Ocular Therapeutix™ Investor Day to Highlight Exceptional AXPAXLI™ Progress Across SOL Program and Detail Registrational Trial Plans to Pursue a Diabetic Retinopathy Label with a Novel Primary Endpoint

September 30, 2025

SOL-1 superiority trial continues to demonstrate outstanding patient retention and protocol adherence, with no new or unexpected safety signals observed to date; topline data on track for 1Q 2026

Event to detail how robust SOL-R patient selection strategy, trial design, and potential SOL-1 success could drive confidence in SOL-R outcomes; topline data on track for 1H 2027

Will showcase planned HELIOS-2 and HELIOS-3 registrational trials to evaluate AXPAXLI in non-proliferative diabetic retinopathy (NPDR) using novel primary endpoint, aligned with FDA in HELIOS-2 Special Protocol Assessment (SPA) agreement

To outline SOL-X open label extension program and AXPAXLI's potential to improve long-term outcomes and expand the retinal vascular disease market

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

BEDFORD, Mass., Sept. 30, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), an integrated biopharmaceutical company committed to redefining the retina experience, will host an Investor Day today where it will highlight outstanding progress in the SOL wet AMD registrational program, announce plans for a registrational program in non-proliferative diabetic retinopathy (NPDR), and share further details on how AXPAXLI™ (also known as OTX-TKI) is being positioned to redefine retina treatment.

"I continue to be incredibly confident and enthusiastic about the future of Ocular Therapeutix," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer of Ocular Therapeutix**. "At our Investor Day, we will highlight how Ocular is uniquely positioned for success, anchored by AXPAXLI's potential to have the first superiority label compared to a single dose of aflibercept (2 mg) in wet AMD, targeting a large market opportunity with significant potential for expansion, and seamless adoptability into clinical practice. A superiority label may allow physicians to avoid step therapy, enabling them to choose the optimal drug for their patients. We believe AXPAXLI is well-positioned to optimize retina practices worldwide, allowing physicians to see more patients, less often."

Dr. Dugel continued, "We are especially thrilled to unveil our plans for diabetic retinopathy (DR) with our HELIOS-2 and HELIOS-3 registrational trials. We have designed these trials to include a novel primary endpoint that we believe has the highest probability of success. This new endpoint is FDA-aligned with a Special Protocol Assessment (SPA) agreement for HELIOS-2. We will also share new details on our SOL-X open label extension study in wet AMD, and why we believe a positive SOL-1 readout could provide strong read through to SOL-R. All of this exceptional progress, coupled with the significant market opportunity, is the reason for our enthusiasm and continued confidence moving forward."

Investor Day Highlights

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

- **SOL-1 (Phase 3, wet AMD) retention and protocol adherence continues to be exceptional, with topline data on track for 1Q 2026.** The SOL-1 superiority trial, conducted under an SPA agreement with the U.S. Food and Drug Administration (FDA), has the potential to support the first label with a superiority claim over a single dose of aflibercept (2 mg) for any wet AMD product. Retention in the trial continues to be outstanding, with >95% of randomized subjects remaining on-study to date. Rescues reviewed under masking suggest >95% of rescue events have met protocol-defined criteria. Further, to ensure patient safety, the SOL-1 trial is overseen by an independent data and safety monitoring committee (DSMC) which has not identified any new or unexpected safety signals to date.

- **Robust SOL-R (Phase 3, wet AMD) patient selection strategy, trial design, and potential SOL-1 success drive confidence in SOL-R outcomes, with topline data on track for 1H 2027.** The SOL-R non-inferiority trial complements SOL-1 with the potential to provide data supporting the immediate adoption of AXPAXLI into clinical practice, if approved. Prior Phase 3 trials for other wet AMD drugs have shown that patients with persistent retinal fluid introduce variability and can disrupt non-inferiority trials. Therefore, SOL-R incorporates a comprehensive 24-week screening and loading phase to exclude subjects with early persistent fluid and to randomize subjects with less variability in visual acuity. In addition to patient selection, Ocular believes the singular Week 56 primary endpoint in SOL-R is favorable as subjects will have

received their most recent aflibercept or AXPAXLI injection eight weeks prior, at Week 48.

Assuming positive data from its registrational trials, Ocular expects a New Drug Application (NDA) package would include SOL-1 two-year safety data (including re-dosing every six months in year two of the trial), along with SOL-R 56-week data. Ocular believes this NDA package would exceed the requirements for the FDA's safety database at the maximum dose and most frequent cadence being proposed for marketing. Ocular plans to leverage the 505(b)(2) NDA pathway to potentially streamline the FDA review process.

"The complementary SOL-1 and SOL-R trials have positioned Ocular to elegantly answer the questions that data purists like myself are looking for," said **Adnan Tufail, MBBS, MD, FRCOphth, Consultant Ophthalmologist in Medical Retina Service at Moorfields Eye Hospital, London and Professor at The Institute of Ophthalmology, University College London**. "What we really need in our clinical environments, worldwide, is a genuinely more durable therapy. Even with our best and latest therapies, when we begin to use them in the real-world setting, we see vision trailing off over time. If these trials both succeed, we will have seen that AXPAXLI was more durable than aflibercept (2mg) and sustained a benefit at a predictable low frequency of re-dosing, giving retina specialists the data and confidence needed to plan clinical use optimally to be able to reach more patients. I believe two successful readouts should set up AXPAXLI for strong and immediate adoption."

- **SOL-X open-label wet AMD extension study to evaluate the potential of AXPAXLI to improve long-term outcomes and provide commercial advantages.** Subjects who have completed two-year follow-up in either SOL-1 or SOL-R will have an opportunity to enroll in the SOL-X study for an additional three years. SOL-X outcomes may further expand AXPAXLI's potential by highlighting the need to start AXPAXLI treatment early or risk worse long-term visual outcomes due to potential fibrosis and atrophy that may be seen with pulsatile treatments. By reducing the treatment burden and improving long-term outcomes, Ocular believes the data from SOL-X could increase both short-term and long-term patient retention significantly, thereby expanding the market opportunity.

Diabetic Retinopathy (DR) Program Highlights

- **Ocular announced plans to initiate two superiority registrational trials in non-proliferative diabetic retinopathy (NPDR), targeting a broad DR label: HELIOS-2 and HELIOS-3 (Phase 3, NPDR).** Proactive anti-VEGF treatment of NPDR has been observed to benefit patients, but this treatment regimen is burdensome for a working-age patient population. The treatment burden is unsustainable for many, if not most, of these patients, as evidenced by less than 1% of the prevalent population currently receiving treatment. Ocular plans to target a broad label in DR by including subjects with non-center-involved diabetic macular edema (non-CI-DME) in its Phase 3 program. Based on the success of the HELIOS-1 trial, Ocular is preparing to initiate the HELIOS registrational program imminently with the goal of evaluating 6- and 12-month dosing intervals.

  HELIOS-2 is a two-arm superiority trial to be conducted in approximately 432 subjects (randomized 1:1) under an SPA agreement with the FDA. The trial is designed to evaluate a single AXPAXLI injection compared to a single ranibizumab (0.3 mg) injection, with a 52-week primary endpoint. Subjects will be re-treated at Week 52, then followed for safety until the end of Year 2.

  HELIOS-3 is a three-arm superiority trial to be conducted in approximately 930 subjects (randomized 1:1:1) designed to compare two dosing regimens of AXPAXLI to sham, with a 52-week primary endpoint. The first AXPAXLI arm will be treated at Day 1 and Week 24. The second AXPAXLI arm will be treated at Day 1 and will receive a sham injection at Week 24. The third arm will receive a sham injection at Day 1 and Week 24. This trial will conclude after the primary endpoint. While HELIOS-3 uses sham injections for masking, Ocular has not used sham injections in their ongoing registrational wet AMD trials where such use could influence outcomes as wet AMD trials rely on a subjective vision-based primary endpoint. DR trials, on the other hand, use an objective photographic DRSS primary endpoint and the use of sham injections for masking should not influence outcomes. Furthermore, similar to sham injections, the standard of care (SoC) in NPDR is largely watchful waiting, with <1% of patients being treated with approved anti-VEGF treatments.

- **Registrational NPDR trials will leverage a novel ordinal ≥2-step diabetic retinopathy severity score (DRSS) primary endpoint, aligned with FDA in the SPA agreement for HELIOS-2.** Historically, either a ≥2-step improvement in DRSS or prevention of ≥2-step DRSS worsening have been used as binary endpoints. The HELIOS program will be the first time an ordinal endpoint is being used in DR trials, which means the statistical analysis will account for both disease improvement and prevention of worsening. These are both clinically meaningful measures for retina specialists in the context of a disease that gets progressively worse if untreated. The use of the novel ordinal endpoint means that every patient will contribute data to the statistical analysis, allowing for a smaller trial size to achieve statistically significant outcomes relative to the size required for a binary analysis. Ocular believes the ordinal DRSS endpoint enables a higher probability of success with smaller, shorter, more relevant, and less expensive trials, relative to other potential endpoints.

"Securing regulatory agency agreement on a novel ordinal endpoint for a pivotal trial in NPDR through an SPA agreement is a significant achievement that highlights the deliberate approach of the Ocular Therapeutix team based on strong scientific and clinical capabilities," said **Arshad M. Khanani, MD, MA, FASRS, Director of Clinical Research at Sierra Eye Associates in Reno, Nevada**. "Based on the encouraging HELIOS-1 data, AXPAXLI shows promise in addressing the unmet need for a long-acting treatment for diabetic retinopathy. The use of an ordinal endpoint, which is more clinically meaningful and de-risking, could support a smaller and efficient pivotal trial, potentially accelerating the availability of AXPAXLI for DR patients. I am looking

forward to participating in the planned pivotal trial and enrolling eligible patients."

"We at Ocular Therapeutix believe that this novel ordinal endpoint has the potential to become the gold standard for all DR trials going forward," said **Peter K. Kaiser, MD**, **Chief Development Officer** of Ocular Therapeutix. "The ordinal endpoint is ideal for DR, offering what we believe is a logical, ethical, and efficient approach. This new approach is validated with the FDA's written agreement on our HELIOS-2 trial design, being conducted under an SPA agreement. Typical "binary" DRSS change endpoints exclude clinically meaningful data by limiting focus to either disease improvement or worsening. A "prevention of vision threatening complications (VTC)" endpoint forces patients and their doctors to wait for actual loss of vision before rescuing these late-occurring events, which is an impractical approach as this could result in permanent loss of vision especially in proliferative diabetic retinopathy (PDR). Considering these limitations, we developed a novel endpoint that answers clinically relevant questions while remaining centered around patients."

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, diabetic retinopathy, and other retinal diseases.

About the SOL-1 Study
The registrational Phase 3 SOL-1 trial (NCT06223958) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye.

The superiority study has an eight-week loading segment prior to randomization. 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 or gain at least 10 early treatment diabetic retinopathy study (ETDRS) letters at Day 1 along with a CSFT of ≤350 µm are then randomized to receive a single dose of AXPAXLI 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 or aflibercept (2 mg). Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. The clinical trial protocol requires that, during the study, subjects in either arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, defined as a loss of <15 ETDRS letters of BCVA, at Week 36. Subjects will continue to be evaluated for durability up to Week 52. The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

About the SOL-R Study
The registrational Phase 3 SOL-R trial (NCT06495918) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (2:2:1), three-arm study that includes sites located in the U.S., Argentina, India, and Australia. The trial is intended to randomize approximately 555 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, subjects must have a BCVA ETDRS letter score of ≥34 (~20/200).

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 significant retinal fluid fluctuations. Subjects that 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 will enter a run-in period and receive two loading doses of aflibercept (2 mg) prior to Day 1. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Weeks 24, 48, and 72. Subjects in the second arm receive aflibercept (2 mg) on-label every eight weeks. 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 Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. 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-micron 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 study, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled study in support of a potential New Drug Application and product label for wet AMD.

About the SOL-X Study

The SOL-X trial 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 completed either the SOL-1 or SOL-R studies through the end of the Year 2 visit.

All subjects will be given AXPAXLI every 6 months starting at Week 0 (Week 104 in SOL-1, Week 96 in SOL-R), at Week 24, Week 48, Week 72, Week 96, and Week 120. Subjects are assessed at Week 4 and Week 12, 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-1 Study
The Phase 1 HELIOS-1 trial was a multi-center, double-masked, randomized (2:1), parallel group study conducted in the U.S. The study was designed to evaluate the safety, tolerability, and efficacy of AXPAXLI compared to a sham control in subjects with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) without center-involved diabetic macular edema (CI-DME). The primary endpoint of the study was frequency of treatment emergent adverse events (TEAEs). Secondary study endpoints included changes in the diabetic retinopathy severity score (DRSS), changes in best corrected visual acuity (BCVA) compared to baseline, changes in central subfield thickness (CSFT) compared to baseline, and the portion of subjects receiving rescue therapy. The study has been completed.

About the HELIOS-2 Study
The planned registrational Phase 3 HELIOS-2 trial is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study.

This trial is a superiority study of AXPAXLI in approximately 432 subjects with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) without center-involved diabetic macular edema (CI-DME). Eligible subjects are randomized to receive a single dose of AXPAXLI or a single dose of ranibizumab (0.3 mg). At Week 52, all subjects are re-dosed with their respective initial treatment of AXPAXLI or ranibizumab (0.3 mg). Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2.

The primary endpoint of HELIOS-2 is the ordinal DRSS 2-step change status at Week 52 from baseline (≥2-step improvement, ≥2-step worsening, less than 2-step change in either direction). The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

About the HELIOS-3 Study
The planned registrational Phase 3 HELIOS-3 trial is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1:1), three-arm study. This trial will be the second superiority study of AXPAXLI in approximately 930 subjects with moderately severe to severe non-proliferative diabetic retinopathy (NPDR) without center-involved diabetic macular edema (CI-DME).

Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Week 24. Subjects in the second arm receive a single dose of AXPAXLI at Day 1 and sham at Week 24. Subjects in the third arm receive sham at Day 1 and at Week 24 aligned with the AXPAXLI treatment arms for adequate masking. Throughout the study, subjects are assessed every 12 weeks.

The primary endpoint of HELIOS-3 is the ordinal DRSS 2-step change status at Week 52 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 14.5 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 Eye Disease
Diabetic eye 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 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), with a Phase 3 clinical program for non-proliferative diabetic retinopathy (NPDR) planned to be initiated imminently.

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 is currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Explore the Company's new corporate branding and follow the Company on its website, LinkedIn, or X.

Forward-Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company's product candidates, the timing, design, enrollment, randomization, conduct and retention of subjects in the Company's clinical trials, including the Company's SOL-1 and SOL-R Phase 3 clinical trials of AXPAXLI (also known as OTX-TKI) for the treatment of wet AMD, the Company's planned SOL-X clinical trial of AXPAXLI for the treatment of wet AMD, and the Company's planned HELIOS-2 and HELIOS-3 Phase 3 clinical trials of AXPAXLI for the treatment of NPDR; the Company's plan to plans to advance AXPAXLI, OTX-TIC, and its other product candidates; the potential utility or adoption, if approved, of any of the Company's product candidates; the Company's cash runway and the sufficiency of the Company's cash resources; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "designed", "goal", "may", "might", "plan", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials, including the SOL-1 trial, the SOL-R trial, the planned SOL-X trial, the planned HELIOS-2 trial, and the planned HELIOS-3 trial; the risk that the 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 and HELIOS-2 trials; the risk that even though the FDA has agreed with the overall design of the SOL-1 and HELIOS-2 trials, the FDA may not find that the data generated by the applicable trial supports potential marketing approval; the risk that the FDA might not agree to the Company's design, protocol, and statistical analysis plan of the SOL-R trial or the planned HELIOS-3 trial; the risk that the Company and the FDA may not agree on the registrational pathway for any of its product candidates; 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 (including masked safety or masked rescue data from the Company's SOL-1 trial or SOL-R 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 whether data from the Company's SOL-X trial will demonstrate clinically meaningful, long-term benefits; uncertainties regarding the potential commercial advantages and/or position of the Company's product candidates; 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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