Oculis Reports Q1 2026 Financial Results and Provides Company Update

May 11, 2026

- *Pipeline Advancing as Planned, Leading with OCS-01 Key Milestone Completion of LPLV in Both DIAMOND Phase 3 Trials; Data Readout on Track for June 2026*
- *Licaminlimab PREDICT-1 Trial in Active Site Recruitment Phase, Pioneering a Genotype-Driven Path to Precision Medicine in Dry Eye Disease*
- *Privosegtor Regulatory Path Cleared via FDA SPA; PIONEER-1 Phase 3 Trial Advances with Ongoing Site Activation*
- *Cash, cash equivalents, and short-term investments of $277.6 million as of March 31, 2026, providing cash runway into 2H 2029*

ZUG, Switzerland, May 11, 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 results for the first quarter ended March 31, 2026, and provided an overview of the Company's progress.

Riad Sherif, M.D., Chief Executive Officer of Oculis, stated, "We began 2026 with strong execution momentum across our late-stage clinical trials. We are positioned for a pivotal year, with key readouts for OCS-01 in diabetic macular edema (DME) expected in June and Licaminlimab in dry eye disease (DED) around year-end, while the Privosegtor PIONEER program is making significant progress, including PRIME designation in Europe and an agreement with the FDA on the Special Protocol Assessment (SPA) regarding PIONEER-1 and ongoing centers activation. Driven by a mission to restore vision, we are targeting global market opportunities exceeding $30 billion."

Recent Development Highlights and Upcoming Milestones:

OCS-01:

- Last patient last visit (LPLV) completed in the DIAMOND (**DIA**betic **M**acular edema patients **ON** a **D**rop) program, consisting of two Phase 3, double-masked, randomized, multi-center trials to evaluate the efficacy and safety of OCS-01 eye drops in patients with DME following 52-weeks of treatment. Topline results are expected to readout in June 2026, and, if positive, an NDA submission to the FDA is planned for Q4 2026.
- The DME AWARE Delphi study results were recently presented at the 17th annual congress on Controversies in Ophthalmology (COPHy) and at the Association for Research in Vision and Ophthalmology (ARVO) 2026 annual meeting. In this study, supported by Oculis, 25 leading global retina and ophthalmology experts were surveyed to establish consensus on unmet needs in DME. Among other results, the DME AWARE Delphi study revealed broad consensus on the need for novel therapies to enable early treatment. In fact, consensus was reached: 70% of respondents agreed they would initiate therapy with a non-invasive treatment following a 5-letter BCVA vision loss, compared with 5% with the current standard of care, intravitreal treatments. This strongly aligns with our efforts to develop OCS-01 eye drops and our ambition to potentially bring to market the first non-invasive topical treatment for DME.
- Despite available therapies, in the U.S. alone, an estimated 1 million patients out of the 1.8 million people diagnosed with the disease remain untreated with mild to moderate vision impairments, or are inadequately responding to the current standard of care.[1,2,3] OCS-01 is intended to be strategically positioned to capture this significant opportunity by providing a non-invasive, topical eye drop for those requiring early intervention and a versatile option for patients who do not respond to existing injections.

Licaminlimab:

- In prior Phase 2 studies, Licaminlimab showed a substantially greater treatment effect in patients carrying a specific TNFR1 genotype, with profound improvements ranging from 5-fold greater in signs to 7-fold greater in symptoms. PREDICT-1 is designed to leverage these findings to deliver potentially the first precision medicine treatment in ophthalmology and topline results (TLR) are expected to read out around year end.
- In the U.S. alone, approximately 10 million patients suffer from moderate to severe DED.[4] Current disease management relies on trial and error, with a minority (~13%) of patients reporting sustained relief,[5] leading to an 85-90% discontinuation rate within the first 6 months, underscoring the strong need for a targeted, effective treatment approach.[6] Licaminlimab has the potential to transform the current DED treatment paradigm by providing a precision medicine approach with high efficacy, rapid onset of action, and a comfort level similar to artificial tears.

Privosegtor:

- Privosegtor was granted PRIME (PRIority MEdicines) designation by the EMA (European Medicines Agency), a highly selective process to provide early and proactive support to developers of promising medicines that may offer a major therapeutic advantage over existing treatments or provide benefits to patients without treatment options. These medicines are considered priority medicines by the EMA, which aims to optimize development plans and expedite evaluations so that medicines addressing significant unmet medical needs can reach patients faster. This follows the recent granting of Breakthrough Therapy designation for Privosegtor for the treatment of optic neuritis (ON) by the U.S. Food and Drug Administration (FDA), reinforcing global regulatory support for this unique neuroprotective asset.
- Special Protocol Assessment (SPA) agreement received from the FDA regarding the design of the PIONEER-1

(**P**rivosegtor **I**nvestigation in **O**ptic **N**europathies **E**fficacy **E**valuation **R**esearch) registrational trial of Privosegtor in ON. The SPA agreement established a clear pathway to NDA and validates that the clinical trial protocol, size, planned analysis and endpoints are adequate to address scientific and regulatory requirements to support marketing approval, subject to a successful outcome of the trial and review of all data in the NDA. The design of PIONEER-2 is planned to be identical to PIONEER-1. With no currently approved neuroprotective treatments for ON, this SPA agreement is a critical step toward aligning with the FDA on our PIONEER development program.

- Oculis' PIONEER program, supported by the positive Phase 2 ACUITY trial, includes three registrational trials in ON and non-arteritic anterior ischemic optic neuropathy (NAION). These two optic neuropathies can cause permanent visual impairments and represent a potential market opportunity estimated at $7+ billion in the U.S. alone.

Q1 2026 Financial Highlights:

As of March 31, 2026, Oculis held cash, cash equivalents and short-term investments of CHF 222.0 million or $277.6 million, compared to CHF 213.0 million or $268.7 million as of December 31, 2025. The increase in cash, cash equivalents, and short-term investments was primarily due to proceeds received from sales under the Company's existing at-the-market offering program during the quarter, offset by planned operating expenses. Research and development expenses were CHF 14.0 million or $17.9 million for the three months ended March 31, 2026, compared to CHF 14.8 million or $16.4 million in the same period in 2025. The decrease was primarily due to a reduction in spending on external service providers as the DIAMOND program approaches completion and topline data readout. General and administrative expenses were CHF 7.9 million or $10.1 million for the three months ended March 31, 2026, compared to CHF 5.5 million or $6.1 million in the same period in 2025. The increase was primarily driven by share-based compensation expense due to the increased value of awards granted after Q1 2025. The Company's net loss was CHF 28.9 million or $36.8 million for the quarter ended March 31, 2026, compared to CHF 33.2 million or $36.9 million for the same period in 2025. The decrease was primarily due to a CHF 3.9 million or $5.0 million lower non-cash fair value loss on warrant liabilities resulting from decreased warrant shares outstanding compared to Q1 2025, and a favorable foreign currency fluctuation due to favorable U.S. dollar versus Swiss Franc spot rates for U.S. dollar denominated transactions and assets, compared to a weaker U.S. dollar against the Swiss Franc in the prior year period.

Upcoming Events:

Medical Conferences and Industry Events

- European Neuro-Ophthalmology Society Annual Meeting, June 4-6, Milan, Italy
- Clinical Trial at the Summit, June 13, Las Vegas, NV, U.S.
- EuDEC Meeting, June 18-20, Milan, Italy
- European Academy of Neurology (EAN) 12th Congress, June 27-30, Geneva, Switzerland
- American Society of Retina Specialists, July 15-18, Montreal, Canada

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of March 31, 2026	As of December 31, 2025
ASSETS		
Non-current assets		
Property and equipment	503	534
Intangible assets	13,292	13,292
Right-of-use assets	2,365	2,463
Other non-current assets	796	785
Total non-current assets	**16,956**	**17,074**
Current assets		
Other current assets	3,801	4,883
Accrued income	1,202	993
Short-term financial assets	157,470	131,684
Cash and cash equivalents	64,564	81,329
Total current assets	**227,037**	**218,889**
TOTAL ASSETS	**243,993**	**235,963**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	620	587
Share premium	579,217	551,731
Reserve for share-based payment	32,577	30,387
Actuarial loss on post-employment benefit obligations	(1,928)	(1,634)
Treasury shares	(17)	(7)
Cumulative translation adjustments	(455)	(480)
Accumulated losses	(413,366)	(384,514)

Total equity	**196,648**	**196,070**
Non-current liabilities		
Long-term lease liabilities	1,832	1,811
Defined benefit pension liabilities	1,650	1,335
Total non-current liabilities	**3,482**	**3,146**
Current liabilities		
Trade payables	4,496	1,800
Accrued expenses and other payables	18,410	19,967
Short-term lease liabilities	416	502
Warrant liabilities	20,541	14,478
Total current liabilities	**43,863**	**36,747**
Total liabilities	**47,345**	**39,893**
TOTAL EQUITY AND LIABILITIES	**243,993**	**235,963**

Condensed Consolidated Statements of Loss (Unaudited)

(Amounts in CHF thousands, except per share data)	**For the three months ended March 31,**	
	2026	**2025**
Grant income	209	285
Operating income	**209**	**285**
Research and development expenses	(14,046)	(14,771)
General and administrative expenses	(7,891)	(5,488)
Operating expenses	**(21,937)**	**(20,259)**
Operating loss	**(21,728)**	**(19,974)**
Finance income	367	493
Finance expense	(173)	(247)
Fair value adjustment on warrant liabilities	(7,983)	(11,911)
Foreign currency exchange gain (loss)	567	(1,567)
Finance result	**(7,222)**	**(13,232)**
Loss before tax for the period	**(28,950)**	**(33,206)**
Income tax benefit (expense)	98	(7)
Loss for the period	**(28,852)**	**(33,213)**
Loss per share:		
Basic and diluted loss attributable to equity holders	(0.49)	(0.69)

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: OCS-01, an eye drop in pivotal registration studies, aiming to become the first non-invasive topical treatment for diabetic macular edema (DME); Licaminlimab, a novel, topical anti-TNFα in registrational trial, which is being developed with a genotype-based approach to drive precision medicine in dry eye disease (DED), and Privosegtor, 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. Headquartered in Switzerland with operations in the U.S., Iceland and Switzerland, 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 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; 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 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:

1. Decision Resources Group: DME – DR Landscape Forecast – Disease Landscape Forecast 2020
2. Iris Registry – Baseline characteristics and demographics of treatment naïve patients at diagnosis (Table S1)
3. Gonzalez 2016 Early and Long-term Responses to VEGF Therapy in DME: Analysis of protocol I data
4. GlobalData - Dry Eye Syndrome Global Drug Forecast and market analysis to 2026
5. Health Union Community Editorial Team. 2021 In America Survey Findings: Living With Chronic Dry Eye. Chronic Dry Eye. 2021. https://chronicdryeye.net/infographic/in-america-findings.
6. Mbagwu M, et al. Characterization of Discontinuation and Switching Patterns of Dry Eye Disease Medications Using Linked EHR Registry and Claims Data. Presented at: ASCRS Annual Meeting 2024 https://ophthalmology360.com/study-finds-high-discontinuation-rate-of-dry-eye-medications/