Ocular Therapeutix™ Investor Day to Highlight U.S. FDA Alignment on AXPAXLI™ NDA with Submission Planned for Fourth Quarter 2026

June 17, 2026

Per May 2026 Type C meeting, AXPAXLI NDA for wet AMD to be based on SOL-1 Week 52 efficacy and safety plus interim SOL-R safety data

Ocular to conduct interim SOL-R safety analysis in 4Q 2026 to reach >300 patients of safety data across SOL-1 and SOL-R, in alignment with FDA requirements

Complete AXPAXLI NDA package in wet AMD planned to be submitted in 4Q 2026

SOL-R efficacy data no longer part of the AXPAXLI NDA submission plan

Ocular will evaluate superiority of AXPAXLI vs aflibercept (8mg) Q6M at Week 96 as a key secondary endpoint of the SOL-R trial

SOL-R to remain masked through Week 96, with topline results now expected in 1Q 2028

New secondary endpoint addition to SOL-R has the potential to establish AXPAXLI as a best-in-disease agent for wet AMD and further differentiate potential label to support broad global adoption, if approved

In alignment with the FDA, Ocular plans to submit its NDA under the 505(b)(2) pathway, with potential to accelerate the review timeline by up to 60 days

Following strong SOL-1 data, diabetic retinopathy program also streamlined to prioritize HELIOS-3 as a potential single registrational trial evaluating Q12M dosing of AXPAXLI

The event will begin at 2:00 PM ET today in New York City with virtual access available

BEDFORD, Mass., June 17, 2026 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, “Ocular”), an integrated biopharmaceutical company committed to redefining the retina experience, will host an Investor Day today to showcase its FDA-aligned plans to submit its NDA for AXPAXLI™ (also known as OTX-TKI) in wet AMD in the fourth quarter of 2026 based on SOL-1 efficacy and safety data together with interim SOL-R safety data. With SOL-R efficacy data no longer part of the planned AXPAXLI NDA submission, Ocular is amending the design of SOL-R and plans to extend masking to evaluate new secondary endpoints at Week 96 to show potential superiority in best corrected visual acuity (BCVA) over aflibercept (8 mg) and to support further differentiation from aflibercept (2 mg) in the potential label for AXPAXLI. Topline data for SOL-R are now expected during the first quarter of 2028. Ocular also plans to streamline its registrational program in non-proliferative diabetic retinopathy (NPDR) to prioritize a single Phase 3 trial, HELIOS-3.

“Our consistently strong execution has brought us to a pivotal milestone today. We are thrilled to announce that we have FDA alignment on our plans to submit the AXPAXLI NDA for wet AMD in the fourth quarter of 2026, based on SOL-1 efficacy and safety data, combined with interim safety data from SOL-R. This approach reflects our unwavering commitment to bring AXPAXLI to patients as quickly as possible while mitigating regulatory risk,” said **Pravin U. Dugel, MD, Executive Chairman, President and CEO of Ocular Therapeutix**. “The strength of the SOL-1 data speaks for itself. It is the first successful trial in wet AMD for a novel agent showing superiority over an approved anti-VEGF. The data for AXPAXLI from SOL-1 showed unmatched durability and a level of sustained disease control that is simply unprecedented in this space. Because of these outstanding data, and with SOL-R year one efficacy data no longer being part of our planned NDA submission, we are now in the extraordinary position of using the SOL-R trial to best serve our long-term strategic objective for AXPAXLI: to become the best-in-disease agent for wet AMD. We are now adding a new key secondary endpoint of superiority in mean change in BCVA compared to aflibercept (8 mg) in SOL-R which will be evaluated at Week 96, and we also hope to demonstrate the prevention of fibrosis and atrophy with AXPAXLI relative to aflibercept (2 mg) at this timepoint. Expanding on our confidence in AXPAXLI and based on the demonstration of up to 12 months of durability seen in SOL-1 and HELIOS-1, we have also made the strategic decision to streamline our diabetic retinopathy program to prioritize a single global registrational trial, HELIOS-3, evaluating Q12M AXPAXLI versus sham. Our market research shows retina specialists strongly favor a once-yearly regimen for rapid uptake in diabetic retinopathy, and HELIOS-3 also supports our global objectives. With FDA alignment regarding our NDA submission for wet AMD, planned for the fourth quarter of 2026, and our commercial readiness efforts advancing rapidly, we are well positioned to bring AXPAXLI to patients in 2027, if approved, not only as a potential best-in-class agent, but also as the first-in-class.”

Lejla Vajzovic, MD, FASRS, Professor of Ophthalmology with Tenure at Duke University School of Medicine, added**,**

“SOL-1 gives retina specialists everything we need to start using AXPAXLI immediately and broadly, if approved. The unmet need in wet AMD is not abstract – it is something we confront daily. Over 40% of patients discontinue or are non-adherent to treatment within the first year alone because the treatment burden can be simply unsustainable. Missed visits mean lost vision, and current therapies offer no cushion for the realities of patients’ lives. AXPAXLI has the potential to provide that cushion. What retina specialists have been searching for is a therapy that can provide sustained disease control without requiring constant retreatment, and the SOL-1 data suggest AXPAXLI may finally deliver that. The results demonstrated clinically meaningful durability, robust anatomical control, and vision outcomes that were maintained through one year with substantially fewer interventions than we are accustomed to seeing in clinical practice. Ocular’s commitment to bringing AXPAXLI to patients as quickly as possible is clear, and that urgency is exactly what these patients deserve.”

Investor Day Highlights

Wet Age-Related Macular Degeneration (wet AMD) Program Highlights

- **During May 2026 Type C Meeting, Ocular reached alignment with U.S. FDA to submit AXPAXLI New Drug Application (NDA) in wet AMD based on SOL-1 data plus confirmatory evidence under the 505(b)(2) pathway.** SOL-1 constitutes an adequate and well-controlled study, as previously aligned through a Special Protocol Assessment (SPA) agreement, with a p-value for its primary endpoint (p=0.0006) that is highly supportive of a single trial approval. Based on its Type C Meeting with the FDA, Ocular plans to submit its NDA under the 505(b)(2) pathway. The 505(b)(2) pathway can accelerate the review timeline for new formulations, dosages, routes of administration, or indications of previously approved drugs by up to 60 days.

- **FDA indicates it will review the NDA submission based on a single pivotal trial in light of results from SOL-1 at Week 52.** SOL-1 demonstrated superiority on the pre-specified primary endpoint of maintenance of vision at Week 36, with strengthening effect size over time, consistent visual outcomes, and supportive anatomic benefits, which together create a highly persuasive data package around substantial evidence of efficacy. All six pre-specified sensitivity analyses for the SOL-1 primary endpoint at Week 36 were statistically significant, and the first three of five hierarchically controlled key secondary endpoints were also met with statistical significance.

- **Ocular plans to support its NDA submission for AXPAXLI with broad confirmatory evidence.** The U.S. FDA defines confirmatory evidence in its September 2023 draft guidance for industry titled *“Demonstrating Substantial Evidence of Effectiveness with One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence”.* The AXPAXLI NDA is expected to be supported by strong confirmatory evidence, including mechanistic, pharmacodynamic, animal model, natural history, class consistency, and real-world evidence.

- **To meet FDA requirements for safety exposure, Ocular plans to conduct an interim safety analysis for SOL-R in fourth quarter of 2026.** The U.S. FDA notes that one trial may establish effectiveness but still requires adequate safety exposure, defined in the 2023 guidance for neovascular AMD trials as a minimum of 300 patients at the time of NDA submission. With 170 subjects receiving AXPAXLI in SOL-1, Ocular plans to conduct an interim safety analysis of patients completing one year in SOL-R during the fourth quarter of 2026 to reach an aggregate of greater than 300 patients with at least one year of treatment across SOL-1 and SOL-R. Because of the interim analysis, SOL-R will incur a 0.0001 alpha penalty during its statistical analysis.

- **Ocular plans to hold a pre-NDA meeting in third quarter of 2026 with U.S. FDA.** The meeting is intended to confirm the format and content of information to be submitted in the NDA and to ensure the FDA has exactly what it needs to review the drug for marketing approval.

- **The Company expects to submit a complete NDA package in fourth quarter of 2026.** At the standard 120-day safety update following the submission of its NDA, Ocular plans to submit Year 2 SOL-1 safety data to the FDA to support repeat dosing on a potential label for AXPAXLI, if approved.

- **Because SOL-R efficacy is no longer part of the planned NDA submission or review, Ocular intends to leverage the trial to best serve its long-term strategic objectives for AXPAXLI. This includes maintaining masking of SOL-R to subjects, investigators, and the Company until Week 96 to evaluate new secondary endpoints, with topline data now expected in first quarter of 2028.**

    - A new key secondary endpoint is evaluating superiority to aflibercept (8 mg) in terms of mean change in BCVA from baseline to Week 96. Subjects in the masking arm of SOL-R receive aflibercept (8 mg) every 24 weeks, matching the same cadence as the AXPAXLI arm. The aflibercept (8 mg) dosing interval in wet AMD was recently expanded for up to every five months dosing after one year of treatment. This new key secondary endpoint in SOL-R will be evaluated at Week 96 to align as closely with aflibercept (8 mg) Year 2 approved dosing interval as possible.

    - To show further differentiation from aflibercept (2 mg), dosed every eight weeks in SOL-R, Ocular intends to evaluate prevention of fibrosis and atrophy at Week 96 in a masked manner, potentially enabling its inclusion on the AXPAXLI label.

- The SOL-R primary endpoint of non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept (2 mg) arms at Week 56 remains unchanged. Ocular will not enroll additional subjects in SOL-R, and the Company does not plan to include SOL-R efficacy data as part of its planned NDA submission in the fourth quarter of 2026 or during the subsequent review period.

"The regulatory framework for single-trial approval requires an adequate and well-controlled study, a protocol that is aligned with the FDA, the primary endpoint to be met with high statistical significance, clinically meaningful results, a robust safety dataset, and supporting confirmatory evidence," commented **Arshad M. Khanani, MD, MA, FASRS, Director of Clinical Research at Sierra Eye Associates in Reno, Nevada, and Steering Committee Chair for the SOL Program.** "SOL-1 trial results potentially meet this high bar of a single trial approval with the combined data from the planned SOL-R interim analysis providing the required >300 patients for the safety dataset. SOL-1 was aligned with the FDA through its SPA agreement in advance, met its primary endpoint with a p-value of 0.0006, showed clinically meaningful visual outcomes with durability up to one year with robust anatomic benefit to match, and a well-tolerated safety profile. Each criterion independently is compelling, and collectively they provide an incredibly strong regulatory package. If approved, AXPAXLI has the potential to significantly reduce treatment burden and optimize long-term vision outcomes for our patients with wet AMD."

Diabetic Retinopathy (DR) Program Highlights

- **Ocular announced plans to streamline its diabetic retinopathy (DR) program to prioritize a single global registrational superiority study, HELIOS-3.** Based on the strength of the SOL-1 and prior HELIOS-1 data, along with emerging market research indicating strong physician preference for a once-yearly treatment paradigm in DR, the Company plans to advance a streamlined superiority trial evaluating AXPAXLI Q12M versus sham. In HELIOS-3, non-proliferative diabetic retinopathy (NPDR) subjects will receive either AXPAXLI or sham injections at randomization and Week 48. The primary endpoint for HELIOS-3, an ordinal ≥2-step change in diabetic retinopathy severity score (DRSS), will be measured at Week 56. The Company expects the streamlined approach to preserve its ability to achieve global regulatory objectives and maximize the commercial opportunity for AXPAXLI in diabetic retinal disease. The trial is intended to support a broad DR label, including patients with non-center-involved diabetic macular edema (non-CI DME).

Click here to register for Ocular's Investor Day which will begin at 2:00 PM ET today. A live webcast of the presentation will be available on the "Events and Presentations" section of the Company's website. A replay of the webcast will be archived for at least 30 days following the presentation.

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 (~20/200). In December 2025, the trial completed the randomization of 631 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 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 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 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 1.7 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.

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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 and Week 52 data from an interim safety analysis to be conducted in the Company's SOL-R clinical trial 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 and SOL-R Phase 3 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; 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 label of AXPAXLI, if approved; 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; 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; 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 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.

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