Oculis Reports Q2 and First Half 2023 Financial Results and Provides Company Update

Aug 29, 2023

- Achieved two landmark milestones with OCS-01, Oculis' lead product candidate as first investigational eye drop for both front and back of the eye indications: positive topline results in Phase 3 DIAMOND Stage 1 trial for diabetic macular edema (DME) announced in May, and in Phase 3 OPTIMIZE trial for inflammation and pain following cataract surgery announced in August
- Advancing clinical programs with OCS-01, OCS-02 and OCS-05, including first patient enrolled in the investigator-initiated LEOPARD trial evaluating OCS-01 for treatment of cystoid macular edema (CME)
- Successfully listed on NASDAQ and raised gross proceeds of approximately $146 million during the first half of 2023

ZUG, Switzerland, and BOSTON, Aug. 29, 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 second quarter and first half 2023 financial results for the period ended June 30, 2023, and an overview of the Company's progress.

Riad Sherif MD, Chief Executive Officer of Oculis: "This has been a very exciting period for Oculis. Following our successful listing on NASDAQ, we had two OCS-01 positive Phase 3 readouts with robust statistically significant results in two different indications, further validating the potential of OCS-01 to treat both back and front of the eye conditions. We are optimistic about our portfolio and remain on track for multiple readouts in 2024. We look forward to building upon the positive momentum we've achieved thus far in 2023 as we continue to execute on our strategic goals."

First Half 2023 and Recent Corporate Developments

Clinical Developments

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:

- Announced positive topline results in May 2023 from Stage 1 of the Phase 3 DIAMOND trial of OCS-01 in DME. The trial met its primary endpoint with robust statistical significance and allowed confirmation of the loading and maintenance dosing regimen to optimize Stage 2 of the trial. Further, OCS-01 met all functional, clinical and pharmacodynamic endpoints, including improvement in visual acuity, increase in the percentage of patients with a 3-line or greater gain in visual acuity, and reduction in macular edema as measured by optical coherence tomography (OCT) imaging compared to vehicle. OCS-01 was well-tolerated with no unexpected adverse events observed. Stage 2 of the Phase 3 program is expected to commence by the end of 2023.
- Reported positive topline results in August 2023 from Phase 3 OPTIMIZE trial of OCS-01 in treating inflammation and pain following ocular surgery. The trial met both hierarchical primary endpoints, showing a statistically significant higher percentage of patients with: 1) no inflammation at Day 15; and 2) no pain at Day 4 following cataract surgery compared to vehicle. The second Phase 3 trial is expected to commence before the end of 2023.
- Enrolled the first patient in August 2023 in an investigator-initiated trial LEOPARD with OCS-01 for the treatment of CME, a leading cause of vision loss worldwide. The trial is administratively sponsored by the Global Ophthalmic Research Center (Los Altos, California) and led by Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology at the Byers Eye Institute, Stanford University School of Medicine. The study will evaluate the efficacy and safety profile of OCS-01 eye drops for treatment of two different forms of CME: uveitic macular edema (UME) and post-surgical macular edema (PSME). Topline data are expected in 2024.

Key Operational Updates

- Successfully listed on NASDAQ in March 2023 after closing the business combination between European Biotech Acquisition Corp. and Oculis SA under the ticker symbol "OCS", and raised gross proceeds of approximately $146 million during the first half of 2023.
- The Company expanded its U.S. presence and opened an office in Boston, Massachusetts in April 2023 as part of its continued expansion.

Awards and Company Recognition

- Oculis' co-founders were selected as finalists in the 2023 European Inventor Award in recognition of their research developing the OPTIREACH® solubilization formulation technology that is the basis of Oculis' lead product candidate OCS-01.
- Won the 2023 Knowledge Award from the Icelandic Association of Business and Economics in recognition of the OPTIREACH® technology developed in Oculis' laboratory in Iceland by its co-founders, professors Einar Stefánsson and Thorsteinn Loftsson.

Upcoming Milestones

In the second half of 2023 the Company is focused on advancing its innovative pipeline and planned clinical development programs including:

- Commence Phase 3 DIAMOND Stage 2 trial of OCS-01 in DME. The trial will include a 6-week loading phase, followed by 46-week maintenance phase of OCS-01 vs. vehicle arm following solid validation in stage 1. The primary endpoint is

change in best corrected visual acuity (BCVA) early treatment diabetic retinopathy study (ETDRS) letter score at Week 52 compared to vehicle. 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) as compared to vehicle at Week 52.

- Initiate second OPTIMIZE Phase 3 trial to support an NDA submission (anticipated in late 2024) of OCS-01 for treating inflammation and pain following ocular surgery. 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 at Day 15 and absence of pain at Day 4.
- Advance OCS-02, the first investigational biological eye drop, into a Phase 2b trial initially for dry eye disease (DED) evaluating the safety and efficacy vs. vehicle, and furthermore exploring whether patients with a certain genotype (i.e. single-nucleotide polymorphism, SNP, related to the TNF receptor) respond better to OCS-02 than patients who do not carry the SNP. The first patient's first visit is expected in late 2023. A Phase 2b trial for OCS-02 in the treatment of uveitis is expected to follow thereafter.
- Progress OCS-05, a disease modifying candidate for acute optic neuritis (AON) into a proof-of-concept (PoC) ACUITY trial in France. The trial will evaluate the safety and tolerability of a once daily intravenous infusion of OCS-05 vs. placebo for 5 days in addition to current standard of care and includes a follow up period of 6 months. Concurrently, the Company is working on planned IND enabling activities in the U.S.

Financial Highlights

- **Cash position:** As of June 30, 2023, the Company had total cash, cash equivalents and short-term investments of CHF 114.0 million or $127.0 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 to the end of 2025.
- **Research and development expenses** were CHF 6.2 million or $6.9 million for the three-month period ending June 30, 2023, compared to CHF 6.7 million or $6.9 million in the same period in 2022. The decrease was primarily due to timing of clinical development spending related to the Company's two Phase 3 trials for DME and ocular surgery. Both trials concluded in 2023 and achieved positive topline results as announced in May and August of 2023.
- **General and administrative expenses** were CHF 4.8 million or $5.3 million for the three-month period ending June 30, 2023, compared to CHF 2.8 million or $2.9 million in the same period in 2022. The increase was primarily due to costs related to becoming a public company.
- **Q2 Net loss** was CHF 12.9 million or $14.3 million, or CHF 0.38 or $0.42 per share, for the three-month period ending June 30, 2023, compared to CHF 12.3 million or $12.8 million, or CHF 3.64 or $3.77 per share, in the same period in 2022. The increase in net loss was primarily driven by an increase in operating expenses.
- **Merger and listing expense** was CHF 34.9 million or $38.2 million in the first quarter of 2023, reflected in the year-to-date total operating expenses. This one-time and non-cash expense is the result of accounting for the business combination with EBAC as the equivalent of Oculis issuing shares for the net assets of EBAC at the acquisition closing date, accompanied by a recapitalization.

- **1H Net loss** was CHF 58.9 million or $64.6 million for the six months ending June 30, 2023, or CHF 2.53 or $2.77 loss per share (basic and diluted) compared to CHF 19.6 or $20.8 million, or CHF 5.84 or $6.18 loss per share (basic and diluted) for the first six months of 2022.
- **1H Non-IFRS net loss** was CHF 24.0 million or $26.3 million, or CHF 1.03 or $1.13 per share, for the six months ended June 30, 2023, compared to CHF 19.6 million or $20.8 million, or CHF 5.84 or $6.18 per share, for the same period in 2022. The increase in non-IFRS net loss was primarily driven by increases in clinical development expenses, listing and related expenses, and increase in 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 loss for the period, 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. 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 Balance Sheets (Unaudited)

(Amounts in CHF thousands)

	As of June 30, 2023	As of December 31, 2022
ASSETS		
Non-current assets		
Property and equipment, net	321	365

Intangible assets	12,206	12,206
Right-of-use assets	835	758
Other non-current assets	113	74
Total non-current assets	**13,475**	**13,403**
Current assets		
Other current assets	6,063	2,959
Accrued income	1,296	912
Short-term financial assets	72,078	-
Cash and cash equivalents	41,932	19,786
Total current assets	**121,369**	**23,657**
TOTAL ASSETS	**134,844**	**37,060**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	364	39
Share premium	286,696	10,742
Reserve for share-based payment	4,136	2,771
Actuarial loss on post-employment benefit obligations	(539)	(264)
Treasury shares	-	(1)
Cumulative translation adjustments	(3,591)	(300)
Accumulated losses	(169,870)	(110,978)
Total equity	**117,196**	**(97,991)**
Non-current liabilities		
Long-term lease liabilities	539	491
Long-term financial debt	-	122,449
Defined benefit pension liabilities	305	91
Total non-current liabilities	**844**	**123,031**
Current liabilities		
Trade payables	3,920	3,867
Accrued expenses and other payables	8,407	8,011
Short-term lease liabilities	177	142
Warrant liabilities	4,300	-
Total current liabilities	**16,804**	**12,020**
Total liabilities	**17,648**	**135,051**
TOTAL EQUITY AND LIABILITIES	**134,844**	**37,060**

Condensed Consolidated Statements of Operations (Unaudited)
(Amounts in CHF thousands, except per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Grant income	250	240	479	496
Operating income	**250**	**240**	**479**	**496**
Research and development expenses	(6,198)	(6,702)	(12,346)	(10,743)
General and administrative expenses	(4,797)	(2,776)	(8,840)	(4,143)
Merger and listing expense	-	-	(34,863)	-
Operating expenses	**(10,995)**	**(9,478)**	**(56,049)**	**(14,886)**
Operating loss	**(10,745)**	**(9,238)**	**(55,570)**	**(14,390)**
Finance income	216	7	253	8
Finance expense	(17)	(1,665)	(1,297)	(3,285)
Fair value adjustment on warrant liabilities	(2,625)	-	(2,203)	-
Foreign currency exchange gain (loss), net	408	(1,406)	161	(1,832)
Finance result, net	**(2,018)**	**(3,064)**	**(3,086)**	**(5,109)**
Loss before tax for the period	**(12,763)**	**(12,302)**	**(58,656)**	**(19,499)**

Income tax expense	(114)	(42)	(236)	(64)
Loss for the period	**(12,877)**	**(12,344)**	**(58,892)**	**(19,563)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.38)	(3.64)	(2.53)	(5.84)

Reconciliation of Non-IFRS Measures (Unaudited)
(Amounts in CHF thousands, except per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
IFRS loss for the period	**(12,877)**	**(12,344)**	**(58,892)**	**(19,563)**
Non-IFRS adjustments:				
Merger and listing expense (i)	**-**	**-**	34,863	**-**
Non-IFRS loss for the period	**(12,877)**	**(12,344)**	**(24,029)**	**(19,563)**
IFRS basic and diluted loss attributable to equity holders	(0.38)	(3.64)	(2.53)	(5.84)
Non-IFRS basic and diluted loss attributable to equity holders	**(0.38)**	**(3.64)**	**(1.03)**	**(5.84)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**33,565,542**	**3,392,346**	**23,274,136**	**3,350,458**

(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.

About Oculis

Oculis (Nasdaq: OCS) is a global biopharmaceutical company purposefully driven to save sight and improve eye care. Oculis's 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

Mrs. 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, 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; 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.



Source: Oculis Holding AG