
**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): **February 28, 2022**

OCULAR THERAPEUTIX, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36554
(Commission
File Number)

20-5560161
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 February 28, 2022, Ocular Therapeutix, Inc. announced its financial results for the quarter and year ended December 31, 2021. 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 February 28, 2022](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OCULAR THERAPEUTIX, INC.

Date: February 28, 2022

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

Ocular Therapeutix™ Reports Fourth Quarter and Year-End 2021 Financial Results and Business Update

DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg Recorded Net Quarterly Sales of \$12.2 Million, Representing Year-Over-Year Growth of 77%

Creating New Business Unit Focused on Optimizing the Commercial Opportunity for DEXTENZA in the Office Setting

Completed Enrollment in U.S.-based Clinical Trial for OTX-TKI for the Treatment of Wet AMD; Data Anticipated in the Second Half of 2022

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

BEDFORD, Mass.--(BUSINESS WIRE)— February 28, 2022 -- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today reported financial results for the quarter and year ended December 31, 2021, and provided updates on its ophthalmology pipeline.

“Ocular has had another strong quarter and a productive year,” said Antony Mattessich, President and Chief Executive Officer. “Our commercialization of DEXTENZA® continues to ramp. We successfully expanded the DEXTENZA label and achieved durable reimbursement that will sustain DEXTENZA’s growth well into the future. The creation of a specialized business unit focusing solely on DEXTENZA in the office setting will allow us to build the DEXTENZA franchise beyond the surgical setting and also establish the necessary commercial infrastructure to support our innovative product pipeline. Our pipeline has progressed well. Recent data from our Australia-based OTX-TKI Phase 1 trial continues to support a product profile that we believe could become standard of care in the treatment of wet AMD. We plan to provide data from our U.S.-based Phase 1 clinical trial for OTX-TKI, which recently completed enrollment, later in the year. In the treatment of glaucoma, we are excited to have initiated our Phase 2 trial for OTX-TIC and we are actively screening subjects. In the treatment of dry eye disease, we continue to analyze the full data set from our Phase 2 studies in OTX-CSI and OTX-DED, and look forward to presenting the clinical-regulatory and manufacturing strategies for these programs. Overall, we made great progress and look forward to a busy 2022 that will further advance our strong position within ophthalmology.”

Recent Business Updates

The U.S. Commercial Uptake of DEXTENZA. Net product revenue of DEXTENZA® for the quarter was \$12.2 million, a 77% increase over the fourth quarter of 2020 despite lower than anticipated elective surgeries due to the surge of the Omicron variant of COVID-19. In the fourth quarter of 2021, in-market purchases were in excess of 29,000 billable units, representing sequential quarterly growth of approximately 17%. While the reduced level of elective surgeries continued into January, the Company is seeing encouraging signs that levels are rebounding in February.

Initiation of a New Business Unit Focused on Optimizing the Commercial Opportunity in the Office Setting. In October 2021, the Company received supplemental FDA approval expanding DEXTENZA’s label to include the treatment of ocular itching associated with allergic conjunctivitis. To optimize that opportunity, the Company is establishing a separate commercial business unit consisting of Key Account Managers (KAMs) and Field Reimbursement Managers (FRMs) focused on the office setting. This group could also serve to support the Company’s broader pipeline of product candidates, if approved, and their potential future use in the office setting.

Presented Updated Interim Data on OTX-TKI and OTX-TIC at recent medical meetings.

- At the Angiogenesis, Exudation, and Degeneration 2022 Meeting held February 11-12, 2022, the Company presented interim data from the ongoing Australia-based Phase 1 trial of OTX-TKI for the treatment of wet AMD. In subjects with subretinal and/or intraretinal fluid due to wet AMD, OTX-TKI was observed to be generally well tolerated with a favorable safety profile to date and demonstrated preliminary evidence of biological activity as observed by a clinically meaningful decrease in intraretinal and/or subretinal fluid in some subjects. Extended duration of activity of six months or more was observed in over 60% of subjects across all cohorts and over 80% of subjects in cohort 3a (600µg) which could represent a compelling drug product profile.
- At Glaucoma 360 held February 12, 2022, the Company presented Phase 1 data for OTX-TIC highlighting the product candidate's ability to clinically-meaningfully decrease intraocular pressure for six months or longer with a single implant in many subjects while preserving corneal health. The Company believes these results are comparable to the decrease in intraocular pressure seen with topical travoprost, the current stand of care, and represents OTX-TIC's potential for a unique and differentiated drug product profile. OTX-TIC was observed to be generally well tolerated with a favorable safety profile to date with no clinically meaningful changes in corneal health from baseline as measured by endothelial cell counts, pachymetry assessments and slit lamp examinations.
- Both presentations can be found under the "Events and Presentations" section of the Ocular Therapeutix website.

Key Pipeline Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD and other retinal diseases.***
 - o The U.S.-based Phase 1 clinical trial is now fully enrolled and the Company expects to report interim, six-month data in the second half of the year.
 - o The Company will continue to follow subjects in the ongoing Australia-based Phase 1 clinical trial.
 - ***OTX-TIC (travoprost intracameral implant) for the treatment of patients with primary open-angle glaucoma or ocular hypertension.***
 - o The Company has initiated a Phase 2 clinical trial in the United States and is actively screening subjects.
 - o The U.S.-based Phase 2 clinical trial is a prospective, multi-center, randomized, controlled trial evaluating the safety, tolerability, and efficacy of OTX-TIC for the treatment of patients with primary open-angle glaucoma or ocular hypertension. The trial will enroll approximately 105 subjects in three different arms (~35 subjects per arm; randomized 1:1:1) in which the subjects will receive a single OTX-TIC implant, containing a 5µg or 26µg dose of travoprost, compared with an injection of Allergan's DURYSTA™. The trial will observe the changes in diurnal intraocular pressure (IOP) from baseline (8AM, 10AM, 4PM) at 2, 6, and 12 weeks, and follow duration of IOP response over time.
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- o Under the terms of the Company's licensing agreement with AffaMed, the dosing of the first subject will trigger a \$2.0 million payment from AffaMed to support costs associated with this clinical trial.
- ***OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.***
 - o The Company reported top-line data in late October 2021 from the U.S.-based Phase 2, randomized, double-masked, multi-center clinical trial to evaluate the safety, efficacy, durability, and tolerability of two different formulations of OTX-CSI versus hydrogel vehicle insert.
 - o The Phase 2 study showed that OTX-CSI treated subjects had a clinically meaningful improvement from baseline for both signs and symptoms of dry eye disease for both formulations. This trial, however, did not show separation between the OTX-CSI treated subjects (both formulations) and the vehicle-treated subjects (both formulations) on symptoms or the primary endpoint of increased tear production at 12 weeks as measured by the Schirmer's test.
 - o The Company is currently developing an appropriate clinical-regulatory and manufacturing plan. This plan is expected to include additional formulation work for the OTX-CSI insert to allow improved retention and the development of an appropriate vehicle comparator.
- ***OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.***
 - o In December 2021, the Company announced positive topline results from its Phase 2 clinical trial of OTX-DED for the short-term treatment of dry eye disease. The Phase 2 clinical trial was a U.S.-based, randomized, double-masked, vehicle-controlled, multi-center trial evaluating two different formulations of OTX-DED (0.2 mg and 0.3 mg) in 166 subjects with dry eye.
 - o OTX-DED was observed to be generally safe and well tolerated in this study and the clinical trial achieved its pre-specified primary endpoint, demonstrating a statistically significant change of bulbar conjunctival hyperemia from baseline to day 15 compared to vehicle hydrogel using a central reading photographic assessment in the modified ITT population at both doses (p=0.004 in the 2 mg group and p=0.028 in the 0.3 mg group).
 - o The Company is currently developing an appropriate clinical-regulatory and manufacturing plan. This plan is expected to include some additional formulation work for the OTX-DED insert and the development of an appropriate vehicle comparator.

Fourth Quarter Ended December 31, 2021 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was \$12.3 million for the fourth quarter and represented a 66% increase over the same period in 2020. Net product revenue of DEXTENZA in the fourth quarter was \$12.2 million versus \$6.9 million in the comparable quarter of 2020, reflecting an approximate 77% increase. Total net product revenue for the fourth quarter in 2021 also includes net product revenue of \$58 thousand from ReSure[®] Sealant. Overall, net product revenue for the year was \$43.5 million versus \$17.4 million for 2020, reflecting a strong uptake in DEXTENZA sales.

Research and development expenses for the fourth quarter were \$12.6 million versus \$7.6 million for the comparable period in 2020 driven primarily by an increase in unallocated expenses, predominantly unallocated personnel costs and increased clinical trial costs associated with: the initiation of the US-based Phase 1 trial of OTX-TKI and the initiation of the US-based Phase 2 trial for OTX-TIC; the Phase 2 clinical trials for OTX-CSI and OTX-DED; the ongoing Phase 1 clinical trial of OTX-TKI in Australia; and the ongoing clinical trial for DEXTENZA for post-surgical inflammation and pain in pediatric subjects. Overall R&D expenses for the full year increased \$21.4 million to \$50.1 million from \$28.7 million in 2020, reflecting the trends identified above.

Selling and marketing expenses in the quarter were \$9.1 million as compared to \$6.8 million for the same quarter in 2020, reflecting increased personnel costs associated primarily with an expansion of the field force. Overall, selling and marketing expenses for the full year increased to \$35.2 million from \$26.6 million in 2020, driven primarily by increased personnel costs and increased spending on consulting, trade shows and conferences.

General and administrative expenses were \$7.5 million for the fourth quarter versus \$6.6 million in the comparable quarter of 2020. The increase in expenses stemmed primarily from increased personnel expenses and professional fees. Overall, G&A expenses for the full year increased \$9.0 million to \$31.9 million from \$22.9 million in 2020, again reflecting primarily increased personnel and professional fees.

The Company reported a net loss of \$(3.9) million, or a loss of \$(0.05) per share on a basic basis and a loss of \$(0.23) per share on a diluted basis for the three months ended December 31, 2021. This compares to a net loss of \$(85.6) million, or a loss of \$(1.21) per share on a basic and diluted basis for the same period in 2020. Net loss in the fourth quarter of 2021 included a \$15.9 million non-cash gain in the fair value of the derivative liability associated with the Company's convertible notes, driven by a decrease in the price of its common stock during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were \$4.4 million in the fourth quarter versus \$2.8 million for the same quarter in 2020. Overall, the Company reported 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 for the full year ended December 31, 2021 versus a net loss of \$(155.6) million or a loss of \$(2.56) per share on both a basic and diluted basis in 2020.

As of February 24, 2022, the Company had 76.8 million shares outstanding.

As of December 31, 2021, the Company had \$164.2 million in cash and cash equivalents versus \$179.3 million at September 30, 2021. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and anticipated cash outflows from operating expenses, the Company believes that existing cash and cash equivalents, as of December 31, 2021, will enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements through 2023. This cash guidance is subject to a number of assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues, expenses and reimbursement associated with DEXTENZA, and the pace of research and clinical development programs, among other aspects of the business.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 4:30 pm Eastern Time to review the Company's financial results and provide a general business update. The live webcast can be accessed by visiting the Investors section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (844) 464-3934 (U.S.) or (765) 507-2620 (International) to listen to the live conference call. The conference ID number for the live call will be 1909039. An archive of the webcast will be available until April 30, 2022 on the Company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's first commercial drug product, DEXTENZA[®], is an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix's earlier stage development assets includes OTX-TKI (axitinib intravitreal implant), currently in Phase 1 clinical trials for the treatment of wet AMD and other retinal diseases. OTX-TIC (travoprost intracameral implant) recently began a Phase 2 clinical trial to evaluate the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix has also completed Phase 2 clinical trials for OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease. Ocular Therapeutix's first product, ReSure[®] Sealant, is an FDA-approved device to prevent wound leaks in corneal incisions following cataract surgery.

About DEXTENZA

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

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

Forward Looking Statements

Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA[®], ReSure[®] Sealant, or any of the Company's product candidates; the commercial launch of, and the effectiveness of and amounts applicable to reimbursement codes for, DEXTENZA; the conduct of post-approval studies of and compliance with related labeling requirements for DEXTENZA and ReSure Sealant; the Company's sales and marketing strategy; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, and OTX-TKI for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the size of potential markets for our product candidates; the potential utility of any of the Company's product candidates; the potential benefits and future operations of Company collaborations, including any potential future costs or payments thereunder; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA and ReSure Sealant; potential market sizes for indications targeted by the Company's product candidates, if approved; the expected impact of the COVID-19 pandemic on the Company and its operations; the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to successfully develop and commercialize products for the ophthalmology office setting, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA, the initiation, timing, conduct and outcomes of clinical trials, whether clinical trial data such as the data reported in this release will be indicative of the results of subsequent clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's ability to enter into and perform its obligations under collaborations and the performance of its collaborators under such collaborations, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the Company's ability to meet supply demands, the Company's ability to generate its projected net product revenue and in-market sales on the timeline expected, if at all, the sufficiency of cash resources, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the severity and duration of the COVID-19 pandemic including its effect on the Company's revenues and relevant regulatory authorities' operations, any additional financing needs and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

Ocular Therapeutix, Inc.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	\$ 12,308	\$ 7,349	\$ 43,522	\$ 17,403
Total revenue, net	12,308	7,349	43,522	17,403
Costs and operating expenses:				
Cost of product revenue	1,107	680	4,406	2,083
Research and development	12,578	7,624	50,083	28,294
Selling and marketing	9,136	6,811	35,190	26,614
General and administrative	7,534	6,578	31,880	22,859
Total costs and operating expenses	30,355	21,693	121,559	80,250
Loss from operations	(18,047)	(14,344)	(78,037)	(85,802)
Other income (expense):				
Interest income	6	6	33	168
Interest expense	(1,681)	(1,725)	(6,761)	(6,768)
Change in fair value of derivative liability	15,872	(69,549)	78,121	(86,189)
Other income (expense), net	—	—	1	—
Total other income (expense), net	14,197	(71,268)	(71,484)	(92,789)
Net loss and comprehensive loss	\$ (3,850)	\$ (85,612)	\$ (6,553)	\$ (155,636)
Net loss per share, basic	\$ (0.05)	\$ (1.21)	\$ (0.09)	\$ (2.56)
Weighted average common shares outstanding, basic	76,616,389	70,614,333	76,392,870	60,752,225
Net loss per share, diluted	\$ (0.23)	\$ (1.21)	\$ (0.98)	\$ (2.56)
Weighted average common shares outstanding, diluted	82,385,621	70,614,333	82,162,102	60,752,225

Ocular Therapeutix, Inc.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 164,164	\$ 228,057
Accounts receivable, net	21,135	12,252
Inventory	1,250	1,201
Prepaid expenses and other current assets	4,751	4,650
Total current assets	191,300	246,160
Property and equipment, net	6,956	8,095
Restricted cash	1,764	1,764
Operating lease assets	4,867	5,844
Total assets	<u>\$ 204,887</u>	<u>\$ 261,863</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,592	\$ 2,709
Accrued expenses and other current liabilities	20,121	14,307
Operating lease liabilities	1,624	1,358
Notes payable, net of discount, current	—	8,290
Total current liabilities	26,337	26,664
Other liabilities:		
Operating lease liabilities, net of current portion	5,924	7,548
Derivative liability	20,192	98,313
Deferred revenue	13,000	12,000
Notes payable, net of discount	25,000	16,936
2026 convertible notes, net	26,435	24,307
Total liabilities	116,888	185,768
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, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.0001 par value; 200,000,000 and 1000,000,000 shares authorized and 76,731,940 and 75,996,732 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	8	8
Additional paid-in capital	633,795	615,338
Accumulated deficit	(545,804)	(539,251)
Total stockholders' equity	87,999	76,095
Total liabilities and stockholders' equity	<u>\$ 204,887</u>	<u>\$ 261,863</u>

Investors

Ocular Therapeutix
Donald Notman
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or

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Media

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