Oculis to Spotlight Transformative Late-Stage Pipeline at Eyecelerator and AAO 2025

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ZUG, Switzerland, Oct. 14, 2025 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS / XICE: OCS) (“Oculis”), a global biopharmaceutical company focused on developing innovations for ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced that Oculis’ innovative late-stage pipeline will be highlighted at Eyecelerator and at the American Academy of Ophthalmology (AAO) Annual Meeting.

At Eyecelerator, Riad Sherif, MD, Oculis’ Chief Executive Officer, will provide an update on the Company’s innovative late-stage pipeline. Featured updates will include the acceleration of Privosegtor into registrational trials for acute optic neuritis and non-arteritic anterior ischemic optic neuropathy following a positive meeting with the U.S. Food and Drug Administration (FDA); an update on the Phase 3 DIAMOND program with OCS-01 eye drops for diabetic macular edema with expected topline readouts in Q2 2026; and an update on the upcoming PREDICT-1 registrational trial with a genotype-based approach to investigate Licaminlimab in dry eye disease, anticipated to start in Q4 2025.

Surrounding AAO, Oculis will actively participate and support multiple events including Innovate Retina, the Inaugural Meeting of the Society for Artificial Intelligence in Vision and Ophthalmology (SAIVO) and the COPhy Satellite Symposium. At Innovate Retina, Arshad M. Khanani, MD, MS, FASRS, Chair of Oculis’ Retina Scientific Advisory Board and Board Member of Oculis, will join a panel session to discuss the emerging role of eye drops such as OCS-01 in the future treatment paradigms for diabetic macular edema.

Events details are as follows:

Eyecelerator @ AAO 2025:
Format: Corporate presentation
Session: Presenting Company Showcases
Presenter: Riad Sherif, MD, Chief Executive Officer
Presentation date and time: Thursday, October 16, 2025; 1:15 PM ET
Location: Orange County Convention Center, Orlando, FL

Innovate Retina:
Format: Panel discussion
Session: Session #4 - Can Eye drops Replace Intravitreal Injections?
Presenter: Arshad M. Khanani, MD, MA, FASRS
Presentation date and time: Thursday, October 16, 2025; 5:25 PM ET
Location: Hilton, Orlando, FL

SAIVO:
Event date and time: Thursday, October 17, 2025; 6:00 PM ET
Location: Hotel Landy, Orlando, FL

COPhy Satellite Symposium:
Event date and time: Thursday, October 17, 2025; 6:30 PM ET
Location: Hyatt Regency, Orlando, FL

AAO Annual Meeting
Event dates: October 18-20, 2025
Location: Orange County Convention Center, Orlando, FL (booth 1353)

Arshad M. Khanani, MD, MA, FASRS, is a distinguished ophthalmologist who serves as Managing Partner and Director of Clinical Research at Sierra Eye Associates and Clinical Associate Professor at the University of Nevada, Reno School of Medicine. He founded Sierra Eye Associates' clinical research department, which has become one of the nation's leading clinical research centers, where he has served as principal investigator for over 100 clinical trials and contributed to over 75 scientific publications. Dr. Khanani is an elected member of the Macula Society and Retina Society and has received numerous prestigious awards including the ASRS Senior Honor Award and the ASRS Presidents' Young Investigator Award in 2021.

About Privosegtor

Privosegtor is a novel peptoid small molecule candidate with the potential to become the first neuroprotective therapy for acute optic neuritis (AON) and other neuro-ophthalmic diseases. The positive results in the ACUITY Phase 2 trial showed Privosegtor’s potential neuroprotective effects through anatomical preservation of the retina and visual function improvements after an acute episode of optic neuritis. Consistent results were observed in animal models of neuroinflammation and neurodegeneration, where Privosegtor showed preservation of retinal ganglion cell damage and was associated with improvements in mobility (clinical function disability). Privosegtor has received Orphan Drug designation from both the FDA and the EMA for AON and is now entering registrational trials for this indication as well as a registrational trial in nonarteritic anterior ischemic optic neuropathy (NAION) as part of Oculis’ PIONEER (**P**rivosegtor **I**nvestigation in **O**ptic **N**europathies **E**fficacy **E**valuation **R**esearch) program. In addition to its potential effect on neuroprotection of the optic nerve, Privosegtor could also have wide applicability in treating other neuro-ophthalmic and neurology indications.

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

About Acute Optic Neuritis

Acute Optic Neuritis (AON) 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 sclerosis[1]. It mainly occurs in adults between the age of 20 and 40 years and is more frequent in women (2:1)[2]. The acute inflammatory process of optic neuritis leads to the loss of myelin covering the optic nerve and the axons. At the onset, patients often suffer from ocular pain that increases with eye movement and vision loss. Once the inflammation recedes, remyelination often occurs but it is incomplete. Without the myelin sheath protecting the axon, neurons located in demyelinated segments become fragile and prone to death. Unfortunately, damaged axons cannot regrow, leading to permanent visual impairment. Though most patients do not have permanent severe vision loss, visual impairment for images and things of low contrast is a common impairment. This can interfere with reading, pattern recognition and seeing on gray or cloudy days. To date there is no specific

neuroprotective therapy approved for AON and unmet needs remain for therapies that can prevent vision loss after an acute episode of optic neuritis.

About Non-arteritic Anterior Ischemic Optic Neuropathy

Non-arteritic Anterior Ischemic Optic Neuropathy (NAION) is an acute optic nerve disorder and the most common cause of acute optic nerve injury in individuals over 50 years old[3]. It affects up to 10.2 per 100,000 people worldwide[4] with a U.S. incidence estimated to be >30,000[3,5,6]. NAION and Acute Optic Neuritis (AON) injure the optic nerve leading to progressive axonal loss and visual decline, after the acute event. 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 visual impairment or even irreversible blindness[7]. There are no approved therapies for NAION and there remains an unmet medical need 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[8,9]. 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 innovations addressing neuro-ophthalmic conditions with significant unmet medical needs. Oculis' highly differentiated late-stage clinical pipeline includes three core product candidates: Privosegtor, a neuroprotective candidate in the PIONEER program which consists of studies intended to support registration plans for treatment in optic neuropathies like acute optic neuritis (AON) 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 Licaminlimab, a novel, topical anti-TNFα in Phase 2, is being developed with a genotype-based approach to drive personalized 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

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Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the development plans for Privosegtor, OCS-01, and Licaminlimab; the design and timing of clinical trials of Privosegtor, OCS-01, and Licaminlimab; potential effects of Privosegtor and OCS-01, including patient impact and market opportunity; the potential of Privosegtor to be a neuroprotective therapy or treatment for AON, NAION and other neuro-ophthalmic diseases; the potential of OCS-01 to transform the current treatment paradigm in DME as a non-invasive topical treatment option; and Oculis' research and development programs, regulatory and business strategy, future development plans, and management, 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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