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): **January 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 January 6, 2023, Ocular Therapeutix, Inc. (the "Company") issued a press release (the "Release") to provide a business update. A copy of the Release is included as Exhibit 99.1 hereto and is incorporated by reference herein.

Although the Company is currently in the process of finalizing its financial results for the quarter and year ended December 31, 2022, the Company disclosed in the Release preliminary estimates as to net product revenue for the quarter and year ended December 31, 2022 and cash and cash equivalents as of December 31, 2022. The estimated net product revenue and cash and cash equivalents figures are based on preliminary and unaudited information and management's estimates as of the date of this Current Report on Form 8-K and are subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated net product revenue and cash and cash equivalents figures.

The information in this Current Report on Form 8-K 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 January 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: January 6, 2023

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

Exhibit 99.1

Ocular Therapeutix™ Provides 2022 Year End Corporate Update and Reviews Expected 2023 Milestones

Dextenza® Net Product Revenue in the Fourth Quarter of 2022 is Estimated to be $13.6 million, Growing Approximately 14% Over Previous Quarter and Approximately 11% Over Same Quarter of Prior Year

Dextenza Net Product Revenue for the Year Ending 2022 is Estimated to be $50.2 million, Representing Growth of Approximately 20% Over Prior Year

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 to be Presented at the Upcoming Angiogenesis Conference in February 2023

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

BEDFORD, Mass.–(BUSINESS WIRE)— January 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 provided a corporate update on the progress of its key programs.

“2022 marked a year in which Ocular made good progress against its corporate mission of becoming a mid-tier strategic within ophthalmology”, said Antony Mattessich, President and CEO. “DEXTENZA, despite challenging market conditions, has established itself as a material and important product and demonstrated renewed growth in the fourth quarter of 2022.”

Mr. Mattessich continued: “The highlight of our year at Ocular was further development within our pipeline. At AAO in September, we presented impressive interim 6- and 7-month data from our US-based Phase 1 clinical trial of OTX-TKI for the treatment of wet AMD. We believe the data further strengthen our ongoing development in wet AMD and supports proof of concept for OTX-TKI’s potential in the treatment of VEGF-mediated vascular retinal diseases, including diabetic retinopathy. Both wet AMD and diabetic retinopathy represent large markets where durability could significantly reduce the burden of anti-VEGF injections and improve real-world outcomes for patients. With that in mind, we initiated a Phase 1 clinical trial in diabetic retinopathy in December 2022 and anticipate presenting interim data from this trial in 2023. We also plan to report 9- and 10-month data from the U.S. Phase 1 trial of OTX-TKI in wet AMD at the Angiogenesis meeting in February 2023. Lastly, we plan to present much anticipated data from our Phase 2 clinical trial of OTX-TIC for the treatment of glaucoma in Q4 2023. Overall, executing efficiently and working within the constraints of existing resources, we believe that the Company can pull forward our core development programs to be Phase 3-ready.”

Business Updates

DEXTENZA (dexamethasone ophthalmic insert) 0.4mg is FDA 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 is estimated to be $13.6 million, which would represent growth of approximately 14% over the previous quarter and approximately 11% over the fourth quarter of 2021. DEXTENZA net product revenue for the year is estimated to be $50.2 million, which would represent growth of 20% over 2021.

- The Company believes DEXTENZA remains poised for continued growth in 2023 with continued drug payment in the ambulatory surgery center (ASC) setting through the non-opioid pain provision and with a focus on the growing ophthalmic surgery market, more than offsetting the loss of reimbursement in the hospital outpatient department (HOPD) setting.

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

- The Company presented positive interim 6- and 7-month data from its U.S.-based Phase 1 trial of OTX-TKI for the treatment of wet AMD at the American Academy of Ophthalmology 2022 Annual Meeting.
    - Interim data showed a single OTX-TKI implant was generally well tolerated with no drug-related ocular or systemic serious adverse events (SAEs).
    - 80% of subjects in the OTX-TKI arm were rescue-free up to 6 months and 73% of subjects in the OTX-TKI arm were rescue-free up to 7 months.
    - Subjects treated with a single OTX-TKI implant demonstrated stable and sustained best corrected visual acuity (BCVA) (mean change from baseline of -1.3 letters) and central subfield foveal thickness (CSFT) (mean change from baseline of +9.2 μm) at 7 months, which was comparable with the aflibercept arm dosed every 8 weeks (mean change from BVCA baseline of -1 letter; mean change from CSFT baseline of +0.4 μm).
- The Company intends to present 9-and 10-month interim data at the upcoming Angiogenesis, Exudation, and Degeneration 2023 Meeting at 8:10 am on Saturday, February 11th, 2023, and plans to follow subjects at least until their respective one-year anniversaries of initial dosing, in accordance with the clinical trial protocol.
- The Company plans to meet with the FDA in early 2023 to discuss potential future clinical trial requirements with the goal of being in position to initiate a Phase 2/3 clinical trial for the treatment of wet AMD as early as Q3 2023, subject to obtaining additional funding for the trial from external sources, including potentially a strategic alliance.

OTX-TKI (axitinib intravitreal implant) for the potential treatment of Diabetic Retinopathy (DR)

- The Company believes that the interim 7-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's mechanism of action, support proof of concept for the potential treatment of VEGF-mediated retinal vascular diseases, including diabetic retinopathy.
- DR represents a large, unmet need without an established standard-of-care treatment. Studies show treatment rates as low as 15% in patients with type 2 diabetes and DR is the leading cause of blindness in American working-age adults. Nearly 24,000 patients go blind from DR complications each year in the United States despite DR being a highly treatable disease with early diagnosis and treatment. Patients at risk for or suffering from DR may benefit from the extended durability of a treatment lasting 6 to 12 months. The Company believes that the lack of a standard of care for the treatment of DR may offer a straightforward regulatory path.

- The Company initiated a U.S.-based Phase 1 clinical trial for the treatment of DR in December 2022. This trial will include 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 results of this trial, discussions with the FDA and additional financing to fund the trial, the Company believes it could be well-positioned to initiate its first Phase 3 pivotal trial for the treatment of DR as early as 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 while enabling repeat dosing.

- Due to observed elevations in intraocular pressure in the OTX-TIC 5 µg arm of the trial, the Company has decided to terminate enrollment in the 5 µg arm of the trial and continue forward with the OTX-TIC 26 µg and Durysta® arms of the trial. The Company expects that the Phase 2 clinical trial will consist of approximately 86 patients: approximately 35 patients in the OTX-TIC 26 µg treatment arm, 35 patients in the Durysta arm and 16 patients that were previously enrolled in the OTX-TIC 5 µg treatment arm.

- 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 OTX-DED and OTX-CSI.

2022 Preliminary Results

- On a preliminary basis, total net product revenue for Q4 2022 and the full year 2022 are estimated to be approximately $13.6 million and approximately $50.2 million, respectively. Sequential quarterly growth from Q3 2022 to Q4 2022 is expected to be approximately 14%, signaling a return to quarterly growth from DEXTENZA, driven by sales for the treatment of post-surgical inflammation and pain. Growth in annual total net product revenue from 2021 to 2022 is estimated to be approximately 15%.

- On a preliminary basis, the Company had estimated cash and cash equivalents of $102.3 million as of December 31, 2022. Consistent with the strategy of bringing the Company's core development programs in wet AMD, diabetic retinopathy, glaucoma and dry eye to Phase 3-ready status, the Company believes that it has sufficient cash and cash equivalents to fund planned operating expenses, debt service obligations and capital expenditure requirements through the middle of 2024.

- The Company plans to post an updated corporate presentation that can be found in the 'Investors' section of its corporate website on Monday, January 9, 2023.

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®, ReSure® Sealant, or any of the Company's 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-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD and diabetic retinopathy, 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 potential utility of any of the Company's product candidates; the size of potential markets for the Company's product candidates; the potential benefits and future operations of Company collaborations, including any potential future costs or payments thereunder; estimated 2022 financial results, including estimated net product revenue and cash and cash equivalents; 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 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 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, uncertainties as to the Company's preliminary financial results for Q4 2022 and 2022, which are estimates based on preliminary and unaudited information, subject to the completion of financial closing procedures and have not been audited or reviewed by the Company's independent public accounting firm, 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.

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