Oculis Reports Q3 2025 Financial Results and Provides Company Update

Nov 10, 2025

- *Oculis accelerates its portfolio development with Privosegtor moving into the PIONEER pivotal program in Acute Optic Neuritis (AON) and Non-arteritic Anterior Ischemic Optic Neuropathy (NAION) following positive FDA meeting*
- *OCS-01 DIAMOND Phase 3 trials in diabetic macular edema (DME) remain on track for topline results expected in Q2 2026*
- *Licaminlimab PREDICT-1 registrational trial, the first genotype-based trial to drive precision medicine in dry eye disease (DED), expected to start in Q4 2025*
- *Cash, cash equivalents and short-term investments of $182.2 million as of September 30, 2025 plus recent $110 million financing, extend cash runway into 2029*

ZUG, Switzerland, Nov. 10, 2025 (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 third quarter ended September 30, 2025, and provided an overview of the Company's progress.

Riad Sherif, M.D., Chief Executive Officer of Oculis, stated: "Oculis has entered a pivotal stage in its transformation into a leader in ophthalmology and neuro-ophthalmology, powered by its differentiated and innovative portfolio. We are excited about several key developments: OCS-01 eye drops Phase 3 in DME with anticipated readout in Q2 2026, the initiation of a first in class registrational trial with Licaminlimab in precision medicine for DED, and, very importantly, we are thrilled with our positive discussions with the U.S. Food and Drug Administration (FDA), which paved the way to accelerate Privosegtor development in key unmet medical needs. Our recent financing now secures the resources needed for three pivotal trials in optic neuropathies, a potential market opportunity representing approximately $7 billion in the U.S. alone, with no available therapies. Supported by a strong balance sheet and a robust late-stage pipeline, we are well-positioned to achieve 6 pivotal readouts with the current funding, reinforcing our commitment to delivering groundbreaking treatments."

Recent Clinical Highlights and Upcoming Milestones:

Privosegtor:

- Following a successful meeting with the FDA, Oculis announced the launch of the PIONEER program, which will include three pivotal trials to support registration plans for Privosegtor in AON and NAION (management webcast available here for replay):
  - The first two trials, PIONEER-1 and PIONEER-2, will evaluate Privosegtor following the acute onset of optic neuritis in a broad population consisting of patients with multiple sclerosis (MS) and those without MS. Primary endpoint will be low-contrast visual acuity (LCVA) at 3 months. Dosing and patient enrollment criteria will mirror the positive Phase 2 ACUITY trial, which demonstrated improvement in visual function and anatomical preservation of the retina in patients with AON. PIONEER-1 is expected to initiate in Q4 2025, with PIONEER-2 planned to follow in the first half of 2026.
  - The third trial in the PIONEER program, PIONEER-3, will evaluate Privosegtor after the acute onset of NAION. This study shares the core design and operational elements with PIONEER-1 and PIONEER-2 and is expected to initiate in mid-2026.
  - Running the PIONEER trials concurrently is expected to generate operational synergies, cost efficiencies, and to speed up Privosegtor development timelines.
- Oculis will cross-reference the existing Privosegtor AON Investigational New Drug (IND) when submitting a new IND to the FDA for the acute treatment of relapses in multiple sclerosis (MS).
- Successful ACUITY Phase 2 trial results in patients with AON were presented in late-breaking abstract sessions at the European Society of Retina Specialists (EURETINA) and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) congresses.

OCS-01:

- DIAMOND Phase 3 trials with OCS-01, aims to be the first eye drop for DME, are fully enrolled with over 800 patients across both trials. Topline results from both DIAMOND Phase 3 trials are expected in Q2 2026 with NDA submission to the FDA planned for 2H 2026.
- DME affects approximately 37 million people worldwide and represents a ~$5 billion market opportunity with high unmet medical needs for early intervention and for patients with inadequate response to standard of care.

Licaminlimab:

- Aligned with the FDA on the genotype-based development plan to drive precision medicine in DED. Registrational trial expected to initiate in Q4 2025 following three positive Phase 2 studies previously completed, including the demonstration of profound effects on TNFR1-positive patients.

Q3 2025 Financial Highlights

As of September 30, 2025, Oculis held cash, cash equivalents and short-term investments of CHF 145.2 million or $182.2 million. Following the October capital raise, the Company's cash, cash equivalents and short-term investments was close to $300 million, before disbursing offering expenses. Research and development expenses were CHF 14.1 million or $17.6 million for the three months ended September 30, 2025, compared to

CHF 13.0 million or $15.0 million in the same period in 2024. The increase was primarily due to increase in product development activities and associated personnel expenses. General and administrative expenses were CHF 6.4 million or $8.0 million for the three months ended September 30, 2025, compared to CHF 5.3 million or $6.2 million in the same period in 2024. The increase was primarily driven by share-based compensation expense and external professional services costs. Year-to-date net loss was CHF 75.4 million or $89.7 million for the nine months ended September 30, 2025, compared to CHF 57.1 million or $64.8 million for the same period in 2024. The increase was primarily driven by advancements in clinical development programs, in particular the Phase 3 DIAMOND trials, and a CHF 6.9 million or $8.2 million increase in the non-cash fair value adjustment on warrant liabilities as a result of appreciation of underlying warrant fair value.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of September 30, 2025	As of December 31, 2024
ASSETS		
Non-current assets		
Property and equipment	528	385
Intangible assets	13,292	13,292
Right-of-use assets	2,576	1,303
Other non-current assets	532	476
Total non-current assets	**16,928**	**15,456**
Current assets		
Other current assets	4,306	5,605
Accrued income	1,422	629
Short-term financial assets	98,740	70,955
Cash and cash equivalents	46,440	27,708
Total current assets	**150,908**	**104,897**
TOTAL ASSETS	**167,836**	**120,353**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	559	446
Share premium	466,858	344,946
Reserve for share-based payment	26,514	16,062
Actuarial loss on post-employment benefit obligations	(1,835)	(2,233)
Treasury shares	(35)	(10)
Cumulative translation adjustments	(467)	(271)
Accumulated losses	(361,000)	(285,557)
Total equity	**130,594**	**73,383**
Non-current liabilities		
Long-term lease liabilities	2,045	865
Defined benefit pension liabilities	1,470	1,870
Total non-current liabilities	**3,515**	**2,735**
Current liabilities		
Trade payables	1,221	5,871
Accrued expenses and other payables	19,942	18,198
Short-term lease liabilities	421	315
Warrant liabilities	12,143	19,851
Total current liabilities	**33,727**	**44,235**
Total liabilities	**37,242**	**46,970**
TOTAL EQUITY AND LIABILITIES	**167,836**	**120,353**

Condensed Consolidated Statements of Loss (Unaudited)

(Amounts in CHF thousands, except per share data)	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Grant income	243	216	788	683
Operating income	**243**	**216**	**788**	**683**
Research and development expenses	(14,117)	(12,999)	(43,797)	(40,320)

General and administrative expenses	(6,422)	(5,348)	(18,030)	(16,307)
Operating expenses	**(20,539)**	**(18,347)**	**(61,827)**	**(56,627)**
Operating loss	**(20,296)**	**(18,131)**	**(61,039)**	**(55,944)**
Finance income	438	556	1,451	1,797
Finance expense	(162)	(264)	(592)	(393)
Fair value adjustment on warrant liabilities	3,089	(445)	(9,056)	(2,143)
Foreign currency exchange gain (loss)	89	(1,888)	(6,211)	(361)
Finance result	**3,454**	**(2,041)**	**(14,408)**	**(1,100)**
Loss before tax for the period	**(16,842)**	**(20,172)**	**(75,447)**	**(57,044)**
Income tax benefit (expense)	(13)	(18)	4	(78)
Loss for the period	**(16,855)**	**(20,190)**	**(75,443)**	**(57,122)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.32)	(0.48)	(1.48)	(1.44)

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, which 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 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.