Oculis Reports Q3 2023 Financial Results and Provides Company Update

Nov 15, 2023

- Reported lead product candidate OCS-01 eye drop met both primary endpoints in Phase 3 OPTIMIZE trial for inflammation and pain after cataract surgery following positive readout of Stage 1 of the Phase 3 DIAMOND trial for diabetic macular edema (DME)
- Enrolled first patient in the investigator-initiated LEOPARD trial evaluating OCS-01 for treatment of cystoid macular edema (CME)
- Cash and investments of $116.5 million adequately funded to deliver on key business and clinical milestones

ZUG, Switzerland and BOSTON, Nov. 15, 2023 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today announced third quarter financial results for the period ended September 30, 2023, and an overview of the Company's progress.

Riad Sherif M.D., Chief Executive Officer of Oculis: "In this quarter we advanced on our late stage clinical development programs for our leading assets. Following the two positive readouts for our lead product candidate OCS-01 eye drop, we initiated activities to commence Stage 2 of the Phase 3 DIAMOND 1 & 2 trials for DME and the second Phase 3 trial for inflammation and pain after cataract surgery. The LEOPARD study of OCS-01 in CME enrolled its first patient and enrollment is currently ongoing as planned. In addition, we started preparing for the Phase 2b trial of OCS-02, a novel biologic eye drop, in dry eye disease (DED). We look forward to enrolling the first patients in our planned and ongoing trials and anticipate having multiple readouts and value inflection points in 2024 across our innovative pipeline addressing key areas of high unmet patient need in Ophthalmology."

Q3 2023 Highlights

- Advanced Oculis' lead product candidate OCS-01, a novel high concentration preservative-free topical OPTIREACH ® formulation of dexamethasone with the potential to treat both front and back of the eye indications:
  - Reported positive topline results from Phase 3 OPTIMIZE trial of once daily OCS-01 for inflammation and pain following ocular surgery (August 2023). The trial met both hierarchical primary endpoints, showing a statistically significant higher percentage of patients with no inflammation at Day 15 and no pain at Day 4 following cataract surgery compared to vehicle.
  - Enrolled the first patient in the investigator-initiated study LEOPARD to evaluate the efficacy and safety profile of OCS-01 eye drops for the treatment of two different forms of CME: uveitic macular edema (UME) and post-surgical macular edema (PSME). This study is sponsored by the Global Ophthalmic Research Center (Los Altos, California) and led by Quan Dong Nguyen, M.D., M.Sc., FAAO, FARVO, FASRS, Professor of Ophthalmology at the Byers Eye Institute, Stanford University School of Medicine with financial support provided by Oculis.
  - Commenced start-up activities for Stage 2 of the Phase 3 DIAMOND trial (DIAMOND-1), the second pivotal Phase 3 trial for DME (DIAMOND-2) and the second Phase 3 trial for the treatment of inflammation and pain following cataract surgery (OPTIMIZE-2). Oculis anticipates first patient enrollment toward the end of 2023 and beginning of 2024 in all three pivotal trials.
- Commenced start-up activities for Phase 2b trial with OCS-02, a novel eye drop with potential to become the first approved topical anti-TNFα for DED. Oculis is on track to deliver the first patient first visit before the end of 2023 with clinical data readout expected in mid-2024.
- Strengthened the executive leadership team with the appointment of Rebecca Weil, Ph.D., a seasoned global ophthalmology commercial executive, as Chief Commercial Officer. Ms. Weil is building Oculis' commercial organization readiness plan and preparing for its first potential launch in the U.S. with OCS-01 for the treatment of inflammation and pain following ocular surgery.

Upcoming Clinical Milestones

In the fourth quarter of 2023 the Company continues to focus on advancing its innovative pipeline and planned clinical development programs including:

OCS-01

- Following the positive readout in Stage 1, initiation of Stage 2 of the Phase 3 DIAMOND trial of OCS-01 for DME is underway. Stage 2 will include a 6-week induction phase, followed by 46-week maintenance phase of OCS-01 vs. vehicle. Consistent with Stage 1, the primary endpoint is change in best corrected visual acuity (BCVA) early treatment diabetic retinopathy study (ETDRS) letter score. Secondary endpoints include percentage of patients with ≥ 3-line gain in BCVA and change in central subfield thickness (CST) as measured by spectral domain optical coherence tomography (SD-OCT). All endpoints will be evaluated at Week 52. The second Phase 3 trial for DME (DIAMOND-2) will follow shortly after.
- The second Phase 3 OPTIMIZE-2 trial to support the NDA submission is expected to start in the fourth quarter of 2023. Patients in the trial will be treated with once-daily OCS-01 vs. vehicle arm for 2 weeks. Hierarchical primary endpoints are the absence of anterior chamber cells on Day 15 and absence of pain on Day 4.
- The investigator-initiated study of OCS-01 for the treatment of CME is advancing with all clinical sites activated and patient enrollment on track. Oculis anticipates topline readout in the fourth quarter of 2024.

OCS-02

- Phase 2b trial in DED is on track for first patient first visit in the fourth quarter of 2023. The trial will evaluate the safety and efficacy vs. vehicle in signs and symptoms, and further explore whether patients with a certain genotype (i.e., single-nucleotide polymorphism, SNP, related to the TNF receptor) respond better to OCS-02 than all comers. Another Phase 2b trial of OCS-02 for the treatment of uveitis is expected to follow thereafter.

OCS-05

- Phase 2a PoC ACUITY trial in France for OCS-05, a potential disease-modifying neuroprotective candidate for acute optic neuritis (AON), is ongoing. The trial evaluates the safety and tolerability of a once-daily injection of OCS-05 vs. placebo for 5 days, in addition to current standard of care and includes a follow-up period of 6 months. A topline readout is expected in the fourth quarter of 2024. Concurrently, the Company is working on IND enabling activities in the U.S.

Q3 Financial Highlights

- **Cash position:** As of September 30, 2023, the Company had total cash, cash equivalents and short-term investments of CHF 106.6 million or $116.5 million, compared to CHF 19.8 million or $21.4 million as of December 31, 2022. The increase in cash position reflects proceeds from financing transactions during the first half of 2023. Based on our current development plans, we expect our cash runway to fund operations into late 2025.
- **Research and development expenses** were CHF 8.9 million or $10.0 million for the three-month period ending September 30, 2023, compared to CHF 4.6 million or $4.8 million in the same period in 2022. The increase was primarily due to clinical development activities, including the initiation of the Phase 3 DIAMOND Stage 2 program of OCS-01 in DME.
- **General and administrative expenses** were CHF 4.3 million or $4.9 million for the three-month period ending September 30, 2023, compared to CHF 2.5 million or $2.6 million in the same period in 2022. The increase was primarily due to costs related to becoming a public company.
- **Q3 Quarter-to-date net loss** was CHF 17.4 million or $19.7 million, or CHF 0.48 or $0.54 loss per share (basic and diluted), for the three-month period ending September 30, 2023, compared to CHF 10.0 million or $10.4 million, or CHF 2.88 or $2.98 loss per share (basic and diluted), in the same period in 2022. The increase in net loss was primarily driven by the increase in clinical development expenses.
- **Q3 Year-to-date net loss** was CHF 76.3 million or $84.5 million for the nine months ending September 30, 2023, or CHF 2.76 or $3.06 loss per share (basic and diluted) compared to CHF 29.5 million or $31.0 million, or CHF 8.71 or $9.15 loss per share (basic and diluted) for the nine months ended September 30, 2022. The increase in year-to-date net loss was primarily driven by the increase in clinical development expenses, expenses related to becoming a public company, merger and listing expense and the fair-value (non-cash) adjustment of outstanding warrants.
- **Q3 Year-to-date Non-IFRS net loss** was CHF 36.5 million or $40.4 million, or CHF 1.32 or $1.46 loss per share (basic and diluted), for the nine months ended September 30, 2023, compared to CHF 29.5 million or $31.0 million, or CHF 8.71 or $9.15 loss per share (basic and diluted), for the same period in 2022. The increase in non-IFRS net loss was primarily driven by increases in clinical development expenses, expenses related to becoming a public company, and an increase in the fair-value (non-cash) adjustment of outstanding warrants.

Non-IFRS Financial Information
This press release contains financial measures that do not comply with International Financial Reporting Standards (IFRS) including non-IFRS year-to-date 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 and non-cash expense CHF 34.9 million or $38.2 million in the first quarter of 2023 and in the year-to-date total operating expenses.

- 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 is expected to be completed in the coming months. 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.

The non-IFRS measures presented here are also unlikely to be comparable with non-IFRS disclosures released by other companies. See the "Reconciliation of Non-IFRS Measures (Unaudited)" table below for a reconciliation of these non-IFRS measures to the most directly comparable IFRS measures.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	**As of September 30, 2023**	**As of December 31, 2022**
ASSETS		

Non-current assets		
Property and equipment, net	312	365
Intangible assets	12,206	12,206
Right-of-use assets	798	758
Other non-current assets	129	74
Total non-current assets	**13,445**	**13,403**
Current assets		
Other current assets	7,276	2,959
Accrued income	1,625	912
Short-term financial assets	75,871	-
Cash and cash equivalents	30,724	19,786
Total current assets	**115,496**	**23,657**
TOTAL ASSETS	**128,941**	**37,060**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	366	39
Share premium	288,030	10,742
Reserve for share-based payment	5,337	2,771
Actuarial loss on post-employment benefit obligations	(560)	(264)
Treasury shares	-	(1)
Cumulative translation adjustments	(289)	(300)
Accumulated losses	(187,281)	(110,978)
Total equity	**105,603**	**(97,991)**
Non-current liabilities		
Long-term lease liabilities	505	491
Long-term financial debt	-	122,449
Long-term payables	377	-
Defined benefit pension liabilities	305	91
Total non-current liabilities	**1,187**	**123,031**
Current liabilities		
Trade payables	6,712	3,867
Accrued expenses and other payables	8,680	8,011
Short-term lease liabilities	182	142
Warrant liabilities	6,577	-
Total current liabilities	**22,151**	**12,020**
Total liabilities	**23,338**	**135,051**
TOTAL EQUITY AND LIABILITIES	**128,941**	**37,060**

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,**	
	2023	**2022**	**2023**	**2022**
Grant income	219	202	698	698
Operating income	**219**	**202**	**698**	**698**
Research and development expenses	(8,872)	(4,592)	(21,218)	(15,335)
General and administrative expenses	(4,306)	(2,483)	(13,147)	(6,626)
Merger and listing expense	**-**	**-**	(34,863)	**-**
Operating expenses	**(13,178)**	**(7,075)**	**(69,228)**	**(21,961)**
Operating loss	**(12,959)**	**(6,873)**	**(68,530)**	**(21,263)**
Finance income	520	61	773	70
Finance expense	(11)	(1,834)	(1,303)	(5,119)
Fair value adjustment on warrant liabilities	(2,434)	**-**	(4,638)	**-**

Foreign currency exchange gain (loss), net	(2,645)	(1,302)	(2,485)	(3,134)
Finance result, net	**(4,570)**	**(3,075)**	**(7,653)**	**(8,183)**
Loss before tax for the period	**(17,529)**	**(9,948)**	**(76,183)**	**(29,446)**
Income tax benefit (expense)	116	(6)	(120)	(69)
Loss for the period	**(17,413)**	**(9,954)**	**(76,303)**	**(29,515)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.48)	(2.88)	(2.76)	(8.71)

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,	
	2023	2022	2023	2022
IFRS loss for the period	**(17,413)**	**(9,954)**	**(76,303)**	**(29,515)**
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	**(12,435)**	**(9,954)**	**(36,462)**	**(29,515)**
IFRS basic and diluted loss attributable to equity holders	(0.48)	(2.88)	(2.76)	(8.71)
Non-IFRS basic and diluted loss attributable to equity holders	**(0.34)**	**(2.88)**	**(1.32)**	**(8.71)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**36,330,836**	**3,461,666**	**27,673,950**	**3,387,614**

(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.

About Oculis

Oculis (Nasdaq: OCS) is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis' highly differentiated clinical-stage pipeline comprises multiple innovative product candidates in development for eye diseases of high unmet need. It includes OCS-01 eye drops, a topical candidate in Phase 3 development for diabetic macular edema (DME) and inflammation and pain following ocular surgery; OCS-02 eye drops, a topical biologic candidate in Phase 2 development for dry eye disease (DED) and uveitis; and OCS-05, a disease-modifying candidate for acute optic neuritis (AON) and other neuro-ophthalmic disorders, such as glaucoma, diabetic retinopathy, geographic atrophy, and neurotrophic keratitis. The first in-patient, proof-of-concept trial with OCS-05 is currently ongoing in France. Headquartered in Switzerland and with operations in the US, Oculis' goal is to deliver life-changing eye treatments to patients worldwide. The company is led by an experienced management team with a successful track record in the pharmaceutical industry, supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

Oculis Contacts

Ms. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor & Media Relations

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
1-212-915-2577

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential benefits of OCS-01, OCS-02 and OCS-05, including patient impact and market opportunity; the potential of OCS-01 for treating front- and back-of-the-eye diseases; the potential for OCS-01 to become a new standard of care with the first once-daily, topical, preservative-free corticosteroid for treating inflammation and pain following ocular surgery; the potential of OCS-01 for the treatment of DME, inflammation and pain following ocular surgery and CME; the potential of OCS-02 for treating DED; the potential of OCS-02 to become the first approved topical anti-TNFα for DED; the potential of OCS-05 for treating AON and other neuro-ophthalmic disorders; expected cash runway; expected future milestones and catalysts; the initiation, timing, progress and results of

Oculis' clinical and preclinical studies; 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; and the timing or likelihood of regulatory filings and approvals, 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.

