Oculis Reports Q3 2024 Financial Results and Provides Company Updates

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ZUG, Switzerland, Nov. 07, 2024 (GLOBE NEWSWIRE) --

- Significant advancement on product portfolio, including enrollment in the OCS-01 DIAMOND Phase 3 program in DME and OCS-05 Phase 2 ACUITY trial in acute optic neuritis (AON) with topline readout anticipated in December 2024
- Leadership team bolstered with extensive experience in key areas as the Company advances its late-stage pipeline and prepares for commercial phase
- Cash, cash equivalents and short-term investments of $125.0 million as of September 30, 2024, provides cash runway into 2H 2026

Oculis Holding AG (Nasdaq: OCS; XICE: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced results for the quarter ended September 30, 2024, and provided an overview of the Company's progress.

Riad Sherif M.D., Chief Executive Officer of Oculis: "During the quarter, we achieved excellent momentum in product pipeline development. We continue to accelerate recruitment for both Phase 3 trials in our core DIAMOND program with OCS-01 in DME and expanded this program's committees with several world-renowned retina experts. Looking ahead, we are excited for the upcoming topline readout from the OCS-05 Phase 2 ACUITY trial in AON, anticipated in December 2024. The results will provide us with meaningful insights about the safety and tolerability of OCS-05, and its potential as a neuroprotective candidate in acute optic neuritis and other neuro-ophthalmic diseases. With a strengthened leadership team including recent appointments of Sharon Klier, M.D. as Chief Development Officer and Daniel S. Char as Chief Legal Officer, and a solid balance sheet, Oculis is well positioned to drive execution in pipeline development and create value for key stakeholders."

Q3 2024 and Recent Highlights

Clinical Highlights:

- Substantial enrollment progress was achieved since the end of Q2 2024 through early October, with ~70% of patients enrolled in the Phase 3 DIAMOND-1 trial, and ~40% of patients enrolled in the Phase 3 DIAMOND-2 trial.
- Expanded DIAMOND program committees with leading retina experts announced for the Phase 3 program of OCS-01 in DME.

Presentations and Awards Highlights:

- David Eichenbaum, M.D., presented an update on the DIAMOND Phase 3 program with OCS-01, an OPTIREACH® formulation of high concentration dexamethasone eye drop, for DME at Innovate Retina, an event that focuses exclusively on game-changing innovations in medical and surgical retina care. His presentation highlighted the potential of OCS-01 to become the first non-invasive therapy for DME to address unmet medical needs for early treatment intervention and for patients inadequately controlled with current therapies.
- At the 2024 EURETINA congress, the inaugural Ramin Tadayoni Award, supported by Oculis, was awarded to Andrea Govetto, M.D., Ph.D. who is developing a computational model of fluid flow and retinal tissue deformation in macular edema. The Ramin Tadayoni Award, awarded by EURETINA, was established in partnership with EURETINA in memory of Oculis' Chief Scientific Officer, EURETINA past President, and a world-renowned retina specialist in order to pay a lasting tribute to the legacy of Professor Tadayoni, who passed away unexpectedly earlier this year.

Company Updates and Upcoming Milestones

- OCS-01: Following a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) in August 2024 for post-operative pain and inflammation, the Company plans to be NDA submission ready in Q1 2025.
- OCS-02: The Company is planning to consult with the FDA in Q1 2025 to discuss the positive topline results from the Phase 2b RELIEF trial and next steps for OCS-02 (licaminlimab) development. If approved, OCS-02 (licaminlimab) has the potential to be the first precision medicine for DED given the predictive and more pronounced effects observed in a specific TNFR1 genotype population.
- OCS-05: Topline readout for the Phase 2 ACUITY trial in AON is on track for December 2024.
    - OCS-05 is a peptidomimetic serum glucocorticoid kinase-2 (SGK-2) activator, a novel mechanism of action, with the potential to be a neuroprotective therapy for neuro-ophthalmic diseases.
    - OCS-05 is being evaluated for the treatment of AON in the ACUITY Phase 2 trial, a randomized, double-blind, placebo-controlled, multi-center trial in France, designed to evaluate the safety and tolerability of OCS-05. Enrollment is complete with 36 patients randomized. The primary endpoint is safety, and additional exploratory measurements will be evaluated to explore the potential neuroprotective benefits of OCS-05 in AON patients.
    - AON is a rare disease of an acute inflammation of the optic nerve that can lead to permanent visual impairment. AON mainly occurs in 20- to 40-year-old adults and affects up to 8 in 100,000 people worldwide[1]. While corticosteroids are used to treat the inflammation, there remains a critical unmet medical need for therapies that preserve vision or provide neuroprotection after an acute episode of optic neuritis.
    - In animal models of neuroinflammation and neurodegeneration, OCS-05 has shown evidence of neuroprotective activity, including the prevention of retinal ganglion cell damage in glaucoma and AON models, and promotion of axonal sparing and reduction of demyelination in AON model.
    - There were no drug-related side effects with OCS-05 reported from the Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose trial that was completed in 48 healthy adult volunteers (36 on OCS-05, 12 on placebo) in the U.K.

Q3 2024 Financial Highlights

- **Cash position**: As of September 30, 2024, the Company had total cash, cash equivalents and short-term investments of CHF 105.5 million or $125.0 million, compared to CHF 91.7 million or $109.0 million as of December 31, 2023. The increase in cash position from December 31, 2023 reflects proceeds from the registered direct offering in the second quarter of 2024. Based on its current development plans, the Company's cash balances are expected to fund operations into the second half of 2026.
- **Research and development expenses** were CHF 13.0 million or $15.0 million for the three-months ended September 30, 2024, compared to CHF 8.9 million or $10.0 million in the same period in 2023. The increase was primarily due to higher clinical trial expenses in the ongoing OCS-01 DIAMOND Stage 2 trials and OCS-05 ACUITY trial.
- **General and administrative expenses** were CHF 5.3 million or $6.2 million for the three-months ended September 30, 2024, compared to CHF 4.3 million or $4.9 million in the same period in 2023. The increase was primarily due to stock-based compensation expenses.
- **Q3 Quarter-to-date Net loss** was CHF 20.2 million or $23.3 million for the third quarter ended September 30, 2024, compared to CHF 17.4 million or $19.7 million for the same period in 2023. The increase was primarily driven by increases in OCS-01 clinical development related expenses.
- **Q3 Year-to-date net loss** was CHF 57.1 million or $64.8 million for the nine months ended September 30, 2024, compared to CHF 76.3 million or $84.5 million for the same period in 2023. The decrease was primarily due to a non-recurring and non-cash merger and listing expense recorded in 2023 of CHF 34.9 million or $38.2 million, partially offset by increases in clinical development costs and expenses incurred to operate as a public company.
- **Q3 Year-to-date Non-IFRS net loss** was CHF 57.1 million or $64.8 million, or CHF 1.44 or $1.63 per share, for the nine months ended September 30, 2024, compared to CHF 36.5 million or $40.4 million, or CHF 1.32 or $1.46 per share, for the same period in 2023. The increase in non-IFRS net loss was primarily driven by advances of clinical development programs.

Non-IFRS Financial Information

This press release contains financial measures that do not comply with International Financial Reporting Standards (IFRS) including non-IFRS loss, and non-IFRS loss attributable to equity holders per common share. These non-IFRS financial measures exclude the impact of items that the Company's management believes affect comparability or underlying business trends. These measures supplement the Company's financial results prepared in accordance with IFRS. The Company's management uses these measures to better analyze its financial results and better estimate its financial outlook. In management's opinion, these non-IFRS measures are useful to investors and other users of the Company's financial statements by providing greater transparency into the ongoing operating performance of the Company and its future outlook. Such measures should not be deemed to be an alternative to IFRS requirements.

The non-IFRS measures for the reported periods reflect adjustments made to exclude:

- Merger and listing expense, which was a one-time non-cash expense CHF 34.9 million or $38.2 million in total operating expenses in the nine months ended September 30, 2023.
- During the third quarter of 2023, the Company gave effect to the impending dissolution of its Merger Sub 2 entity pursuant to the Business Combination Agreement with EBAC, which was ultimately completed in April 2024. As a result, the cumulative translation adjustments related to Merger Sub 2 previously reported in equity and recognized in other comprehensive loss, were reclassified from equity to the Condensed Consolidated Interim Statement of Loss for the three and nine months ended September 30, 2023. The resulting non-cash foreign exchange impact of such reclassification amounted to CHF 5.0 million or $5.7 million for the three and nine months ended September 30, 2023.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of September 30, 2024	As of December 31, 2023
ASSETS		
Non-current assets		
Property and equipment, net	366	288
Intangible assets	12.206	12.206
Right-of-use assets	1.386	755
Other non-current assets	159	89
Total non-current assets	**14.117**	**13.338**
Current assets		
Other current assets	4.450	8.488
Accrued income	1.568	876
Short-term financial assets	69.841	53.324
Cash and cash equivalents	35.632	38.327
Total current assets	**111.491**	**101.015**
TOTAL ASSETS	**125.608**	**114.353**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	429	366
Share premium	340.645	288.162
Reserve for share-based payment	13.319	6.379
Actuarial loss on post-employment benefit obligations	(1.919)	(1.072)
Treasury shares	(10)	-
Cumulative translation adjustments	(334)	(327)
Accumulated losses	(256.902)	(199.780)
Total equity	**95.228**	**93.728**
Non-current liabilities		
Long-term lease liabilities	929	431
Long-term payables	-	378
Defined benefit pension liabilities	1.734	728
Total non-current liabilities	**2.663**	**1.537**
Current liabilities		
Trade payables	4.892	7.596
Accrued expenses and other payables	14.704	5.948
Short-term lease liabilities	314	174
Warrant liabilities	7.807	5.370
Total current liabilities	**27.717**	**19.088**
Total liabilities	**30.380**	**20.625**
TOTAL EQUITY AND LIABILITIES	**125.608**	**114.353**

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,	
	2024	2023	2024	2023
Grant income	216	219	683	698
Operating income	**216**	**219**	**683**	**698**
Research and development expenses	(12.999)	(8.872)	(40.320)	(21.218)
General and administrative expenses	(5.348)	(4.306)	(16.307)	(13.147)
Merger and listing expense	-	-	-	(34.863)
Operating expenses	**(18.347)**	**(13.178)**	**(56.627)**	**(69.228)**
Operating loss	**(18.131)**	**(12.959)**	**(55.944)**	**(68.530)**
Finance income	556	520	1.797	773
Finance expense	(264)	(11)	(392)	(1.303)
Fair value adjustment on warrant liabilities	(445)	(2.434)	(2.144)	(4.638)
Foreign currency exchange gain (loss), net	(1.888)	(2.645)	(361)	(2.485)
Finance result, net	**(2.041)**	**(4.570)**	**(1.100)**	**(7.653)**
Loss before tax for the period	**(20.172)**	**(17.529)**	**(57.044)**	**(76.183)**
Income tax expense	(18)	116	(78)	(120)
Loss for the period	**(20.190)**	**(17.413)**	**(57.122)**	**(76.303)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0,48)	(0,48)	(1,44)	(2,76)

Reconciliation of Non-IFRS Measures (Unaudited)

(Amounts in CHF thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023

IFRS loss for the period	**(20.190)**	**(17.413)**	**(57.122)**	**(76.303)**
Non-IFRS adjustments:				
Merger and listing expense (i)	-	-	-	34.863
Merger Sub 2 reclassification from equity to foreign exchange loss [(ii)]		4.978		4.978
Non-IFRS loss for the period	**(20.190)**	**(12.435)**	**(57.122)**	**(36.462)**
IFRS basic and diluted loss attributable to equity holders	(0,48)	(0,48)	(1,44)	(2,76)
Non-IFRS basic and diluted loss attributable to equity holders	**(0,48)**	**(0,34)**	**(1,44)**	**(1,32)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**41.807.918**	**36.330.836**	**39.659.305**	**27.673.950**

(i) Merger and listing expense is the difference between the fair value of the shares transferred and the fair value of the EBAC net assets per the Business Combination Agreement. This merger and listing expense is non-recurring in nature and represented a share-based payment made in exchange for a listing service and does not lead to any cash outflows.

(ii) The reclassification of cumulative translation adjustments from equity to foreign exchange loss results from the impact of the impending dissolution of Merger Sub 2, which is expected to occur in the coming months. This exchange loss is non-recurring in nature and does not lead to any cash outflows.

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About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS; XICE: OCS) purposefully driven to save sight and improve eye care. Oculis' highly differentiated pipeline comprises multiple innovative product candidates in development. It includes OCS-01, a topical eye drop candidate for diabetic macular edema (DME) and for the treatment of inflammation and pain following cataract surgery; OCS-02 (licaminlimab), a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED) and for non-infectious anterior uveitis; and OCS-05, a neuroprotective candidate for acute optic neuritis (AON). Headquartered in Switzerland and with operations in the U.S. and Iceland, Oculis' goal is to improve the health and quality of life of patients worldwide. The company 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, including patient impact and market opportunity; Oculis' research and development programs, regulatory and business strategy, future development plans, and management; Oculis' ability to advance product candidates into, and successfully complete, clinical trials; the timing of clinical data readouts; the timing or likelihood of regulatory filings and approvals; and the Company's expected 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 (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.

[1] Martínez-Lapiscina et al. J Neurol. 2014 Apr;261(4):759-67