Oculis Reports Q1 Financial Results and Provides Company Update

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ZUG, Switzerland, May 08, 2025 (GLOBE NEWSWIRE) --

- *The recent R&D Day (replay) showcased material progress across all three core assets and highlighted potential first-in-class neuroprotection treatment in neuro-ophthalmology, an area of high unmet medical need, thanks to Privosegtor's (OCS-05) positive results from the ACUITY trial in Acute Optic Neuritis*

- *OCS-01: DIAMOND Ph3 trials enrollment completed with over 800 patients randomized; topline results expected Q2 2026 for the first potential eye drop treatment for diabetic macular edema (DME)*

- *Licaminlimab (OCS-02) genotype-based development plan to drive a personalized medicine approach in dry eye disease (DED) aligned with FDA; first registrational trial initiation anticipated in 2H 2025*

- *Cash, cash equivalents and short-term investments of $206.3 million as of March 31, 2025, reflects proceeds from the $100.0 million financing in February 2025, providing cash runway into early 2028*

Oculis Holding AG (Nasdaq: OCS / ICX: OCS.IC) ("Oculis" or the "Company"), a global biopharmaceutical company focused on innovations addressing ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs, today announced results for the first quarter ended March 31, 2025 and provided an overview of the Company's progress.

Riad Sherif M.D., Chief Executive Officer of Oculis: "We began 2025 with an exciting evolution of our portfolio, driven by strong execution and solid science. We've made significant advancements on all three of our highly differentiated assets: completing randomization of over 800 patients in both Phase 3 DIAMOND-1 and DIAMOND-2 trials with OCS-01; initiating the first-ever genotype-based development program in ophthalmology with Licaminlimab (OCS-02); and announcing promising neuroprotective data with Privosegtor in the ACUITY trial - a potentially transformative catalyst for our company. The ACUITY readout not only validates our approach in acute optic neuritis, but also allows us the ability to expand into neuro-ophthalmology and beyond, significantly increasing our potential addressable patient population by multiple folds. These advancements, combined with a strengthened financial position, have enabled us to expand our innovative pipeline. With several near-term value inflection points ahead, we are well-positioned to drive value creation, while bringing transformative treatments to those who need them most."

R&D Day Key Highlights:

- ***Privosegtor (OCS-05) – A new era in neuroprotection for acute optic neuritis and beyond:*** Additional analyses from the successful Phase 2 ACUITY trial further supported the previously announced neuroprotective effects on retinal ganglion cells and axons, as well as vision improvement in patients with acute optic neuritis. These analyses also revealed that Privosegtor led to lower neurofilament release, a prominent biomarker of reduced neuro-axonal damage in neurological disorders, including MS. Oculis is planning to pursue a global registration program in acute optic neuritis, and evaluate Privosegtor in NAION and as a treatment of acute MS relapses.

- ***OCS-01 – A non-invasive eye drop for DME:*** The Company has completed enrollment in the Phase 3 DIAMOND-1 and DIAMOND-2 trials of OCS-01 eye drops in DME, with over 800 patients randomized; topline results are expected in Q2 2026.

- ***Licaminlimab (OCS-02) – An innovative TNF inhibitor specifically design for ocular inflammation*** : An FDA meeting in Q1 2025 confirmed the path forward for genotype-based development with Licaminlimab (OCS-02) to deliver a precision medicine treatment in DED with initiation of the first phase 2/3 activities to start in 2H 2025.

Recent Clinical Highlights and Upcoming Milestones:

- ***OCS-01***:
    - Phase 3 DIAMOND trials investigating OCS-01 in DME completed enrollment with over 800 patients randomized. DIAMOND is the first ever Phase 3 program investigating a topical, non-invasive treatment for DME.
    - DME is a progressive complication of diabetic retinopathy, estimated to affect around 37 million people worldwide currently representing a ~$5 billion market opportunity and the unmet needs for early intervention and patients with inadequate response to standard of care.
    - The topline results from both DIAMOND Phase 3 trials are expected in Q2 2026 with the NDA submission to the FDA for OCS-01 for the treatment of DME planned for 2H 2026.
- ***Licaminlimab (OCS-02):***

- Following three positive Phase 2 trials and a successful meeting with the FDA, a genotype-based development plan investigating Licaminlimab for the treatment of DED has been aligned with the Agency; a phase 2/3 is anticipated to initiate 2H 2025.

- ***Privosegtor (OCS-05):***
  - Results from Phase 2 ACUITY trial investigating Privosegtor, a novel, first-in-class peptidomimetic small molecule in development for the treatment of acute optic neuritis, showed significant neuroprotective anatomical benefits and functional vision improvement.
  - Plan to meet with the FDA in Q3 2025 to discuss the development program for Privosegtor, including a registrational program for acute optic neuritis, expected to initiate in 1H 2026.
  - Privosegtor's demonstration of neuroprotection in the ACUITY trial supports its potential for broad applicability in multiple neuro-ophthalmology and neurology indications. Oculis intends to expand its Privosegtor development program into NAION, an orphan indication often leading to permanent vision loss, for which there are no approved therapies and as a treatment of acute MS relapses. Pre-IND discussions with the FDA are planned for 2H 2025, to support applications relying on existing Privosegtor data.

Q1 2025 Financial Highlights

- ***Cash position****:* As of March 31, 2025, the Company had total cash, cash equivalents and short-term investments of CHF 181.9 million or $206.3 million, compared to CHF 98.7 million or $109.0 million as of December 31, 2024. The increase in cash position from December 31, 2024 reflected proceeds from the $100.0 million (CHF 90.2 million) equity financing in February 2025. Based on its current development plans, the Company's cash balances are expected to fund operations into early 2028.
- ***Research and development expenses*:** The Company's research and development expenses were CHF 14.8 million or $16.4 million for the three months ended March 31, 2025, compared to CHF 10.9 million or $12.4 million in the same period in 2024. The increase was primarily due to development costs associated with the Company's active clinical trials, in particular the two DIAMOND Phase 3 trials, as well as personnel-related costs.
- ***General and administrative expenses:*** The Company's general and administrative expenses were CHF 5.5 million or $6.1 million for the three months ended March 31, 2025, compared to CHF 4.7 million or $5.4 million in the same period in 2024. The increase was primarily driven by personnel-related costs.
- ***Q1 Net loss:*** The Company's net loss was CHF 33.2 million or $36.9 million, or CHF 0.69 or $0.77 per share, for the three months ended March 31, 2025, compared to CHF 16.1 million or $18.4 million, or CHF 0.44 or $0.50 per share, for the same period in 2024. The increase was primarily driven by advancements in clinical development programs, G&A expenses, as well as a CHF 8.8 million or $9.8 million increase in the non-cash fair value adjustment on warrant liabilities.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	**As of March 31, 2025**	**As of December 31, 2024**
ASSETS		
Non-current assets		
Property and equipment, net	364	385
Intangible assets	13,292	13,292
Right-of-use assets	1,218	1,303
Other non-current assets	508	476
Total non-current assets	**15,382**	**15,456**
Current assets		
Other current assets	5,931	5,605
Accrued income	930	629
Short-term financial assets	122,055	70,955
Cash and cash equivalents	59,873	27,708
Total current assets	**188,789**	**104,897**
TOTAL ASSETS	**204,171**	**120,353**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	555	446
Share premium	464,190	344,946
Reserve for share-based payment	18,642	16,062
Actuarial loss on post-employment benefit obligations	(1,646)	(2,233)
Treasury shares	(35)	(10)
Cumulative translation adjustments	(310)	(271)
Accumulated losses	(318,770)	(285,557)
Total equity	**162,626**	**73,383**

Non-current liabilities		
Long-term lease liabilities	799	865
Defined benefit pension liabilities	1,294	1,870
Total non-current liabilities	**2,093**	**2,735**
Current liabilities		
Trade payables	4,351	5,871
Accrued expenses and other payables	19,860	18,198
Short-term lease liabilities	304	315
Warrant liabilities	14,937	19,851
Total current liabilities	**39,452**	**44,235**
Total liabilities	**41,545**	**46,970**
TOTAL EQUITY AND LIABILITIES	**204,171**	**120,353**

Condensed Consolidated Statements of Loss (Unaudited)

(Amounts in CHF thousands, except per share data)	**For the three months ended March 31,**	
	2025	**2024**
Grant income	285	222
Operating income	**285**	**222**
Research and development expenses	(14,771)	(10,856)
General and administrative expenses	(5,488)	(4,694)
Operating expenses	**(20,259)**	**(15,550)**
Operating loss	**(19,974)**	**(15,328)**
Finance income	493	581
Finance expense	(247)	(41)
Fair value adjustment on warrant liabilities	(11,911)	(3,069)
Foreign currency exchange loss, net	(1,567)	1,794
Finance result, net	**(13,232)**	**(735)**
Loss before tax for the period	**(33,206)**	**(16,063)**
Income tax expense	(7)	(30)
Loss for the period	**(33,213)**	**(16,093)**
Loss per share:		
Basic and diluted loss attributable to equity holders	(0.69)	(0.44)

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About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS / XICE: OCS) focused on innovations addressing ophthalmic and neuro-ophthalmic diseases with significant unmet medical needs. Oculis' highly differentiated pipeline of multiple innovative product candidates in clinical development includes: OCS-01, a topical eye drop candidate for diabetic macular edema (DME); Privosegtor (OCS-05), a neuroprotective candidate for acute optic neuritis with potentially broad clinical applications in other neuro-ophthalmic diseases; and Licaminlimab (OCS-02), a topical biologic anti-TNFα eye drop candidate for 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 is 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 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; 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 other documents filed with the U.S. Securities and Exchange Commission (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.