	652,213
Accumulated deficit	(667,842)	(616,842)
Total stockholders' equity	3,087	35,379
Total liabilities and stockholders' equity	$ 122,558	$ 149,289