



Oculis to Showcase Transformative Late-stage Pipeline in Neuro-ophthalmology and Ophthalmology at the 2026 J.P. Morgan Healthcare Conference

Jan 8, 2026

- *Breakthrough therapy designation granted as Company advances the PIONEER registrational program in optic neuropathies to create a potential market of \$7B+ in the U.S. alone*
- *Multiple milestones anticipated from late-stage portfolio including topline results from DIAMOND Phase 3 trials with OCS-01 eye drops in diabetic macular edema (DME) expected in Q2 2026*
- *Riad Sherif, M.D., Chief Executive Officer, will present at the J.P. Morgan Healthcare Conference on Wednesday, January 14, 2026, at 1.30pm PST*

ZUG, Switzerland, Jan. 08, 2026 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) ("Oculis"), a global biopharmaceutical company focused on breakthrough innovations to address significant unmet medical needs in ophthalmology and neuro-ophthalmology, today announced that the transformative potential of its late-stage pipeline, including breakthrough therapy Privosegtor, the novel neuroprotective candidate in development for optic neuropathies, and novel eye drop candidate, OCS-01, for diabetic macular edema, will be highlighted in its company presentation at the upcoming 44th Annual J.P. Morgan Healthcare Conference in San Francisco, California.

Oculis recently announced that Privosegtor, a neuroprotective candidate, has been granted breakthrough therapy designation by the U.S. FDA for the treatment of optic neuritis based on the successful ACUITY Phase 2 trial results. Privosegtor is a novel peptoid small molecule designed to cross both the blood-brain and retinal barriers and has the potential to become the first neuroprotective therapy for optic neuropathies. These serious conditions carry a significant unmet need as they can lead to permanent vision loss from nerve cell damage or death.

In the ACUITY trial, Privosegtor delivered substantial improvements in vision on the 2.5% ETDRS Low-Contrast Letter Acuity chart. Patients receiving Privosegtor 3mg/kg/day plus IV methylprednisolone gained an average of 18 letters at three months compared with placebo plus IV methylprednisolone. For context, a 15-letter (three-line) gain represents a two-fold improvement in visual resolution and is considered clinically meaningful for patients. Privosegtor also showed anatomical preservation of retinal and optic nerve structure, which are typically damaged during acute optic neuritis. Additional analyses showed reduced neurofilament release, a biomarker of neuroaxonal damage, in conditions such as multiple sclerosis. The most common drug-related adverse events (AEs) were headache and acne (each in two participants; 10.5%). No drug-related serious AEs or AEs leading to treatment or study discontinuations occurred.

Following a successful meeting with the FDA in 2025, Oculis launched the PIONEER program, which includes three pivotal trials to support registration plans for Privosegtor in two indications: optic neuritis and a second rare neuro-ophthalmic disease, non-arteritic anterior optic neuropathy (NAION). These two optic neuropathies represent a potential market opportunity exceeding \$7 billion in the U.S. alone, given the significant unmet medical need. The first trial in the program, PIONEER-1 in optic neuritis, was initiated in Q4 last year. This global study spans three continents, sites activation is underway, and enrollment is expected to begin shortly.

Oculis's most advanced product candidate, OCS-01, is currently in Phase 3 development and aims to be the first eye drop for diabetic macular edema (DME). In the U.S. alone, the diagnosed DME population is estimated to be around 1.8 million¹ and currently represents a ~\$3 billion market opportunity¹ with high unmet medical needs for early intervention and for patients with inadequate response to standard of care, which could be addressed with OCS-01 eye drops, if approved. Topline results from both DIAMOND Phase 3 trials are expected in Q2 2026 with NDA submission to the FDA planned for Q4 2026.

Riad Sherif, M.D., Chief Executive Officer of Oculis, stated, "With Privosegtor advancing as a neuroprotective platform, starting with optic neuropathies as the initial focus, Oculis is uniquely positioned to transform the treatment landscape in areas with substantial unmet needs in neuro-axonal diseases, potentially creating a market exceeding \$30 billion. 2026 is set to be a milestone-rich year across Oculis' late-stage portfolio, including the much-anticipated OCS-01 DIAMOND Phase 3 trials readout in diabetic macular edema, which we look forward to in Q2 2026."

Riad Sherif, M.D., Chief Executive Officer of Oculis, will present at the 44th Annual J.P. Morgan Healthcare Conference as below:

Date: Wednesday, January 14, 2026

Time: 1:30pm (PST)

Venue: Westin St. Francis Hotel, 335 Powell Street, San Francisco, CA94102 (USA)

An audio webcast and replay of the presentation will be available on [the J.P. Morgan website](#). The presentation will also be posted to the Oculis website on the [Events & Presentation](#) page under the Investors & Media section.

About Privosegtor

Privosegtor, a novel peptoid small-molecule candidate that penetrates the blood-brain and retinal barriers, has the potential to become the first neuroprotective therapy for optic neuritis (ON) and other neuro-ophthalmic diseases. Positive results from the ACUITY Phase 2 trial demonstrated Privosegtor's neuroprotective potential through anatomical preservation of the retina and improvements in visual function after an acute episode of optic neuritis. Consistent results were observed in animal models of neuroinflammation and neurodegeneration, where Privosegtor preserved retinal ganglion cell damage and was associated with improvements in mobility (clinical function disability). Privosegtor has received Breakthrough Therapy designation from the FDA and Orphan Drug designation from both the FDA and the EMA for ON and is now entering registrational trials for this indication, as well as a registrational trial in non-arteritic anterior ischemic optic neuropathy (NAION), as part of Oculis' PIONEER (Privosegtor Investigation in Optic Neuropathies Efficacy Evaluation Research) program. In addition to its potential neuroprotective effect on the optic nerve, Privosegtor could also have wide applicability in treating other neuro-ophthalmic and neurological indications.

Privosegtor is an investigational drug and has not received regulatory approval for commercial use in any country.

About Optic Neuritis

Optic Neuritis (ON) is a rare condition characterized by an acute inflammation of the optic nerve that can lead to permanent visual impairment. It affects up to 8 in 100,000 people worldwide with a U.S. incidence estimated to be >30,000 and often represents the first sign of multiple sclerosis². It

mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1)³. ON is a type of neuropathy (nerve disease) that happens when acute inflammation of the optic nerve affects the signals traveling from the eyes through the brain, causing pain, vision loss and other symptoms. The cells that make up the optic nerve have a lipid protective coating called a myelin sheath, which is preferentially damaged in ON. Without myelin, the optic nerve cells can't send signals properly and axons can be irreversibly lost. To date there is no specific therapy approved for acute optic neuritis and the unmet needs remain for therapies that can prevent vision loss after an acute episode by reducing nerve cell permanent damage or death.

About Non-arteritic Anterior Ischemic Optic Neuropathy

Non-arteritic anterior ischemic optic neuropathy (NAION) is an acute optic nerve disorder that causes permanent visual impairment in >60% of affected patients⁴. It is the most common cause of acute optic nerve injury in individuals over 50 years old⁵ and affects up to 10.2 per 100,000 people worldwide⁵ with a U.S. incidence estimated to be >30,000^{5,7,8}. In NAION, the optic nerve head region swells and there is painless sudden vision loss. The swelling eventually resolves, but the optic nerve axons and neuronal cell bodies (in the retina) are permanently lost, leading to significant irreversible visual impairment or even blindness⁹. There are no approved therapies for NAION and the unmet medical need is for therapies that preserve vision and provide neuroprotection for patients suffering from NAION.

About OCS-01 eye drops and the OPTIREACH® technology

Leveraging Oculis' proprietary technology, OCS-01 is an OPTIREACH® formulation of high concentration dexamethasone eye drop. It is being developed as an eye drop to treat the retina to offer a non-invasive treatment alternative for diabetic macular edema (DME). This route of administration enables easy access to treatment in the early stages of the disease and can be used in combination with other therapies in later stages. In contrast, all currently available treatments require invasive delivery methods, such as intravitreal injections or ocular implants, to reach the retina. The OPTIREACH® solubilizing formulation technology addresses the main limitations of conventional eye drops by improving the solubility of lipophilic drugs, increasing the residence time on the eye surface and thereby, enabling the drug passage from the eye surface to the posterior segment of the eye. Oculis' OCS-01 is being developed with the aim to transform the current treatment paradigm in DME as a non-invasive topical treatment option.

OCS-01 is an investigational drug in Phase 3 that has not received regulatory approval for commercial use in any country.

About Diabetic Macular Edema

Diabetic Macular Edema (DME) is the leading cause of visual loss and legal blindness in patients with diabetes. Currently, it is estimated to affect around 37 million people worldwide and, with the rise of diabetes, the prevalence is expected to increase to 53 million by 2040^{10,11}. DME is an irreversible and progressive complication of diabetic retinopathy and is related to consistently having high blood sugar levels that damage nerves and blood vessels in the macula, the area of the retina responsible for sharp vision. DME occurs when blood vessels in the retina swell, and then leak, leading to a fluid build-up (edema) into the retina. There remains a significant need for safe, efficacious, and less burdensome treatments for DME patients.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) focused on breakthrough innovations to address significant unmet medical needs in neuro-ophthalmology and ophthalmology. Oculis' highly differentiated late-stage clinical pipeline includes three core product candidates: Privosegtr, a breakthrough neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies like optic neuritis (ON) and non-arteritic anterior ischemic optic neuropathy (NAION), with potentially broad clinical applications in various other neuro-ophthalmic and neurological diseases; OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema (DME); and Licamintimab, a novel, topical anti-TNF α in Phase 2, which is being developed with a genotype-based approach to drive precision medicine in dry eye disease (DED). Headquartered in Switzerland with operations in the U.S. and Iceland, Oculis is led by an experienced management team with a successful track record and supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

Oculis Contact

Ms. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor Relations

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com

Media Relations

ICR Healthcare
Amber Fennell / David Daley / Sean Leous
oculis@icrhealthcare.com

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of the Company's product candidates, the initiation, timing, progress and results of current and future clinical trials, Oculis' research and development programs, regulatory and business strategy, including planned interactions with the FDA; Oculis' future development plans; the timing or likelihood of regulatory filings and approvals; statements about market opportunity, and the Company's expected financial position and cash runway, are forward-looking. All forward-looking statements are based on estimates and assumptions that, while considered reasonable by Oculis and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Oculis' control. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. All forward-looking statements are subject to risks, uncertainties and other factors that may cause actual results to differ materially from those that we expected and/or those expressed or implied by such forward-looking statements. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of Oculis, including those set forth in the Risk Factors section of Oculis' annual report on Form 20-F and any other documents filed with the U.S. Securities and Exchange Commission (SEC). Copies of these documents are available on the SEC's website, www.sec.gov. Oculis undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

References:

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