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 6, 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 March 6, 2023, Ocular Therapeutix, Inc. announced its financial results for the quarter and year ended December 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 March 6, 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: March 6, 2023

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

Exhibit 99.1

Ocular Therapeutix™ Provides Fourth Quarter and Year-End 2022 Results and Corporate Update

Presented Positive 10-month Interim Data from the U.S.-based Phase 1 Clinical Trial of OTX-TKI (axitinib intravitreal implant) for the Treatment of Wet AMD at the Angiogenesis, Exudation, and Degeneration Annual 2023 Meeting

Initiated Phase 1 Clinical Trial of OTX-TKI (axitinib intravitreal implant) for the Treatment of Diabetic Retinopathy in December 2022

Top-Line Data from Phase 2 Clinical Trial of OTX-TIC (travoprost intracameral implant) for the Treatment of Patients with Primary Open-Angle Glaucoma or Ocular Hypertension Expected in Q4 2023

Total Net Revenue for Full Year 2022 was $51.5 million, Representing Growth of 18% Over the Prior Year

DEXTENZA® Net Product Revenue in the Fourth Quarter of 2022 was $13.9 million, Representing Growth of approximately 17% Over Previous Quarter and 14% Over Comparable Quarter of 2021

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

BEDFORD, Mass.–(BUSINESS WIRE)— March 6, 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 fourth quarter and year ended December 31, 2022, and provided updates on its ophthalmology pipeline.

“2022 was a productive year for Ocular and we are off to a great start in 2023,” said Antony Mattessich, President and CEO. “Most notably, we are really excited to see the potential value of our pipeline continue to emerge following the recent interim data we shared on OTX-TKI, our axitinib-containing hydrogel insert for the treatment of wet AMD, diabetic retinopathy and other VEGF mediated retinal diseases. We believe the results we shared in February at the Angiogenesis Annual Meeting demonstrated the potential for best-in-class durability in a $15B global market for wet AMD and diabetic retinopathy that is increasingly driven by durability. As we enter 2023, we expect our pipeline to achieve key milestones as we look to advance OTX-TKI into pivotal trials and also present much anticipated top-line data from our Phase 2 clinical trial of OTX-TIC for the treatment of glaucoma. On the commercial side, DEXTENZA has established itself as a material and important product and I am encouraged that we have begun to regain sales momentum with volumes up more than 20% in in-market sales over the first two months of 2023 versus 2022. Overall, I am pleased with our progress and believe the realization of anticipated milestones in 2023 will further our corporate mission of becoming a mid-tier strategic within ophthalmology.”

Business Updates

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

- The Company presented positive interim 10-month data from its U.S.-based Phase 1 trial of OTX-TKI for the treatment of wet AMD at the Angiogenesis, Exudation, and Degeneration 2023 Annual Meeting held virtually in February.
    - All OTX-TKI treated subjects who were rescue-free at the Month 7 interim analysis remained rescue-free, extending the 73% rescue-free rate up to Month 10. Overall, a 92% reduction in treatment burden was observed in OTX-TKI treated subjects for up to 10 months.
    - Subjects treated with a single OTX-TKI implant demonstrated stable and sustained BCVA (mean change from baseline of -0.3 letters) and CSFT (mean change from baseline of -1.3 µm) in the OTX-TKI arm at 10 months, which was comparable with the aflibercept arm (mean change from BCVA baseline of -0.8 letters; mean change from CSFT baseline of -4.5 µm).
    - Interim data showed a single OTX-TKI implant was generally well tolerated with no drug-related ocular or systemic serious adverse events (SAEs) observed.
    - The Company will follow subjects at least until their respective one-year anniversaries of initial dosing, in accordance with the clinical trial protocol.

- The Company is in active discussions with the FDA for potential clinical trial requirements. Subject to those discussions and obtaining the necessary financing, which could be provided through a strategic alliance, the Company aims to be prepared to initiate a pivotal trial in wet AMD in Q3 2023.

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

- The Company believes that the interim 10-month data from the U.S.-based Phase 1 clinical trial evaluating OTX-TKI for the treatment of wet AMD, as well as the product candidate's mechanism of action, support the use of OTX-TKI as a potential treatment of other VEGF-mediated retinal vascular diseases, including diabetic retinopathy.
- The Company initiated a Phase 1 clinical trial for the treatment of diabetic retinopathy in December 2022. This masked trial includes approximately 10 sites and is designed to include approximately 21 patients randomized 2:1 to either a 600 µg OTX-TKI single implant containing axitinib or sham control.
- Subject to the initial results of this trial, discussions with the FDA, and obtaining additional financing, the Company believes it will be positioned to initiate a pivotal trial for the treatment of diabetic retinopathy in Q1 2024.

OTX-TIC (travoprost intracameral implant) for the treatment of patients with 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. 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 plans to provide top-line data from the trial 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 continues to advance both dry eye programs and plans to launch a small study in the first half 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 fourth quarter of 2022 was $13.9 million, representing growth of approximately 17% over the previous quarter and approximately 14% over the fourth quarter of 2021. Overall, DEXTENZA net product revenue for the year was $50.5 million versus $42.0 million for 2021, representing growth of 20%.
- The Company is guiding 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. DEXTENZA market share is believed to be less than 5% of the overall potential market and growth in 2023 is anticipated to be driven by: continued separate reimbursement now available under the non-opioid pain management drug as a surgical supply provision in the ambulatory surgery center (ASC); a renewed focus on sales to ASCs; and ASCs operating at higher capacity as staffing issues continue to resolve from challenges caused by the COVID-19 pandemic, leading to continued modest annual growth in cataract procedure volume. We believe the momentum with ASCs will more than offset the impact of the loss of separate drug reimbursement in the hospital outpatient department setting in 2023.

Fourth Quarter and Year End December 31, 2022 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 $14.1 million for the fourth quarter of 2022 and represented 18% growth over the prior quarter and 15% growth over the comparable period in 2021.

Total net revenue for the full year 2022 was $51.5 million versus $43.5 million in 2021, an increase of 18%.

Research and development expenses for the fourth quarter of 2022 were $13.5 million versus $12.6 million for the comparable period in 2021 driven primarily by an increase in personnel offset by both a reduction in overall clinical trial expenses and a delay in timing of clinical trials. Overall R&D expenses for the full year increased $3.4 million to $53.5 million from $50.1 million in 2021, reflecting the trends identified above.

Selling and marketing expenses in the fourth quarter of 2022 were $10.5 million as compared to $9.1 million for the comparable quarter of 2021, reflecting primarily an increase in field force personnel. Overall, selling and marketing expenses for the full year increased to $39.9 million from $35.2 million in 2021, driven primarily by increased personnel costs and increased spending on consulting, trade shows and conferences.

General and administrative expenses were $8.3 million for the fourth quarter of 2022 versus $7.5 million in the comparable quarter of 2021, primarily due to an increase in personnel related costs, including stock-based compensation. Overall, G&A expenses for the full year increased $0.3 million to $32.2 million from $31.9 million in 2021, again reflecting the trends identified above.

The Company reported a net loss for the fourth quarter of 2022 of $(15.5) million, or a loss of $(0.20) per share on a basic basis and a loss of $(0.24) on a diluted basis, compared to a net loss of $(3.9) million, or net loss of $(0.05) per share on a basic basis and a loss of $(0.23) per share on a diluted basis for the comparable period in 2021. Net loss in the fourth quarter of 2022 included a $5.2 million non-cash item attributable to a decrease in the fair value of the derivative liability associated with the Company's convertible notes, as the price of its common stock decreased during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $4.7 million in the fourth quarter of 2022 versus $4.4 million for the comparable quarter in 2021. Overall, the Company reported a net loss of $(71.0) million or a loss of $(0.92) per share on a basic basis and a loss of $(0.97) on a diluted basis for the full year ended December 31, 2022 versus a net loss of $(6.6) million or a loss of $(0.09) per share on a basic basis and a loss of $(0.98) on a diluted basis in 2021.

As of March 1, 2023, the Company had 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 December 31, 2022, the Company had $102.3 million in cash and cash equivalents versus $121.0 million at September 30, 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.

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 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, 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, 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
Ocular Therapeutix
Donald Notman
Chief Financial Officer
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or

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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,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product revenue, net	$ 13,902	$ 12,308	$ 50,457	$ 43,522
Collaboration revenue	174	—	1,037	—
Total revenue, net	14,076	12,308	51,494	43,522
Costs and operating expenses:				
Cost of product revenue	1,013	1,107	4,540	4,406
Research and development	13,543	12,578	53,462	50,083
Selling and marketing	10,533	9,136	39,922	35,190
General and administrative	8,348	7,534	32,224	31,880
Total costs and operating expenses	33,437	30,355	130,148	121,559
Loss from operations	(19,361)	(18,047)	(78,654)	(78,037)
Other income (expense):				
Interest income	423	6	798	33
Interest expense	(1,847)	(1,681)	(7,022)	(6,761)
Change in fair value of derivative liability	5,243	15,872	13,841	78,121
Other income (expense), net	—	—	(1)	1
Total other income , net	3,819	14,197	7,616	71,484
Net loss	$ (15,542)	$ (3,850)	$ (71,038)	$ (6,553)
Net loss per share, basic	$ (0.20)	$ (0.05)	$ (0.92)	$ (0.09)
Weighted average common shares outstanding, basic	77,010,385	76,616,389	76,875,035	76,392,870
Net loss per share, diluted	$ (0.24)	$ (0.23)	$ (0.97)	$ (0.98)
Weighted average common shares outstanding, diluted	82,779,617	82,385,621	82,644,267	82,162,102

OCULAR THERAPEUTIX, INC.

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 102,300	$ 164,164
Accounts receivable, net	21,325	21,135
Inventory	1,974	1,250
Prepaid expenses and other current assets	4,028	4,751
Total current assets	129,627	191,300
Property and equipment, net	9,856	6,956
Restricted cash	1,764	1,764
Operating lease assets	8,042	4,867
Total assets	$ 149,289	$ 204,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,123	$ 4,592
Accrued expenses and other current liabilities	24,097	20,121
Deferred revenue	576	—
Operating lease liabilities	1,599	1,624
Total current liabilities	31,395	26,337
Other liabilities:		
Operating lease liabilities, net of current portion	8,678	5,924
Derivative liability	6,351	20,192
Deferred revenue, net of current portion	13,387	13,000
Notes payable, net of discount	25,257	25,000
Other Non-Current Liabilities	93	—
2026 convertible notes, net	28,749	26,435
Total liabilities	113,910	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 December 31, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 77,201,819 and 76,731,940 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	652,213	633,795
Accumulated deficit	(616,842)	(545,804)
Total stockholders' equity	35,379	87,999
Total liabilities and stockholders' equity	$ 149,289	$ 204,887