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): **November 8, 2021**

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 November 8, 2021, Ocular Therapeutix, Inc. announced its financial results for the quarter ended September 30, 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 November 8, 2021
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: November 8, 2021

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

Exhibit 99.1

Ocular Therapeutix™ Reports Third Quarter 2021 Financial Results and Business Update

DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg Recorded Net Quarterly Sales of $11.9 Million, Representing Year-Over-Year Growth of 120%

FDA Approved Supplemental New Drug Application (sNDA) for DEXTENZA for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis

DEXTENZA Will Be Paid Through the End of 2022 and is Eligible for Separate Payment in the Ambulatory Surgery Center Beyond 2022

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

BEDFORD, Mass.--(BUSINESS WIRE)— November 8, 2021 -- 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 third quarter of 2021, and provided updates on its ophthalmology pipeline.

“The previous four months have been an exceptionally busy time at Ocular,” said Antony Mattessich, President and Chief Executive Officer. “We had a couple of positive outcomes that we believe will set the course for the future of DEXTENZA®. The first was the approval of the sNDA for itching associated with allergic conjunctivitis that opens a large, new and discrete opportunity for DEXTENZA in the office setting. The second was Medicare’s final rule that determined that DEXTENZA will be paid separately in the hospital outpatient and ASC settings in 2022 and is eligible under the current criteria for separate payment in the ASC as a non-opioid pain management drug beyond 2022, positioning our vibrant business in the surgical setting to grow into the foreseeable future. We also continued to advance our pipeline. While we were disappointed with the outcome of our Phase 2 dry eye clinical trial with OTX-CSI, we expect to announce the Phase 2 clinical trial topline results for OTX-DED, our clinical trial in episodic dry eye disease in the first quarter of 2022. Further, our U.S.-based clinical trial of OTX-TKI in wet-AMD is enrolling well, and we expect to initiate a Phase 2 clinical trial for OTX-TIC in glaucoma by the end of the year. Overall, we are pleased with our continued progress as we enter a period of significant data and news flow that will shape our leadership position within ophthalmology.”

Recent Business Updates

FDA Approved Supplemental New Drug Application (sNDA) for DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis. The approval represents the second label expansion for DEXTENZA and makes it the first FDA-approved, physician-administered intracanalicular insert capable of delivering a preservative-free drug for the treatment of ocular itching associated with allergic conjunctivitis with a single administration for up to 30 days. Allergic conjunctivitis represents the Company’s first indication that will primarily be prescribed by physicians within the office setting and begins to lay the commercial foundation for additional potential pipeline product candidates to be used to treat patients in that setting.

Received Final Rules for the Outpatient Prospective Payment System (OPPS) and Medicare Physician Fee Schedule (MPFS) from the Centers for Medicare and Medicaid (CMS).

- The OPPS final rule confirms that DEXTENZA will continue to be separately paid by Medicare in the ambulatory surgical center (ASC) and hospital outpatient department (HOPD) settings for 2022. CMS further indicated that DEXTENZA is eligible to receive separate payment in the ASC setting because it meets the criteria set forth in the non-opioid as a surgical supply provision, which is favorable for 2023 and beyond.

- The MPFS final rule establishes payment for Category I Current Procedural Terminology (CPT) Code 68841, which replaces Category III CPT Code 0356T, effective January 1, 2022. The physician payment for the insertion of DEXTENZA in the physician office is $37.29 and in the ASC or the HOPD is $31.58. The Company believes achieving Category I status for the new CPT Code represents an important milestone because, although the procedure payments are reduced in some locations, Category I codes standardize payment and are more widely accepted by the payer community, resulting in broader coverage.

The U.S. Commercial Uptake of DEXTENZA. Net product revenue of DEXTENZA® for the quarter was $11.9 million, a 120% increase over the third quarter of 2020 and a 7% sequential improvement over the second quarter of 2021. The Company believes that DEXTENZA recorded a solid third quarter performance in light of lower than anticipated elective surgery volumes due to COVID-19. While it is early in the fourth quarter, monthly growth in ASC volumes appears to be coming back on track as the Company estimates sales of in-market sales of over 9,600 billable units in October, its second-largest month ever. In-market sales of billable units were 6,924, 9,321 and 8,737 for the months of July, August and September respectively.

Announced Results from Phase 2 Clinical Trial Evaluating OTX-CSI (cyclosporine intracanalicular insert) for the Treatment of Dry Eye Disease. The Phase 2 clinical trial of OTX-CSI was designed to evaluate the safety, tolerability, durability, and efficacy of two different formulations of OTX-CSI by measuring signs and symptoms of dry eye disease in 140 subjects treated in both eyes over approximately 16 weeks (a 12-week study period, with an additional 4-week safety follow-up). The Phase 2 study did not show separation between the OTX-CSI treated subjects (both formulations) and the vehicle-treated subjects (both formulations) for the primary endpoint of increased tear production at 12 weeks as measured by the Schirmer's Test. All formulations of OTX-CSI were observed to have a generally favorable safety profile and were well tolerated. The Company is continuing to analyze the data, including retention data showing lower than anticipated insert retention rates in the active drug groups.

Expanded Board of Directors and Leadership Team. In September 2021, the Company added Merilee Raines to its board of directors and Karen-Leigh Edwards as Senior Vice President of Technical Operations, and in October 2021, promoted Chris White to the new role of Chief Business Officer. The organizational moves add expertise in finance, experience building high-performance global enterprise-wide manufacturing operations, and a focus on building Ocular's position as a leading ophthalmology company.

Presenting Data on Commercial Products and Pipeline at Major Medical Meetings: Six Abstracts Accepted for Presentation at the 2021 American Academy of Ophthalmology Annual Meeting and Four Presentations at American Academy of Optometry Annual Meeting 2021.

- Six poster presentations will be made at the American Academy of Ophthalmology (AAO) 2021 Annual Meeting being held November 12 -15, 2021. Presentations will highlight the Company's broad pipeline, including new interim data from the Phase 1 Australia-based clinical trial assessing the safety and biological activity of OTX-TKI.

- Four Company-sponsored and investigator-initiated presentations were made at the American Academy of Optometry (AAOPT) Annual Meeting 2021 November 3 - 6, 2021. Presentations highlighted the use of DEXTENZA® for the treatment of ocular inflammation and pain as well as for our recently approved label, for the treatment of ocular itching associated with allergic conjunctivitis.

Key Program Updates

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

    - The Company continues enrolling subjects in the U.S.-based Phase 1 clinical trial evaluating a single OTX-TKI implant containing a 600µg dose of axitinib plus anti-VEGF injection compared to aflibercept administered every 8 weeks in subjects previously treated with anti-VEGF therapy.

    - The Company continues to enroll patients in the Australia-based Phase 1 clinical trial and plans to present interim data from the trial at the upcoming AAO annual meeting later this month.

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

    - Following supportive data from a U.S.-based Phase 1 clinical trial, the Company is targeting the initiation of a randomized, double-masked, active-controlled Phase 2 clinical trial by year end 2021 in the United States.

    - The clinical trial will enroll approximately 105 subjects to evaluate two different formulations of OTX-TIC versus a control arm receiving Durysta™.

- ***OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.***

    - The Company reported top-line data in late October 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.

    - While the Phase 2 clinical trial did not show separation between the OTX-CSI treated subjects (both formulations) and the vehicle-treated subjects (both formulations) for the primary endpoint of increased tear production at 12 weeks as measured by the Schirmer's, the Company is analyzing the data to inform the development of this program.

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

    - The Company completed enrollment of a U.S.-based, prospective, randomized, double-masked, vehicle-controlled, multi-center Phase 2 clinical trial in approximately 150 subjects with dry eye disease.

    - Topline data from the Phase 2 clinical trial is expected in the first quarter of 2022.

Third Quarter Ended September 30, 2021 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $12.2 million and represented a 107% increase over the same period in 2020 and a 4% increase over the second quarter in 2021. Net product revenue of DEXTENZA in the third quarter was $11.9 million versus $5.4 million in the comparable quarter of 2020, reflecting an approximate 120% increase. Total net product revenue for the third quarter in 2021 also includes net product revenue of $0.3 million from ReSure® Sealant.

Research and development expenses for the third quarter were $12.7 million versus $7.0 million for the comparable period in 2020 driven primarily by increased headcount, increased unallocated expenses and increased clinical trial costs associated with the initiation of the US-based Phase 1 trial of OTX-TKI as well as the ongoing 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.

Selling and marketing expenses in the quarter were $9.6 million as compared to $6.5 million for the same quarter in 2020, reflecting increased personnel costs associated with an expansion of the field force and an increase in facility-related and other costs.

General and administrative expenses were $8.1 million for the third quarter versus $6.0 million in the comparable quarter of 2020. The increase in expenses stemmed primarily from increased personnel expenses and professional fees.

The Company reported net income of $2.7 million, or income of $0.03 per share on a basic basis and a loss of $(0.23) per share on a diluted basis for the three months ended September 30, 2021. This compares to a net loss of $11.9 million, or a loss of $(0.19) per share on a basic and a loss of $(0.21) per share on a diluted basis for the same period in 2020. Net income in the 2021 period was due primarily to a $23.8 million non-cash, net change in the fair value of the derivative liability associated with our convertible note, driven by a decrease in the price of our common stock during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $4.4 million in the third quarter versus $2.6 million for the same quarter in 2020.

As of November 3, 2021, the Company had 76.6 million shares outstanding.

As of September 30, 2021, the Company had $179.3 million in cash and cash equivalents versus $191.9 million at June 30, 2021. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and ReSure product sales and anticipated cash outflows from operating expenses, the Company believes that existing cash and cash equivalents, as of September 30, 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 3683601. An archive of the webcast will be available until February 8, 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 currently in Phase 1 clinical trials include OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases and OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix is currently evaluating 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 in Phase 2 clinical trials. 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.

About ReSure

ReSure Sealant is indicated for intraoperative management of clear corneal incisions (up to 3.5mm) with a demonstrated wound leak for which a temporary dry surface can be achieved, in order to prevent postoperative fluid egress from such incisions following cataract surgery with intraocular lens (IOL) placement in adults.

Please see Instructions for Use.

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 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, 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue, net	$ 12,153	$ 5,876	$ 31,214	$ 10,054
Total revenue, net	12,153	5,876	31,214	10,054
Costs and operating expenses:				
Cost of product revenue	1,310	450	3,298	1,403
Research and development	12,719	6,951	37,505	21,070
Selling and marketing	9,576	6,520	26,054	19,803
General and administrative	8,077	5,961	24,345	16,282
Total costs and operating expenses	31,682	19,882	91,202	58,558
Loss from operations	(19,529)	(14,006)	(59,988)	(48,504)
Other income (expense):				
Interest income	7	6	27	162
Interest expense	(1,658)	(1,715)	(4,991)	(5,042)
Change in fair value of derivative liability	23,837	3,771	62,249	(16,640)
Total other income (expense), net	22,186	2,062	57,285	(21,520)
Net income (loss) and comprehensive income (loss)	$ 2,657	$ (11,944)	$ (2,703)	$ (70,024)
Net income (loss) per share, basic	$ 0.03	$ (0.19)	$ (0.04)	$ (1.22)
Weighted average common shares outstanding, basic	76,552,060	62,992,558	76,317,563	57,440,885
Net loss per share, diluted	$ (0.23)	$ (0.21)	$ (0.75)	$ (1.22)
Weighted average common shares outstanding, diluted	85,446,886	68,761,790	82,086,795	57,440,885

Ocular Therapeutix, Inc.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 179,281	$ 228,057
Accounts receivable, net	19,552	12,252
Inventory	1,222	1,201
Prepaid expenses and other current assets	3,877	4,650
Total current assets	203,932	246,160
Property and equipment, net	6,914	8,095
Restricted cash	1,764	1,764
Operating lease assets	5,129	5,844
Total assets	$ 217,739	$ 261,863
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,246	$ 2,709
Accrued expenses and other current liabilities	19,358	14,307
Operating lease liabilities	1,554	1,358
Notes payable, net of discount, current	—	8,290
Total current liabilities	25,158	26,664
Other liabilities:		
Operating lease liabilities, net of current portion	6,355	7,548
Derivative liability	36,064	98,313
Deferred revenue	12,000	12,000
Notes payable, net of discount	24,936	16,936
2026 convertible notes, net	25,886	24,307
Total liabilities	130,399	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 September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 76,606,968 and 75,996,732 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	8	8
Additional paid-in capital	629,286	615,338
Accumulated deficit	(541,954)	(539,251)
Total stockholders' equity	87,340	76,095
Total liabilities and stockholders' equity	$ 217,739	$ 261,863

Investors
Ocular Therapeutix
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or

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