

**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): **August 7, 2024**

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.)

**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:

<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 August 7, 2024, Ocular Therapeutix, Inc. announced its financial results for the quarter ended June 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 August 7, 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: August 7, 2024

By: /s/ Donald Notman

Donald Notman
Chief Financial Officer

Ocular Therapeutix™ Reports Second Quarter 2024 Results*SOL-R AXPAXLI™ Repeat Dosing Study in Wet AMD Acceptable to FDA as Registrational Trial**Enrollment in SOL-1 Continues to Accelerate and SOL-R Actively Enrolling Patients**Cash Balance of \$459.7M as of June 30, 2024, Expected to Fund Operations into 2028**Ocular Will Host a Q2 2024 Conference Call and Webcast Today, August 7th, at 8:00 AM ET*

BEDFORD, MA, August 7, 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 second quarter ended June 30, 2024 and provided recent business highlights, including an update on the Phase 3 AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI) wet age-related macular degeneration (wet AMD) program.

"I am pleased to report that Ocular is making outstanding progress in 2024. Over the last six months, we have clarified our mission of becoming a leader in the treatment of retinal disease and thoughtfully assembled the team to deliver this mission. The exemplary work of our clinical team has allowed Ocular to accelerate enrollment in the SOL-1 superiority study of AXPAXLI in wet AMD and to swiftly design and initiate the SOL-R non-inferiority repeat dosing study. We are also pleased to report that the FDA has now confirmed that SOL-R is appropriate for use as our second registrational study," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix. "In June, we held a successful Investor Day that allowed us to put SOL-1 and SOL-R into context as complementary studies, addressing questions on durability and repeat dosing. We believe this could put us in a strong position to target a favorable label for AXPAXLI in wet AMD, potentially providing desired flexibility for physicians. The Investor Day also provided us with an opportunity to review the durable and consistent data from the HELIOS study in non-proliferative diabetic retinopathy (NPDR). With these HELIOS data, plus data from our two prior clinical trials in wet AMD, we remain extremely enthusiastic about our SOL-1 and SOL-R registrational studies."

Dr. Dugel concluded, "We believe this is just the beginning of a new age in retinal disease care, and we look forward to updating the investment community and our stakeholders on our progress."

Recent Achievements and Upcoming Milestones:

- **Initiated site activation and patient enrollment in SOL-R AXPAXLI repeat dosing registrational study (Phase 3, wet AMD).** Multiple sites are now active with several subjects enrolled in this study designed to produce commercially meaningful data and which the U.S. Food and Drug Administration (FDA) has confirmed is appropriate for use as Ocular's second adequate and well controlled study to support a potential New Drug Application (NDA). SOL-R compares AXPAXLI dosed every six months (Q6M) to the current standard of care, aflibercept (2 mg) dosed every eight weeks. A third arm evaluating 8 mg aflibercept dosed Q6M is incorporated to ensure adequate masking, in alignment with FDA guidance for non-inferiority studies. The study incorporates five aflibercept (2 mg) loading doses around two evaluation visits to exclude subjects with significant retinal fluid fluctuations, designed specifically for patient enrichment. The Company believes this patient enrichment design may improve the probability of success for the clinical trial by reducing patient variability. SOL-R aims to randomize approximately 825 subjects who are treatment naïve or have been diagnosed with wet AMD in the study eye within three months prior to enrollment.

- **Patient enrollment accelerating in SOL-1 AXPAXLI registrational study (Phase 3, wet AMD).** During its June Investor Day, the Company announced 60 active study sites, and 151 subjects enrolled in various stages of loading and randomization, as of June 7, 2024. Site activation and patient enrollment continue to accelerate in the superiority study comparing a single AXPAXLI implant to a single aflibercept (2 mg) injection, after both arms receive two aflibercept (2 mg) loading doses.
- **Positive HELIOS 48-week data presented at June Investor Day and ASRS (Phase 1, NPDR).** The 48-week HELIOS results showed that all signals of diabetic retinopathy severity scale (DRSS) improvement were observed in AXPAXLI-treated subjects while any vision threatening complications that developed in the study were in the sham-treated control group. In the Phase 1 study, AXPAXLI was administered without a loading dose of aflibercept and demonstrated DRSS stability or improvement with durable effect through 48 weeks and was generally well-tolerated, with no reported incidence of intraocular inflammation, iritis, vitritis or vasculitis, in subjects with NPDR. The impressive data were selected for a late-breaker presentation during the 42nd American Society of Retina Specialist (ASRS) Annual Scientific Meeting.

Second Quarter Ended June 30, 2024, Financial Results

Total cash and cash equivalents were \$459.7 million as of June 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 \$16.4 million for the second quarter of 2024, an 8.3% increase over total net revenue of \$15.2 million in the comparable period in 2023, driven by increased revenues from DEXTENZA sales. 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 in 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 second quarter of 2024 were \$28.9 million versus \$15.1 million for the comparable period in 2023, reflecting an increase in overall clinical expenses associated with product development programs, specifically the ongoing enrollment in the SOL-1 Phase 3 clinical trial, and the design and initiation of start-up activities in the SOL-R Phase 3 clinical trial, as well as additional personnel and professional services to support these clinical trials.

Selling and marketing expenses were \$10.0 million in the second quarter of 2024, as compared to \$11.2 million for the comparable quarter of 2023, primarily reflecting a decrease in professional fees and stock compensation and other personnel costs.

General and administrative expenses were \$19.7 million for the second quarter of 2024 versus \$8.2 million in the comparable quarter of 2023, primarily due to an increase in one-time personnel-related costs, including stock-based compensation expense for certain employees who departed the Company, restructuring costs, and professional services, including legal expense.

Net loss for the second quarter of 2024 was \$(43.8) million, or a net loss of \$(0.26) per share on both a basic and diluted basis, compared to a net loss of \$(20.7) million, or a net loss of \$(0.26) per share on both a basic and diluted basis, for the comparable period in 2023. The net loss in the second quarter of 2024 included a \$(3.0) million non-cash loss attributable to the changes in the fair value of the derivative liability associated with the Barings credit facility, as compared to a \$1.1 million non-cash gain attributable solely to the change in the fair value of the derivative liability associated with the Company's convertible notes for the comparable quarter in 2023.

Outstanding shares as of August 2, 2024, were approximately 155.9 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 second quarter financial results. To access the call, please dial: 1 (800) 343-4136 (*United States*) or 1 (203) 518-9843 (*International*) and reference the *conference ID "OCULAR"*. To access the webcast, please click [here](#). 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 90 days.

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 PAXTRA™ (travoprost intracameral implant or OTX-TIC), which has completed a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Follow the Company on its website, LinkedIn or X.

The Ocular Therapeutix logo and DEXTENZA® are registered trademarks of Ocular Therapeutix, Inc. AXPAXLI™, PAXTRA™, ELUTYX™, and Ocular Therapeutix™ are trademarks of Ocular Therapeutix, Inc.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 459,690	\$ 195,807
Accounts receivable, net	30,232	26,179
Inventory	2,547	2,305
Restricted cash	—	150
Prepaid expenses and other current assets	6,116	7,794
Total current assets	498,585	232,235
Property and equipment, net	10,887	11,739
Restricted cash	1,614	1,614
Operating lease assets	6,005	6,472
Total assets	<u>\$ 517,091</u>	<u>\$ 252,060</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,689	\$ 4,389
Accrued expenses and other current liabilities	24,358	28,666
Deferred revenue	269	255
Operating lease liabilities	1,656	1,586
Total current liabilities	29,972	34,896
Other liabilities:		
Operating lease liabilities, net of current portion	6,100	6,878
Derivative liabilities	22,078	29,987
Deferred revenue, net of current portion	14,000	14,135
Notes payable, net	67,132	65,787
Other non-current liabilities	114	108
Convertible Notes, net	—	9,138
Total liabilities	139,396	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 June 30, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.0001 par value; 400,000,000 shares and 200,000,000 shares authorized and 155,624,363 and 114,963,193 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	16	12
Additional paid-in capital	1,183,882	788,697
Accumulated deficit	(806,203)	(697,578)
Total stockholders' equity	377,695	91,131
Total liabilities and stockholders' equity	<u>\$ 517,091</u>	<u>\$ 252,060</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	\$ 16,379	15,029	\$ 31,094	\$ 28,243
Collaboration revenue	62	157	121	318
Total revenue, net	<u>16,441</u>	<u>15,186</u>	<u>31,215</u>	<u>28,561</u>
Costs and operating expenses:				
Cost of product revenue	1,509	1,304	2,835	2,517
Research and development	28,857	15,094	49,592	29,842
Selling and marketing	9,994	11,153	20,177	21,989
General and administrative	19,671	8,205	33,818	17,332
Total costs and operating expenses	<u>60,031</u>	<u>35,756</u>	<u>106,422</u>	<u>71,680</u>
Loss from operations	<u>(43,590)</u>	<u>(20,570)</u>	<u>(75,207)</u>	<u>(43,119)</u>
Other income (expense):				
Interest income	6,036	748	9,958	1,312
Interest expense	(3,196)	(1,991)	(7,247)	(3,760)
Change in fair value of derivative liabilities	(3,027)	1,131	(8,179)	(5,432)
Loss on extinguishment of debt	—	—	(27,950)	—
Other expense	—	—	—	(1)
Total other income (expense), net	<u>(187)</u>	<u>(112)</u>	<u>(33,418)</u>	<u>(7,881)</u>
Net loss	<u>\$ (43,777)</u>	<u>\$ (20,682)</u>	<u>\$ (108,625)</u>	<u>\$ (51,000)</u>
Net loss per share, basic	<u>\$ (0.26)</u>	<u>\$ (0.26)</u>	<u>\$ (0.73)</u>	<u>\$ (0.66)</u>
Weighted average common shares outstanding, basic	<u>165,824,778</u>	<u>78,047,705</u>	<u>148,922,937</u>	<u>77,718,823</u>
Net loss per share, diluted	<u>\$ (0.26)</u>	<u>\$ (0.26)</u>	<u>\$ (0.73)</u>	<u>\$ (0.66)</u>
Weighted average common shares outstanding, diluted	<u>165,824,778</u>	<u>78,047,705</u>	<u>148,922,937</u>	<u>77,718,823</u>