
**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 3, 2026**

OCULAR THERAPEUTIX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36554
(Commission
File Number)

20-5560161
(IRS Employer
Identification No.)

14 Crosby Drive, 3rd Floor
Bedford, MA 01730
(Address of Principal Executive Offices) (Zip Code)

Registrant'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 August 3, 2026, Ocular Therapeutix, Inc. announced its financial results for the quarter ended June 30, 2026. 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 3, 2026](#)

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 3, 2026

By: /s/ Jason S. Robins

Jason S. Robins

Chief Financial Officer



Ocular Therapeutix™ Reports Second Quarter 2026 Financial Results and Business Highlights

Ocular's AXPAXLI™ wet AMD NDA submission on track for Q4 2026 following positive Type C Meeting with the U.S. FDA in May 2026

FDA Type C Meeting Minutes Formalize SOL-1 Trial with Confirmatory Evidence as Sufficient to Support Submission of AXPAXLI NDA in wet AMD

AXPAXLI NDA submission to be based on SOL-1 Week 52 efficacy and safety data, interim SOL-R safety data, and confirmatory evidence

Pre-NDA meeting scheduled with FDA in Q3 2026 with the NDA submission to follow the Section 505(b)(2) pathway which could accelerate the review timeline by up to 60 days

New Post Hoc SOL-1 analysis demonstrates up to an estimated 72% reduction in treatment burden over 60 weeks with AXPAXLI as compared to a projected on-label aflibercept (2 mg) dosing schedule of every 8 weeks

Commercial readiness accelerating ahead of a potential 2027 launch

Cash balance of \$598.6 million as of June 30, 2026, with expected runway into 2028

BEDFORD, MA, August 3, 2026 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, today reported financial results for the second quarter ended June 30, 2026, and provided recent business highlights focused on its NDA submission plan and further clinical development for AXPAXLI (also known as OTX-TKI). The Company will not be hosting a second quarter 2026 conference call following its recent investor day in June. The Company plans to resume quarterly earnings calls for its third quarter 2026 financial results.

"We continue to execute with discipline, precision, and urgency to redefine the retina experience and make AXPAXLI available to patients as early as possible. Our June Investor Day marked a pivotal milestone with the announcement of a clear, FDA-aligned path to submit the AXPAXLI NDA for wet AMD in the fourth quarter of 2026," said **Pravin U. Dugel, MD, Executive Chairman, President and CEO** of Ocular Therapeutix. "This approach is designed to support the fastest risk-mitigated path to NDA submission and review. Consistent with the FDA Type C meeting minutes, the AXPAXLI NDA submission will be based on SOL-1 efficacy and safety data, interim safety data from SOL-R and supporting confirmatory evidence, including axitinib's established profile as a VEGFR inhibitor from more than a decade of clinical use since FDA approval for renal cell carcinoma. By pursuing the 505(b)(2) regulatory pathway, we believe the AXPAXLI NDA submission is strongly positioned to benefit from a review timeline up to 60 days shorter than the typical new molecular entity."

Peter K. Kaiser, MD, Chief Development Officer of Ocular Therapeutix added, “SOL-1 is the first and only successful superiority trial of a novel agent against an approved anti-VEGF therapy since the class emerged two decades ago. Today, up to 40% of wet AMD patients discontinue therapy within the first year alone, largely attributable to the treatment burden and its impact on patients and caregivers. In a new post-hoc analysis of SOL-1 data applying the SOL-R rescue criteria of >5 ETDRS letter loss and ≥ 75 μm CSFT increase from baseline, we estimate a treatment burden reduction of up to 72% as compared to a projected on-label dosing regimen of aflibercept (2 mg) over 60 weeks. The robust potential of AXPAXLI to reduce treatment burden in the real-world may improve adherence and long-term outcomes for our patients.”

Estimated Reduction in Treatment Burden Excluding Loading Doses

Mean Number of Expected Injections Per Subject*	AXPAXLI	aflibercept (2 mg)	Injection Burden Reduction
From Week -8 to Week 52	1.95	7.00	72%

Estimated Reduction in Treatment Burden Including Loading Doses

Mean Number of Expected Injections Per Subject*	AXPAXLI	aflibercept (2 mg)	Injection Burden Reduction
From Week -8 to Week 52	3.95	9.00	56%

*Methodology outlined below in “Recent Achievements and Upcoming Milestones”

Recent Achievements and Upcoming Milestones:

- New Drug Application (NDA) submission for AXPAXLI in wet AMD planned for Q4 2026, with FDA alignment confirmed in May 2026 Type C meeting minutes.** The NDA submission will be based on SOL-1 efficacy and safety data, an interim SOL-R safety analysis of patients who have reached Week 52 to be conducted in the fourth quarter of 2026, and confirmatory evidence. Together with the existing SOL-1 safety database, this interim SOL-R safety analysis will bring the aggregate safety dataset to more than 300 patients with at least one year of AXPAXLI safety data and in-line with FDA requirements. A pre-NDA meeting with the FDA is scheduled for the third quarter of 2026. Ocular intends to submit the NDA under the 505(b)(2) pathway, which could accelerate the review timeline by up to 60 days.
- Post-hoc Analysis of SOL-1 (Phase 3, wet AMD) demonstrates up to an estimated 72% reduction in treatment burden over 60 weeks with AXPAXLI relative to a projected on-label dosing regimen of aflibercept (2 mg) every 8 weeks.** The proportion of SOL-1 patients who would have remained rescue-free under the SOL-R rescue criteria of >5 ETDRS letter loss and ≥ 75 μm CSFT increase from baseline was 66.5% at Week 52. Applying the observed mean rescue treatment rates in SOL-1 to the estimated 33.5% of subjects requiring rescue under the SOL-R criteria corresponded to an average of 0.95 aflibercept (2 mg) rescues per subject for all subjects in the AXPAXLI arm through Week 52 after a single AXPAXLI injection at baseline. The total estimated mean injection burden with AXPAXLI represents a 72% reduction counting from the first screening visit at Week -8 excluding loading doses and a 56% reduction when loading doses are included, as compared to a projected on-label dosing regimen of aflibercept (2 mg) with no rescues.

- **SOL-R (Phase 3, wet AMD) to be amended to maximize AXPAXLI label potential following robust SOL-1 results and confirmation from FDA that SOL-R efficacy data is not required for the AXPAXLI NDA submission.** With superiority demonstrated at Weeks 36 and 52 against a single injection of aflibercept (2 mg) in SOL-1, Ocular now plans to evaluate a new key secondary endpoint of superiority to aflibercept (8 mg) at Week 96 in SOL-R. Another secondary endpoint will evaluate prevention of fibrosis and atrophy relative to aflibercept (2 mg) at Week 96. To facilitate these evaluations, Ocular will extend the efficacy analysis and sponsor-masking in SOL-R until the end of study at Week 96. These outcomes, if positive, have the potential to establish AXPAXLI as a best-in-disease agent in wet AMD. Following these changes, topline SOL-R results are now expected in the first quarter of 2028. The trial's primary endpoint, non-inferiority of AXPAXLI to aflibercept (2 mg) at Week 56, remains unchanged.
 - **SOL-X (wet AMD) enrollment continues to accelerate, with the vast majority of trial investigators and eligible patients opting to participate in the open-label extension study.** Subjects who have completed their two-year follow-up in either the SOL-1 or SOL-R trials are eligible to enroll in the three-year open-label extension study evaluating the long-term safety and outcomes of AXPAXLI dosed every 24 weeks. Ocular believes sustained VEGF suppression with AXPAXLI may reduce the incidence of fibrosis and atrophy in wet AMD, thereby improving long-term outcomes. The first subject enrolled in SOL-X in April 2026.
 - **Diabetic retinopathy program streamlined to prioritize HELIOS-3 (Phase 3, NPDR) as Ocular's potential single registrational trial.** HELIOS-3 will now evaluate AXPAXLI dosed every 12 months (Q48W) versus sham with the trial size being reduced from 930 to 620 patients. The decision to amend the HELIOS-3 design was based on AXPAXLI's observed durability of up to 12 months in SOL-1, HELIOS-1 data, and market research showing physician preference for once-yearly dosing. HELIOS-3 is designed to support a broad label in diabetic retinal disease, including patients with diabetic macular edema (DME).
 - **Commercial readiness activities, including market and payer research, advancing rapidly ahead of a potential 2027 launch of AXPAXLI, if approved.** Following SOL-1's results, market research found that approximately 80% of retina specialists surveyed would likely use a product with AXPAXLI's profile based on SOL-1 data alone, with more than 90% expected to adopt such a product within its first year, if approved. Physicians cited disease control, predictable dosing interval, and seamless fit within existing workflows as key drivers of anticipated use. Ocular's payer team has also engaged 100% of Tier 1 Medicare Advantage and commercial payers, who have indicated that a label demonstrating superior durability could command premium pricing.
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Second Quarter Ended June 30, 2026, Financial Results:

Total cash and cash equivalents were \$598.6 million as of June 30, 2026. 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 operating expenses, debt service obligations, and capital expenditure requirements into 2028.

This cash projection factors in the completion of the SOL-1 trial and the continued execution of the SOL-R, the SOL-X and the HELIOS-3 trials. The projection also includes investment in pre-commercial activities and preparations for the potential FDA approval and initial launch of AXPAXLI but does not currently include the full expenses the Company anticipates it needs to support the near-term commercialization of AXPAXLI, if approved.

Total net revenue was \$13.5 million for the second quarter of 2026, flat as compared to the comparable quarter of 2025. Total net revenue includes both gross DEXTENZA product revenue, net of discounts, rebates, and returns, which increased \$0.1 million or 0.6% over Q2 2025, and collaboration revenue, which was \$0.0 million in Q2 2026 versus \$0.1 million in Q2 2025.

Research and development expenses for the second quarter of 2026 were \$54.1 million versus \$51.1 million for the comparable quarter in 2025, reflecting an increase in overall clinical expenses associated with the ongoing SOL-1, SOL-R, SOL-X and HELIOS-3 clinical trials, with additional personnel and professional services to support these clinical trials and preparations to submit the planned NDA for AXPAXLI in wet AMD.

Selling and marketing expenses were \$17.3 million for the second quarter of 2026, as compared to \$13.7 million for the comparable quarter of 2025, reflecting an increase in personnel-related costs, including stock-based compensation expense, related to the expansion of our commercial team and pre-commercial investments to support a potential AXPAXLI launch.

General and administrative expenses were \$22.2 million for the second quarter of 2026, as compared to \$14.3 million for the comparable quarter of 2025, reflecting an increase in personnel-related costs, including stock-based compensation expense, professional fees and facility-related costs.

Net loss for the second quarter of 2026 was \$(78.8) million, or a net loss of \$(0.35) per share on both a basic and diluted basis, compared to a net loss of \$(67.8) million, or a net loss of \$(0.39) per share on a basic and diluted basis, for the comparable quarter of 2025.

Outstanding shares as of July 31, 2026, were approximately 225.0 million.

About AXPAXLI

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

About the SOL-1 Trial

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 trial that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 treatment-naïve subjects with a diagnosis of wet AMD in the study eye. Two randomized subjects withdrew from the trial prior to receiving Day 1 treatment.

The superiority trial has an eight-week loading segment prior to randomization. During the loading segment, subjects who have 20/80 vision or better and a central subfield thickness (CSFT) of ≤ 500 μm receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 (baseline) or gain at least 10 Early Treatment Diabetic Retinopathy Study (ETDRS) letters at Day 1 along with a CSFT of ≤ 350 μm were then randomized to receive a single dose of AXPAXLI (0.45 mg) or a single dose of aflibercept (2 mg). At Week 52 and at Week 76, all subjects are re-dosed with their respective initial treatment of AXPAXLI (0.45 mg) or aflibercept (2 mg). Subjects will be followed for safety until the end of Week 104.

Throughout the trial, subjects are assessed monthly. Trial subjects and designated trial personnel will remain masked through the end of Week 104. The clinical trial protocol requires that, during the trial, subjects in either arm meeting the pre-specified rescue criteria, which include a BCVA loss of ≥ 15 ETDRS letters from baseline or new vision-threatening macular hemorrhage, will receive a supplemental dose of aflibercept (2 mg). The protocol provides that after the first rescue injection, rescue therapy may be provided at investigator discretion per their clinical judgement.

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 from baseline, at Week 36. Predefined statistical rules were applied to adjust for treatment discontinuation or deviation as per the pre-specified statistical analysis plan. The trial remained masked following Week 36 and subjects were evaluated for treatment durability at Week 52. The trial is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

In February 2026, Ocular reported positive SOL-1 Week 52 topline data. The superiority primary endpoint was met with 74.1% of subjects in the AXPAXLI (0.45 mg) arm maintaining vision at Week 36, a 17.5% risk difference ($p=0.0006$), compared to the aflibercept (2 mg) arm. A key secondary endpoint was met with 65.9% of subjects treated with AXPAXLI (0.45 mg) maintaining vision at Week 52, a 21.1% risk difference ($p<0.0001$), compared to the aflibercept (2 mg) arm.

About the SOL-R Trial

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 trial that includes sites located in the U.S., Argentina, India, and Australia in subjects who are treatment-naïve or were diagnosed with wet AMD in the study eye within about four months prior to enrollment. Further, to qualify for screening, a subject's study eye must have had a BCVA ETDRS letter score of ≥ 34 ($\sim 20/200$). In December 2025, the trial completed the randomization of 640 subjects.

This non-inferiority trial reflects a patient enrichment strategy over the six months prior to randomization that includes three screening doses of any anti-VEGF therapy, excluding brolocizumab-dbl, and monitoring to exclude those subjects with early persistent fluid or significant retinal fluid fluctuations. Subjects who continue to meet eligibility, defined as a CSFT of ≤ 350 μm at Week -12 and Week -8, with ≤ 35 μm CSFT increase at Week -8 from the lowest CSFT at any prior visit, entered a run-in period and received two loading doses of aflibercept (2 mg) prior to Day 1. Subjects in the first arm receive a single dose of AXPAXLI (0.45 mg) at Day 1 and are re-dosed at Weeks 24, 48, and 72. Subjects in the second arm receive aflibercept (2 mg) on Day 1 and per label every eight weeks thereafter. Subjects in the third arm receive a single dose of aflibercept (8 mg) at Day 1 and are re-dosed at Weeks 24, 48, and 72, aligned with the AXPAXLI treatment arm for adequate masking. Subjects will be followed for safety until the end of Week 96. Throughout the trial, subjects are assessed monthly. Trial subjects and designated trial personnel will remain masked through the end of Week 96. Subjects in any arm that meet pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg). The pre-specified rescue criteria include a >5 -letter loss in visual acuity plus a ≥ 75 μm increase in CSFT.

The primary endpoint of SOL-R is to demonstrate non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at Week 56. As per the protocol agreed to by the FDA, the non-inferiority margin for the lower bound is -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every eight weeks. In a written Type C response received in August 2024, and a subsequent written response received in December 2024, the FDA agreed that the SOL-R repeat dosing wet AMD trial, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled trial in support of a potential New Drug Application and product label for wet AMD. The trial will remain masked to the Company following the primary endpoint Week 56 time point, as key secondary endpoints will be evaluated through Week 96.

About the SOL-X Trial

The SOL-X trial (NCT07516132) is a multi-center, 36-month open-label extension trial designed to evaluate the long-term safety, efficacy, and disease modifying potential of AXPAXLI in wet AMD for subjects who have successfully completed their two-year safety follow-up visits in either the SOL-1 or SOL-R trials. The first subject enrolled in the study in April 2026.

According to the trial design, all subjects will be given AXPAXLI every 24 weeks, starting at Day 1 (after completion of the Week 104 visit in SOL-1, or Week 96 visit in SOL-R), and again at Weeks 24, 48, 72, 96, and 120. Subjects are assessed at Week 4, Week 12, and then every 12 weeks thereafter. Additional visits can be conducted with supplemental anti-VEGF injection administered based on investigator discretion.

The primary objectives of SOL-X are to evaluate the long-term safety of AXPAXLI; to explore long-term visual outcomes, including visual acuity and the incidence and/or progression of fibrosis and macular atrophy; and to evaluate the impact of delayed initiation of AXPAXLI in patients who initially were randomized to receive aflibercept in either SOL-1 or SOL-R.

About the HELIOS-3 Trial

The registrational Phase 3 HELIOS-3 trial (NCT07235085) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1) two-arm superiority trial. The trial is designed to enroll approximately 620 subjects with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) without center-involved diabetic macular edema (CI-DME). The first patient was randomized in the HELIOS-3 trial in November 2025.

Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Week 48. Subjects in the second arm receive a sham injection at Day 1 and Week 48 aligned with the AXPAXLI treatment arm for adequate masking. Throughout the trial, subjects are assessed every 4 weeks from Day 1 through Week 56 and every other month thereafter through Week 96.

The primary endpoint of HELIOS-3 is the ordinal diabetic retinopathy severity score (DRSS) 2-step change status at Week 56 from baseline (≥ 2 -step improvement, ≥ 2 -step worsening, less than 2-step change in either direction).

About Wet AMD

Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14.8 million individuals globally and 1.8 million in the United States alone. 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 within one year of initiating treatment with continued disease progression. Taken together, these factors lead to undertreatment and a lack of long-term vision improvement for patients.

About Diabetic Retinal Disease

Diabetic retinal disease is an increasingly prevalent global health concern, driven by the rapidly rising number of individuals diagnosed with diabetes each year.

Diabetic retinopathy (DR) is the most common category of retinal diseases, affecting over an estimated 103 million people worldwide. DR is a progressive condition in which retinal blood vessels are damaged following a cascade of events triggered by chronically elevated levels of blood glucose. As many as half of all diabetic patients are expected to develop some form of DR in their lifetime. DR can progress from the non-proliferative (NPDR) stages to the proliferative (PDR) stage characterized by the growth of abnormal new blood vessels. Fewer than 1% of the 6.4 million NPDR patients in the U.S. receive treatment today, despite the availability of anti-VEGF therapies approved for the indication, largely due to the burden of frequent injections.

Diabetic macular edema (DME) is also a leading cause of vision loss in the working-age population. DME, the result of an accumulation of fluid in the macula that can afflict patients with diabetes, can occur at any stage of DR. In patients with DME, blood vessels in the eyes leak and start to swell, which can cause vision loss or blindness. Anti-VEGF drugs are approved to treat DME, but these treatments typically require frequent intravitreal injections, placing a significant burden on patients and physicians alike.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is an integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI™ (also known as OTX-TKI), Ocular's investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel 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) and diabetic retinal disease, including non-proliferative diabetic retinopathy (NPDR).

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 in adults and pediatric patients and ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in its investigational product candidate OTX-TIC, which is a travoprost intracameral hydrogel that has completed a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension. Ocular is currently evaluating next steps for the OTX-TIC program.

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

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

Forward-Looking Statements

This press release contains forward-looking statements of the Company regarding its future expectations, plans, and prospects; statements regarding the development and regulatory status of the Company's product candidate AXPAXLI (also known as OTX-TKI), including the Company's intention to submit a new drug application for AXPAXLI for the treatment of wet AMD based on Week 52 efficacy and safety data from the Company's SOL-1 Phase 3 clinical trial, Week 52 data from an interim safety analysis to be conducted in the Company's SOL-R clinical trial, and confirmatory evidence, and planned amendments to the clinical trial protocols of the Company's SOL-R and HELIOS-3 clinical trials; statements regarding the timing, design, enrollment, randomization, conduct and retention of subjects in the Company's ongoing and planned clinical trials for AXPAXLI, including the SOL-1, SOL-R and SOL-X clinical trials for the treatment of wet AMD and the HELIOS-3 trial for non-proliferative diabetic retinopathy; statements regarding the commercial potential of AXPAXLI, including market research findings and potential pricing; statements regarding the timing of the availability of data from the SOL-R trial; statements regarding the potential commercialization of AXPAXLI, including statements regarding the potential pricing and label of AXPAXLI and the timing of a potential commercial launch of AXPAXLI, if approved; statements regarding the Company's plans to leverage the Section 505(b)(2) pathway and its potential to accelerate the review timeline of the Company's planned NDA submission; statements regarding the Company's cash runway and the sufficiency of the Company's cash resources; statements regarding the potential utility or adoption, if approved, of any of the Company's product candidates, including AXPAXLI; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "position", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, all of which 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 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, uncertainties regarding the initiation, design, timing, conduct and outcomes of the Company's ongoing clinical trials, including the Company's SOL-1 trial, SOL-R trial, HELIOS-3 trial, and SOL-X trial; the timing and costs involved in commercializing any product or product candidate that receives regulatory approval; the risk that the U.S. Food and Drug Administration, or FDA, will not agree with the Company's interpretation of the written agreements under the Special Protocol Assessments for AXPAXLI, including for the SOL-1 trial, or of the minutes of the Company's Type C meeting with the FDA; uncertainty as to whether the FDA will accept a new drug application for AXPAXLI on the basis of a single pivotal clinical trial, notwithstanding discussions the Company has had with the FDA regarding its planned NDA submission; uncertainty as to the minimum clinical data required to demonstrate the safety of a proposed product candidate such as AXPAXLI, even if the FDA recognizes that only one pivotal clinical trial may be required to demonstrate efficacy and accepts the Company's NDA submission; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not find that the data generated by the trial and submitted by the Company are sufficient to demonstrate the safety and efficacy of AXPAXLI to the degree necessary to support marketing approval for wet AMD; the risk that the FDA might not agree to the Company's design, protocol, and statistical analysis plan of any of its clinical trials for which the Company has not obtained a Special Protocol Assessment, including the SOL-R trial; the risk that the Company and the FDA may not agree on, or maintain agreement with respect to, the registrational pathway for any of its product candidates, including AXPAXLI; uncertainty as to whether the Company will be able to timely satisfy the FDA's other requirements for regulatory approval of AXPAXLI, including the FDA's Chemistry, Manufacturing and Control's requirements, even if the Company can satisfy the FDA's clinical requirements to demonstrate safety and efficacy; uncertainty as to whether the Company's NDA will qualify for, or whether the FDA will agree to review the NDA, if accepted for filing, under the 505(b)(2) pathway, notwithstanding discussions the Company has had with the FDA regarding its planned regulatory pathway, and whether the 505(b)(2) pathway will provide any time-savings as compared to the traditional 505(b)(1) pathway; uncertainty as to what restrictions, if any, may be imposed on the label for AXPAXLI, if approved, pending the receipt of additional clinical data or otherwise; 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 or post-hoc analyses of clinical data 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; uncertainty as to the Company's ability to retain regulatory approval of any product or product candidate that receives regulatory approval; uncertainty as to whether data from the Company's SOL-X trial will demonstrate additional clinically meaningful, long-term benefits; uncertainties regarding the potential commercial advantages and/or position of the Company's product candidates; uncertainty regarding the implementation and impact of most-favored-nation and other reference pricing regimes on the commercial potential of AXPAXLI, especially in markets outside the United States; 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; 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)
(Unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 598,641	\$ 737,060
Accounts receivable, net	30,261	30,650
Inventory	3,826	3,564
Prepaid expenses and other current assets	11,699	10,855
Total current assets	644,427	782,129
Property and equipment, net	19,456	19,676
Restricted cash	1,614	1,614
Operating lease assets	5,820	4,638
Total assets	<u>\$ 671,317</u>	<u>\$ 808,057</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 6,996	\$ 4,154
Accrued expenses and other current liabilities	39,056	43,835
Operating lease liabilities	3,122	2,817
Total current liabilities	49,174	50,806
Other liabilities:		
Operating lease liabilities, net of current portion	3,466	2,815
Derivative liability	10,910	13,903
Deferred revenue	14,000	14,000
Notes payable, net	72,795	71,336
Other non-current liabilities	931	887
Total liabilities	151,276	153,747
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, 2026 and December 31, 2025, respectively	—	—
Common stock, \$0.0001 par value; 400,000,000 and 400,000,000 shares authorized and 219,589,303 and 215,927,600 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	22	22
Additional paid-in capital	1,844,417	1,811,311
Accumulated deficit	(1,324,398)	(1,157,023)
Total stockholders' equity	520,041	654,310
Total liabilities and stockholders' equity	<u>\$ 671,317</u>	<u>\$ 808,057</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	\$ 13,475	\$ 13,395	\$ 24,260	\$ 24,028
Collaboration revenue	—	64	—	128
Total revenue, net	13,475	13,459	24,260	24,156
Costs and operating expenses:				
Cost of product revenue	2,011	1,944	3,340	3,206
Research and development	54,138	51,081	120,351	93,938
Selling and marketing	17,276	13,729	33,853	27,877
General and administrative	22,159	14,346	42,166	30,694
Total costs and operating expenses	95,584	81,100	199,710	155,715
Loss from operations	(82,109)	(67,641)	(175,450)	(131,559)
Other income (expense):				
Interest income	5,449	3,455	11,500	7,282
Interest expense	(2,792)	(3,016)	(5,569)	(6,000)
Change in fair value of derivative liabilities	689	(641)	2,144	(1,619)
Gain on sale of property and equipment	—	29	—	29
Total other income (expense), net	3,346	(173)	8,075	(308)
Net loss	\$ (78,763)	\$ (67,814)	\$ (167,375)	\$ (131,867)
Net loss per share, basic	\$ (0.35)	\$ (0.39)	\$ (0.75)	\$ (0.77)
Weighted average common shares outstanding, basic	224,952,428	172,594,662	224,528,253	171,004,629
Net loss per share, diluted	\$ (0.35)	\$ (0.39)	\$ (0.75)	\$ (0.77)
Weighted average common shares outstanding, diluted	224,952,428	172,594,662	224,528,253	171,004,629