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 14, 2024**

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.)

15 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 14, 2024, Ocular Therapeutix, Inc. announced its financial results for the quarter ended September 30, 2024. 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 14, 2024
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 14, 2024

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

Exhibit 99.1

Ocular Therapeutix™ Reports Third Quarter 2024 Results and Business Highlights

SOL-1 expected to be fully randomized by YE 2024 with topline data expected in Q4 2025

Active clinical trial sites now enrolling patients directly into SOL-R

Cash balance of $427.2M as of September 30, 2024, expected to fund operations into 2028

Ocular to host a Q3 2024 conference call and webcast today, November 14th, at 8:00 AM ET

BEDFORD, MA, November 14, 2024 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular", the "Company"), a biopharmaceutical company committed to improving vision in the real world through the development and commercialization of innovative therapies for retinal diseases and other eye conditions, today reported financial results for the third quarter ended September 30, 2024 and provided recent business highlights, including an update on the Phase 3 registrational program for AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI) in development for wet age-related macular degeneration (wet AMD).

"2024 has been a year of significant change and tremendous execution at Ocular, but this is all in anticipation of what's ahead. We are making outstanding progress on enrollment in the two complementary studies in our registrational program for AXPAXLI in wet AMD, SOL-1 and SOL-R. I'm thrilled to share that SOL-1 has reached a key enrollment milestone, as we have now 'flipped the switch' to allow direct enrollment of subjects into SOL-R. We expect to complete SOL-1 randomization by year-end, with topline data to follow in the fourth quarter of 2025. As SOL-1 quickly approaches complete randomization, eligible subjects who are not ultimately randomized can seamlessly enroll in SOL-R, creating a streamlined and efficient pathway that capitalizes on recruitment momentum at our clinical sites," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix.

Dr. Dugel continued, "SOL-1 and SOL-R were strategically designed with the goals of de-risking clinical outcomes, aligning with regulatory standards, enhancing each other's enrollment, and providing a broad evaluation of AXPAXLI's durability, repeatability, and flexibility. Thanks to the team's strong execution, attention to patient care, and long-standing relationships in the retina community, we have enrolled SOL-1 faster than we expected and continue to build enthusiasm for SOL-R. Supported by our dedicated team and strong financial resources, Ocular is on solid footing as we head towards what we expect will be an important milestone year in 2025."

Recent Achievements and Upcoming Milestones:

- **Accelerated timelines for SOL-1 AXPAXLI registrational trial (Phase 3, wet AMD).** The exceptional pace of recruitment in the SOL-1 superiority trial is expected to result in full randomization by the end of 2024. This is meaningfully ahead of prior guidance. Topline data from the SOL-1 trial are now expected during the fourth quarter of 2025. The study is being conducted under a Special Protocol Agreement (SPA) with the U.S. Food and Drug Administration (FDA).

- **Direct enrollment open for SOL-R AXPAXLI repeat dosing registrational trial (Phase 3, wet AMD).** Initial subjects enrolling in SOL-R were previously required to be loading or randomization failures in SOL-1. As SOL-1 nears the completion of randomization, physicians can now directly enroll eligible subjects into SOL-R. This trial was designed to complement SOL-1 with repeat and flexible dosing while providing commercially meaningful data. In a written Type C response, the FDA confirmed in August of this year that the SOL-R trial should be appropriate for use as Ocular's second adequate and well-controlled study to support a potential New Drug Application (NDA) and product label for wet AMD.

Third Quarter Ended September 30, 2024, Financial Results:

Total cash and cash equivalents were $427.2 million as of September 30, 2024. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA®, the Company believes that its current cash balance is sufficient to support its planned expenses, obligations, and capital expenditure requirements into 2028.

Total net revenue was $15.4 million for the third quarter of 2024, a 2.3% increase over total net revenue of $15.1 million in the comparable period in 2023. This increase was driven by increased gross revenues from DEXTENZA sales offset by higher gross-to-net provisions in the 2024 period compared to the prior comparable period. The Company expects full-year 2024 total net revenues for DEXTENZA to be between $62.0 million and $67.0 million, compared to $57.9 million reported for 2023. Total net revenue includes both gross DEXTENZA product revenue, net of discounts, rebates, and returns, which the Company refers to as net product revenue, and collaboration revenue.

Research and development expenses for the third quarter of 2024 were $37.1 million versus $15.0 million for the comparable period in 2023, reflecting an increase in overall clinical expenses associated with product development programs, specifically the SOL-1 and SOL-R Phase 3 clinical trials, as well as additional personnel and professional services to support these clinical trials.

Selling and marketing expenses were $10.6 million in the third quarter of 2024, as compared to $9.3 million for the comparable quarter of 2023, primarily reflecting an increase in professional fees and personnel costs, including stock-based compensation.

General and administrative expenses were $12.2 million for the third quarter of 2024 versus $8.6 million for the comparable quarter of 2023, primarily due to an increase in professional fees and personnel-related costs, including stock-based compensation.

Net loss for the third quarter of 2024 was $(36.5) million, or a net loss of $(0.22) per share on both a basic and diluted basis, compared to a net loss of $(0.5) million, or a net loss of $(0.01) per share on a basic basis and $(0.25) per share on a diluted basis, for the comparable period in 2023. The net loss in the third quarter of 2024 included a $7.6 million non-cash gain attributable to the change in the fair value of the derivative liability associated with the Barings Credit Facility, partially offset by $0.5 million expense related to royalty fees under the Barings Credit Facility, compared to a $7.1 million non-cash gain, net, attributable to the changes in the fair value of the derivative liability associated with the Barings Credit Facility and the derivative liability associated with the Company's convertible notes, partially offset by $0.4 million expense related to royalty fees under the Barings Credit Facility, for the third quarter of 2023.

Outstanding shares as of November 11, 2024, were approximately 157.2 million.

Conference Call and Webcast Information:

Ocular Therapeutix will host a conference call and webcast today at 8:00 AM ET to discuss recent business progress and third quarter 2024 financial results. To access the call, please dial: *1 (877) 407-9039 (United States)* or *1 (201) 689-8470 (International)*. The live and archived webcast can also be accessed by visiting the Ocular Therapeutix website on the Events and Presentations section of the Investor Relations page. A replay of the webcast will be archived for at least 30 days.

About AXPAXLI

AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI) is an investigational, bioresorbable, hydrogel implant incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD, diabetic retinopathy, and other retinal diseases.

About the SOL-1 Study

The registrational Phase 3 SOL-1 trial (NCT06223958) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study that involves more than 100 clinical trial sites located in the U.S. and Argentina. The trial is intended to randomize approximately 300 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye.

The superiority study has an eight-week loading segment prior to randomization, a 9-month treatment segment, and a safety follow-up. During the loading segment, subjects who have 20/80 vision or better and who satisfy other enrollment criteria receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Eligible subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 or gain at least 10 early treatment diabetic retinopathy (ETDRS) letters at Day 1 are then randomized to receive a single dose of AXPAXLI or a single dose of aflibercept (2 mg) and assessed monthly for the duration of the study. The clinical trial protocol requires that, during the study, subjects in any arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, defined as a loss of <15 ETDRS letters of BCVA, at Week 36. The study is being conducted under a Special Protocol Agreement (SPA) with the FDA.

About the SOL-R Study

The registrational Phase 3 SOL-R trial (NCT06495918) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (2:2:1), three-arm study that will involve sites located in the U.S. and the rest of the world. The trial is intended to randomize approximately 825 subjects who are treatment-naïve or were diagnosed with wet AMD in the study eye within three months prior to enrollment.

The non-inferiority study reflects a patient enrichment strategy that includes multiple loading doses of aflibercept (2 mg) and monitoring to exclude subjects with significant retinal fluid fluctuations. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Week 24. Subjects in the second arm receive aflibercept (2 mg) on-label every 8 weeks. Subjects in the third arm receive a single dose of aflibercept (8 mg) at Day 1 and are re-dosed at Week 24, aligned with the AXPAXLI treatment arm for adequate masking. Subjects in any arm that meet pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-R is non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at one year. In a written Type C response received in August 2024, the FDA agreed that the SOL-R repeat dosing wet AMD study should be appropriate as an adequate and well-controlled study in support of a potential New Drug Application and product label.

About Wet AMD

Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14 million individuals globally and 1.65 million in the United States alone (2023 Market Scope® Retinal Pharmaceuticals Market Report). Wet AMD causes vision loss due to abnormal new blood vessel growth and hyperpermeability and associated retinal vascularity in the macula, which is primarily stimulated by local upregulation of vascular endothelial growth factor (VEGF). Without prompt and continuous treatment to control this exudative activity, patients develop irreversible vision loss. With proper treatment, patients may maintain visual function for a period of time and may temporarily regain lost vision. Challenges with current therapies include pulsatile, repeated intraocular injections, treatment-related adverse events and up to 40% patient discontinuation with continued disease progression. Taken together, these factors lead to undertreatment and a lack of long-term vision improvement for patients.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company committed to improving vision in the real world through the development and commercialization of innovative therapies for retinal diseases and other eye conditions. AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI), Ocular's product candidate for retinal disease, is based on its ELUTYX™ proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in Phase 3 clinical trials for wet age-related macular degeneration (wet AMD).

Ocular's pipeline also leverages the ELUTYX technology in its commercial product DEXTENZA®, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis, and in its product candidate PAXTRAVA™ (travoprost intracameral implant or OTX-TIC), which is currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Follow the Company on its website, LinkedIn, or X.

Forward-Looking Statements

Any statements in this press release about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company's product candidates; the timing, design, and enrollment of the Company's SOL-1 and SOL-R Phase 3 clinical trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI and its other product candidates; the potential utility of any of the Company's product candidates; the Company's objective to become a leader in retinal care; the Company's guidance regarding its projected total net product revenues for DEXTENZA; the Company's cash runway and 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 any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of any product or product candidate that receives regulatory approval; the initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials; the ability to grow DEXTENZA revenues in accordance with the Company's forecasts; the risk that the FDA will not agree with the Company's interpretation of the written agreement under the Special Protocol Assessment for the SOL-1 trial; the risk that the FDA may not agree that the protocol and statistical analysis plan of SOL-R or the data generated by the SOL-1 and SOL-R trials support marketing approval, even if the trials are successful; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials, whether preliminary or interim data from a clinical trial will be predictive of final data from such trial, or whether data from a clinical trial assessing a product candidate for one indication will be predictive of results in other indications; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; the Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments may 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 & Media

Ocular Therapeutix, Inc.
Bill Slattery
Vice President, Investor Relations
bslattery@ocutx.com

Ocular Therapeutix, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 427,220	$ 195,807
Accounts receivable, net	30,235	26,179
Inventory	2,405	2,305
Restricted cash	—	150
Prepaid expenses and other current assets	13,151	7,794
Total current assets	473,011	232,235
Property and equipment, net	10,050	11,739
Restricted cash	1,614	1,614
Operating lease assets	5,694	6,472
Total assets	$ 490,369	$ 252,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,001	$ 4,389
Accrued expenses and other current liabilities	30,451	28,666
Deferred revenue	190	255
Operating lease liabilities	1,717	1,586
Total current liabilities	36,359	34,896
Other liabilities:		
Operating lease liabilities, net of current portion	5,592	6,878
Derivative liabilities	14,465	29,987
Deferred revenue, net of current portion	14,000	14,135
Notes payable, net	67,815	65,787
Other non-current liabilities	117	108
Convertible Notes, net	—	9,138
Total liabilities	138,348	160,929
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, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 400,000,000 shares and 200,000,000 shares authorized and 156,654,938 and 114,963,193 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	16	12
Additional paid-in capital	1,194,701	788,697
Accumulated deficit	(842,696)	(697,578)
Total stockholders' equity	352,021	91,131
Total liabilities and stockholders' equity	$ 490,369	$ 252,060

Ocular Therapeutix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 15,347	14,950	$ 46,441	$ 43,193
Collaboration revenue	78	131	200	449
Total revenue, net	15,425	15,081	46,641	43,642
Costs and operating expenses:				
Cost of product revenue	1,561	1,377	4,396	3,895
Research and development	37,054	15,019	86,646	44,860
Selling and marketing	10,573	9,315	30,750	31,304
General and administrative	12,235	8,584	46,054	25,915
Total costs and operating expenses	61,423	34,295	167,846	105,974
Loss from operations	(45,998)	(19,214)	(121,205)	(62,332)
Other income (expense):				
Interest income	5,653	1,212	15,611	2,524
Interest expense	(3,224)	(3,426)	(10,471)	(7,187)
Change in fair value of derivative liabilities	7,076	6,722	(1,103)	1,290
Gains and losses on extinguishment of debt, net	—	14,190	(27,950)	14,190
Other expense	—	—	—	(1)
Total other income (expense), net	9,505	18,698	(23,913)	10,816
Net loss	$ (36,493)	$ (516)	$ (145,118)	$ (51,516)
Net loss per share, basic	$ (0.22)	$ (0.01)	$ (0.94)	$ (0.66)
Weighted average common shares outstanding, basic	166,992,735	79,373,272	154,990,112	78,276,341
Net loss per share, diluted	$ (0.22)	$ (0.25)	$ (0.94)	$ (0.77)
Weighted average common shares outstanding, diluted	166,992,735	85,142,504	154,990,112	84,045,573