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 9, 2026**

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

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 November 9, 2026, Ocular Therapeutix, Inc. announced its financial results for the quarter ended September 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 November 9, 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: November 9, 2026

By: /s/ Jason S. Robins
Jason S. Robins
Chief Financial Officer

Exhibit 99.1

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

AXPAXLI™ NDA submission for wet AMD on track for 4Q 2026 following upcoming SOL-R interim Week 52 safety analysis

Several FDA interactions, including most recent September 2026 Pre-NDA Meeting, reaffirm alignment on submission package under 505(b)(2) pathway

SOL-1 post-hoc analyses presented at AAO and Empire Forum show subjects without early persistent retinal fluid and fluid variability had better visual outcomes with fewer rescues

SOL-R prospectively excludes subjects with early persistent retinal fluid and fluid variability, with preliminary analysis indicating ~20% of otherwise eligible subjects excluded from SOL-R randomization for these reasons

SOL-R primary endpoint moved to Week 40 (from Week 56) to ensure all subjects complete primary efficacy visit before the interim safety analysis in accordance with the FDA-aligned masking plan, with key secondary endpoints at Weeks 56 and 96

SOL-X enrollment continues with plans to implement every 48-week dosing in the open-label protocol based on the durability shown in SOL-1

HELIOS-3 Phase 3 Diabetic Retinopathy trial enrollment progressing

Commercial readiness activities accelerated with investments in commercial infrastructure, market access planning, and launch execution capabilities

Ocular appoints Riad Sherif, MD, to Board of Directors, bringing extensive global commercial experience at Alcon, Novartis, Sanofi, and Oculis

Cash balance of $530.6 million as of September 30, 2026, with expected runway into 2028

BEDFORD, MA, November 9, 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 third quarter ended September 30, 2026, and provided recent business highlights including upcoming NDA submission plans for AXPAXLI™ (also known as OTX-TKI), its investigational product candidate for the treatment of wet age-related macular degeneration (wet AMD) and diabetic retinal diseases.

“2026 has been a transformational year for Ocular Therapeutix and we are in a strong position as we prepare to submit our NDA for AXPAXLI in wet AMD under the 505(b)(2) regulatory pathway,” said **Pravin U. Dugel, MD, Executive Chairman, President and CEO of Ocular Therapeutix**. “Frequent injections define today’s wet AMD treatment experience, and we believe AXPAXLI has the transformative potential to drastically reduce the burden on patients and caregivers. Following our positive pre-NDA meeting in September, we remain aligned with the FDA on our planned submission in the fourth quarter. Recent clinical results from our peers underscore the critical importance of molecular potency, sustained durability, and thoughtful clinical trial design – principles that have guided our AXPAXLI development strategy from the outset. SOL-1 post-hoc analyses presented at AAO reinforce AXPAXLI's remarkable sustained anatomical control, with approximately 70% of subjects who were quantitatively dry at Week 8 remaining dry through Week 36 following a single injection, using a strict AI-based fluid analysis that detects even trace fluid. At last week’s Empire Forum in New York City, we presented additional post hoc analyses showing that approximately 28% of AXPAXLI-treated subjects in SOL-1 experienced early persistent retinal fluid. These patients had worse visual outcomes, increased variability in total retinal fluid volume, increased need for supplemental injections, and a 32-week earlier time to first supplemental injection compared to subjects without early persistent fluid in the same period. These findings are particularly encouraging for SOL-R, which was deliberately designed with the goal of randomizing patients with minimal early retinal fluid and fluid variability. Preliminary analyses of SOL-R screening indicate that approximately 20% of otherwise eligible subjects were excluded from randomization due to early persistent retinal fluid or fluid variability. By contrast, this volatile group of patients were not excluded from SOL-1. The combination of axitinib’s differentiated potency, AXPAXLI’s disease control and durability shown in SOL-1, and our disciplined patient selection strategy further strengthens our confidence in the likelihood of SOL-R’s success.”

Dr. Dugel concluded, “With the competitive landscape evolving, AXPAXLI is now the only intravitreal sustained release maintenance agent with positive Phase 3 data in wet AMD. We believe our opportunity to fundamentally transform the treatment paradigm has never been greater. As such, we are rapidly advancing our commercial readiness, including the addition of Dr. Riad Sherif to our Board of Directors, who brings extensive global commercial experience in ophthalmology at Alcon, Novartis, Sanofi, and Oculis. We continue to progress our diabetic retinopathy program in parallel, as we work expeditiously toward bringing AXPAXLI to patients who urgently need more durable treatment options as quickly as possible.”

Peter K. Kaiser, MD, Chief Development Officer of Ocular Therapeutix added, “Building on AXPAXLI’s demonstrated durability in SOL-1, we have modified SOL-X to evaluate retreatment every 48 weeks. This change reflects our confidence in AXPAXLI’s sustained disease control with up to 12-month dosing. We expect SOL-X will provide valuable evidence supporting AXPAXLI’s potential role as a long-term maintenance therapy following a brief course of bolus anti-VEGF injections to achieve initial retinal dryness. SOL-R further supports dosing flexibility by evaluating AXPAXLI retreatment every six months. While SOL-R efficacy data are not required for our planned NDA submission, the trial remains important to our U.S. commercial and ex-U.S. regulatory objectives. Following our May Type C meeting we moved the SOL-R primary endpoint to Week 40 to ensure all subjects complete their primary efficacy assessments *before* the planned Week 52 interim safety analysis to preserve the primary endpoint’s statistical integrity and limit operational bias. As we continue to learn more about AXPAXLI, and the population randomized to SOL-R, our confidence in the trial’s success and AXPAXLI’s potential to dramatically reduce treatment burden has never been greater.”

Recent Achievements and Upcoming Milestones:

- **Following completion of positive Pre-NDA Meeting in September 2026, AXPAXLI New Drug Application (NDA) submission on track for 4Q 2026.** Consistent with prior communications, the planned AXPAXLI NDA for wet AMD will be supported by SOL-1 Week 52 efficacy data, SOL-1 and interim SOL-R Week 52 safety data, and confirmatory evidence. In connection with the NDA review process, Ocular plans to submit data from subjects who have received multiple AXPAXLI injections in both Phase 3 trials to support the inclusion of repeat dosing on AXPAXLI's label, if approved. Ocular believes its extensive regulatory engagement, including the Special Protocol Assessment (SPA) agreement for SOL-1 and positive Type C and Pre-NDA meetings, provide a strong foundation for its planned NDA submission. In alignment with the FDA, Ocular intends to submit the AXPAXLI NDA under the 505(b)(2) regulatory pathway, which has the potential to shorten the FDA review timeline by up to 60 days as compared to the traditional 505(b)(1) pathway for a new molecular entity.

- **Interim SOL-R Week 52 safety analysis to be conducted in 4Q 2026, with interim safety data to be included in the planned AXPAXLI NDA submission to FDA.** Together with the existing SOL-1 safety database, the interim safety analysis of SOL-R subjects who have reached Week 52 will bring the aggregate safety dataset to more than 300 patients with at least one year of follow-up after AXPAXLI treatment, in line with FDA requirements. The interim SOL-R Week 52 safety results will be included in the NDA submission to the FDA. SOL-R will remain masked through the end of Year 2 (Week 96) as part of the masking plan aligned to with the FDA. This approach is intended to support the Company's regulatory strategy in the United States and internationally.

- **SOL-R primary endpoint timing updated to Week 40 with topline results on track for 1Q 2028 after key secondary endpoints are evaluated.** Ocular has updated the timing of the SOL-R primary efficacy endpoint from Week 56 to Week 40, while maintaining key secondary endpoints at Weeks 56 and 96. The modification was necessary to preserve the integrity of the ongoing masked trial by ensuring all subjects have passed the new primary endpoint visit before the planned interim Week 52 safety analysis takes place. SOL-R will remain masked through Week 96 to evaluate key secondary and other secondary endpoints of superiority to aflibercept (8 mg), along with prevention of fibrosis and atrophy relative to aflibercept (2 mg). The process to modify the timing of the primary endpoint was initiated in May 2026 after the Company's Type C Meeting, with subsequent FDA engagement, protocol integration, IRB approval, and FDA alignment completed ahead of the upcoming planned interim safety analysis.

- **Recent SOL-1 post hoc analyses further illustrate AXPAXLI's potential for sustained anatomical control and reinforce SOL-R patient selection strategy.**

  A post hoc analysis presented at the 2026 American Academy of Ophthalmology (AAO) Annual Meeting reported that at Week 8 in SOL-1, 71% of AXPAXLI-treated subjects were quantitatively dry (≤10nL total retinal fluid volume in 6x6 OCT scan) using an AI-based analysis that detects even trace fluid. Of these subjects, approximately 70% remained quantitatively dry using this very strict criteria through Week 36, highlighting durability of anatomical control in patients who achieved early disease stability in SOL-1.

  A subsequent SOL-1 post-hoc analysis presented at the 2026 Empire Forum reported that 28% of the AXPAXLI-treated subjects in SOL-1 had early persistent fluid, defined as change in central subfield thickness (CSFT) of >30µm from baseline at Week 8. It is unlikely that these subjects would have qualified for randomization in SOL-R, based on the non-inferiority trial's exclusion criteria during the screening period. Subjects with early persistent fluid in SOL-1 had worse visual outcomes, a 32-week earlier time to supplemental injection, and an increased frequency of needing supplemental injections, compared to subjects without early persistent fluid in the same period.

  These post hoc analyses reinforce the Company's confidence in AXPAXLI's potential to deliver predictable, sustained disease control with significantly fewer injections than currently available therapies.

- **Preliminary analysis of screen failures in SOL-R indicates that approximately 20% of otherwise eligible subjects were excluded due to early persistent fluid or fluid fluctuations.** These findings provide additional support for the SOL-R study's differentiated design, which incorporates a six-month pre-randomization period to screen-out patients with high fluid fluctuations and select patients without early persistent fluid for randomization. The approximate 20% of otherwise eligible subjects that were excluded due to early persistent fluid or fluid fluctuations aligns with Ocular's expectations prior to SOL-R, based on historical literature, and is validated by similar findings in SOL-1. Together, these findings provide confidence that SOL-R is randomizing the intended patient population and increases the Company's conviction in SOL-R's potential success.

- **Commercial readiness advancing rapidly as AXPAXLI is well positioned to potentially be the first intravitreal sustained release maintenance agent approved for wet AMD.** Ocular continues to advance commercial readiness activities in anticipation of a potential U.S. launch of AXPAXLI, if approved, with ongoing investments in commercial infrastructure, market access planning, and launch execution capabilities. Ocular's market research indicates strong physician interest in AXPAXLI's profile based on SOL-1 data alone and launch planning activities are designed to support rapid physician adoption and broad patient access following a potential regulatory approval.

- **Ocular Therapeutix appoints Riad Sherif, MD, to Board of Directors, who joins Ocular with extensive global commercial leadership experience spanning Alcon, Novartis, Sanofi, and Oculis.** Dr. Sherif will overlap with Seung Suh Hong, PhD, until the end of this year, at which point Dr. Hong will step down from the Board. Dr. Sherif is an accomplished ophthalmology executive with decades of commercial strategy, organizational leadership and global market development experience. As Ocular advances AXPAXLI toward potential regulatory approval, the Company believes Dr. Sherif's strategic insights and commercial perspective will be tremendous assets to our Board.

Dr. Sherif currently serves as Chief Executive Officer and Director of Oculis Holding AG. Prior to joining Oculis, Dr. Sherif served as Entrepreneur in Residence at the Novartis Venture Fund from 2016 to 2017. Previously, he served as President of Europe, Middle East and Africa at Alcon from 2014 to 2016, where he held senior leadership responsibility across a broad international ophthalmology business. In addition to his leadership role at Oculis, Dr. Sherif currently serves as a member of the Board of Directors of Revenio Group corporation.

- **SOL-X (wet AMD) enrollment momentum continues as Ocular plans to modify the dosing cadence to every 48 weeks.** To date, the vast majority of trial investigators and eligible patients have chosen to participate in SOL-X. Subjects who have successfully completed two-year follow-up in either SOL-1 or SOL-R are eligible to enroll in the three-year open-label extension study evaluating the long-term safety and outcomes of AXPAXLI treatment. Based on AXPAXLI's demonstrated durability of up to 48 weeks in SOL-1, Ocular plans to modify the SOL-X dosing interval to reflect potential durability of real-world dosing of AXPAXLI. Ocular believes sustained VEGF suppression with AXPAXLI may reduce the incidence of fibrosis and atrophy in wet AMD, thereby improving long-term outcomes.

  Together, the Company's three wet AMD trials serve distinct and complementary objectives. SOL-1 demonstrated AXPAXLI's superiority to a single aflibercept (2 mg) injection, with durability extending beyond 48 weeks in many subjects. SOL-R is designed to demonstrate non-inferiority to Q8W aflibercept (2 mg) and that AXPAXLI can be safely dosed every six months in all subjects, while also evaluating AXPAXLI's potential superiority to aflibercept (8 mg). SOL-X will evaluate durable 48-week dosing intervals and the potential long-term visual and anatomical benefits of initiating AXPAXLI treatment earlier in the disease course. Collectively, these studies are designed to support a comprehensive clinical profile that reinforces AXPAXLI's potential efficacy, durability, and flexibility in clinical practice.

- **HELIOS-3 (Phase 3, non-proliferative diabetic retinopathy, NPDR) enrollment progressing as Ocular's potential single registrational trial in diabetic retinopathy.** HELIOS-3 evaluates AXPAXLI dosed every 12 months (Q48W) versus sham in approximately 620 patients and is designed to support a potential broad label in diabetic retinal disease, including patients with non-center-involved diabetic macular edema (DME).

Third Quarter Ended September 30, 2026, Financial Results:

Total cash and cash equivalents were $530.6 million as of September 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 cash projection includes investment in pre-commercial activities and preparations for the potential FDA approval and initial launch of AXPAXLI. It does not include the full expenses the Company anticipates it needs to scale its manufacturing capacity and commercial team, if approved.

Total net revenue was $12.9 million for the third quarter of 2026, compared with $14.5 million for the comparable quarter of 2025.

Research and development expenses for the third quarter of 2026 were $74.8 million versus $52.4 million for the comparable quarter in 2025. The year over year increase in R&D expenses resulted from an acceleration in enrollment in the Company's HELIOS-3 diabetic retinopathy study and SOL-X long-term extension study, as well as increased headcount and infrastructure to support expanded clinical trial activity.

Selling and marketing expenses were $15.7 million for the third quarter of 2026, compared with $13.1 million for the comparable quarter of 2025, reflecting an increase in personnel and pre-commercial investments to prepare for a potential AXPAXLI wet AMD launch.

General and administrative expenses were $18.8 million for the third quarter of 2026, compared with $16.0 million for the comparable quarter of 2025 reflecting increased personnel costs and additional infrastructure to support an increased scope of clinical trials and manufacturing expansion.

Net loss for the third quarter of 2026 was $(94.8) million, or a net loss of $(0.42) per share on both a basic and diluted basis, compared with a net loss of $(69.4) million, or a net loss of $(0.38) per share on a basic and diluted basis, for the comparable quarter of 2025.

Outstanding shares as of November 06, 2026, were approximately 220.0 million.

Conference Call and Webcast Information:

Ocular Therapeutix will host a conference call and webcast on Monday, November 9, 2026, at 8:00 AM ET to discuss recent business progress and financial results for the third quarter ended September 30, 2026. To access the call, please dial: 1-833-419-0865 (U.S.) or 1-785-838-9333 (International). The live webcast can be accessed HERE (Conference ID: OCULAR) and 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™ (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.

The safety and efficacy profile of AXPAXLI has not been established by the FDA or any other regulatory authority, and AXPAXLI has not been approved for marketing.

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 (~20/200). In December 2025, the trial completed the randomization of 640 subjects.

This non-inferiority trial includes a patient enrichment strategy over the six months prior to randomization that includes three screening doses of any anti-VEGF therapy, excluding brolucizumab-dbll, 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 40. The non-inferiority margin for the lower bound of the 95% confidence interval is -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every eight weeks.

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 48 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 48, and 96. 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 and timing of 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 protocol of the Company's SOL-X clinical trial; 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; 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 and Pre-NDA meetings 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.
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Ocular Therapeutix, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 530,612	$ 737,060
Accounts receivable, net	31,388	30,650
Inventory	4,260	3,564
Prepaid expenses and other current assets	8,340	10,855
Total current assets	574,600	782,129
Property and equipment, net	20,281	19,676
Restricted cash	1,614	1,614
Operating lease assets	5,926	4,638
Other non-current assets	3,226	—
Total assets	$ 605,647	$ 808,057
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,745	$ 4,154
Accrued expenses and other current liabilities	54,440	43,835
Operating lease liabilities	2,832	2,817
Total current liabilities	63,017	50,806
Other liabilities:		
Operating lease liabilities, net of current portion	3,646	2,815
Derivative liability	9,547	13,903
Deferred revenue	14,000	14,000
Notes payable, net	73,535	71,336
Other non-current liabilities	953	887
Total liabilities	164,698	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 September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.0001 par value; 400,000,000 and 400,000,000 shares authorized and 219,884,956 and 215,927,600 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	22	22
Additional paid-in capital	1,860,107	1,811,311
Accumulated deficit	(1,419,180)	(1,157,023)
Total stockholders' equity	440,949	654,310
Total liabilities and stockholders' equity	$ 605,647	$ 808,057

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue:				
Product revenue, net	$ 12,874	$ 14,544	$ 37,134	$ 38,573
Collaboration revenue	—	—	—	128
Total revenue, net	12,874	14,544	37,134	38,701
Costs and operating expenses:				
Cost of product revenue	1,455	1,774	4,795	4,980
Research and development	74,787	52,358	195,138	146,296
Selling and marketing	15,658	13,088	49,511	40,965
General and administrative	18,832	16,022	60,998	46,717
Total costs and operating expenses	110,732	83,242	310,442	238,958
Loss from operations	(97,858)	(68,698)	(273,308)	(200,257)
Other income (expense):				
Interest income	4,978	3,729	16,478	11,012
Interest expense	(2,814)	(3,002)	(8,383)	(9,003)
Change in fair value of derivative liabilities	912	(1,447)	3,056	(3,066)
Gain on sale of property and equipment	—	—	—	29
Total other income (expense), net	3,076	(720)	11,151	(1,028)
Net loss	$ (94,782)	$ (69,418)	$ (262,157)	$ (201,285)
Net loss per share, basic	$ (0.42)	$ (0.38)	$ (1.17)	$ (1.15)
Weighted average common shares outstanding, basic	225,515,234	183,919,808	224,860,835	175,356,729
Net loss per share, diluted	$ (0.42)	$ (0.38)	$ (1.17)	$ (1.15)
Weighted average common shares outstanding, diluted	225,515,234	183,919,808	224,860,835	175,356,729