Oculis Reports Q4 and Full Year 2023 Financial Results and Update on Company Progress

Mar 18, 2024

- A successful year including NASDAQ listing and positive results from two Phase 3 programs in OCS-01: Phase 3 Stage 1 DIAMOND trial for Diabetic Macular Edema (DME), and Phase 3 OPTIMIZE-1 trial for inflammation and pain following cataract surgery
- On-track to report topline data from OCS-02 (Licaminlimab) Phase 2b RELIEF trial in Dry Eye Disease (DED) in Q2 2024, OCS-01 Phase 3 OPTIMIZE-2 trial, and OCS-05 proof-of-concept ACUITY trial in Q4 2024
- Cash, cash equivalents and short-term investments of $108.9 million funding operations and planned clinical trials, as well as advancements in DIAMOND-1 and DIAMOND-2 Phase 3 trials
- R&D Day held on February 28, 2024, showcasing OCS-01 DME and OCS-02 DED and their transformative treatment potentials

ZUG, Switzerland and BOSTON, March 18, 2024 (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 fourth quarter and full year financial results for the period ended December 31, 2023, and an overview of the Company's progress.

Riad Sherif M.D., Chief Executive Officer of Oculis: "2023 was a remarkable milestone-rich year for Oculis. Following our listing on NASDAQ, we had two positive Phase 3 data readouts with OCS-01, the first topical candidate with compelling data in DME, and achieved a strong close of the year with the initiation of three clinical trials, including the OCS-02 Phase 2b RELIEF trial in DED. As our innovative and diversified pipeline continues to advance, we remain laser-focused on delivering our key programs: OCS-01 in DME, OCS-02 in DED and OCS-05 in Acute Optic Neuritis. We are confident and excited as we move into a catalyst-rich 2024 and look forward to updating everyone on the upcoming RELIEF trial readout planned in Q2, the second Phase 3 OPTIMIZE-2 trial readout of OCS-01 in ocular surgery in Q4, which will allow us to submit our first NDA, in addition to the ACUITY trial readout of OCS-05 in Acute Optic Neuritis, also planned in Q4. I would like to thank our exceptional team and all our partners for their great contribution but also for their commitment towards our mission to save sight and improve eye care."

Q4 2023 and Recent Highlights

- Advanced 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, in three ongoing pivotal trials:
  - In DME, following the positive topline results from Stage 1 of Phase 3 DIAMOND program, the Company announced the first patient first visit in Stage 2 of the first Phase 3 DIAMOND-1 trial and in DIAMOND-2, the second Phase 3 trial required for registration.
  - Following the positive topline results achieved in the Phase 3 OPTIMIZE-1 trial, the Company started the second Phase 3 OPTIMIZE-2 trial of OCS-01 for the treatment of inflammation and pain following cataract surgery.
- Achieved a record completion of patient enrolment for the Phase 2b RELIEF trial of OCS-02 (Licaminlimab), a specifically designed ophthalmic formulation of a TNFα inhibitor, eye drop formulation specifically designed with a proprietary antibody fragment technology to treat ocular inflammation. The trial, initiated in November 2023, is evaluating the efficacy and safety of OCS-02 (Licaminlimab) vs. vehicle in signs of inflammation in DED, and is further exploring its potential unique benefit in patients with a certain genotype (i.e., single-nucleotide polymorphism, SNP, related to the TNF receptor).
- Hosted an R&D day on February 28, 2024, with over 100 participants that featured 10 leading experts in retina and anterior segments covering OCS-01 and OCS-02 clinical programs.
- Presented the Phase 3 DIAMOND Stage 1 positive results of OCS-01 in DME as late-breaking abstracts at the 23rd EURETINA Congress and at the American Academy of Ophthalmology.

Upcoming Clinical Milestones

In 2024, the Company is focused on advancing its innovative pipeline and planned clinical development programs including:

Q2 2024

- OCS-02: The Phase 2b RELIEF trial evaluating topical anti-TNFα OCS-02 (Licaminlimab) efficacy and safety in DED is on track for topline results readout in Q2 2024.

Q4 2024

- OCS-01: Topline results from the second Phase 3 OPTIMIZE-2 trial evaluating OCS-01 once daily eye drop for the treatment of inflammation and pain following cataract surgery are anticipated by the end of 2024. If positive, the data from this trial, together with the positive results from the first Phase 3 OPTIMIZE-1 trial, are expected to support the first NDA submission of the Company.
- OCS-05: A serum glucocorticoid kinase-2 (SGK-2) activator and potentially disease-modifying neuroprotective candidate is initially being developed for AON. The Phase 2a PoC ACUITY trial is designed to evaluate the safety and tolerability of a once-daily injection of OCS-05 vs. placebo for 5 days, in addition to current standard of care. The trial is on track for topline readout in the fourth quarter of 2024.The Company aims to achieve IND status for OCS-05 in the U.S. in 2024.

Q4 and Full Year 2023 Financial Highlights

- **Cash position:** As of December 31, 2023, the Company had total cash, cash equivalents and short-term investments of CHF 91.7 million or $108.9 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 completed in 2023. Based on its current development plans, cash runway is expected to fund operations into late 2025.
- **Research and development expenses** were CHF 8.0 million or $9.0 million for the three-months ended December 31, 2023, compared to CHF 6.9 million or $7.1 million in the same period in 2022. The increase was primarily due to the commencement of three clinical trials during the fourth quarter of 2023: DIAMOND-1 Stage 2, OPTIMIZE-2 and RELIEF.
- **General and administrative expenses** were CHF 4.3 million or $4.9 million for the three-months ended December 31, 2023. G&A expenses remained in-line with the same period in 2022, which was CHF 4.4 million or $4.6 million.
- **Q4 Net loss** was CHF 12.5 million or $14.1 million for the fourth quarter ended December 31, 2023, compared to CHF 9.2 million or $9.5 million in the fourth quarter of 2022. The increase in net loss was primarily driven by increases in clinical development expenses, partially offset by changes in the fair value (non-cash) adjustment of outstanding warrants.
- **FY2023 Net loss** was CHF 88.8 million or $98.8 million for the year ended December 31, 2023, or CHF 2.97 or $3.31 loss per share (basic and diluted) compared to CHF 38.7 million or $40.5 million, or CHF 11.32 or $11.86 loss per share (basic and diluted) in the year ended December 31, 2022. The increase in net loss was primarily driven by the non-recurring merger and listing expense in Q1 2023, increases in clinical development expenses, public company expenses, and the fair value (non-cash) adjustment of outstanding warrants.
- **FY2023 Non-IFRS net loss** was CHF 49.0 million or $54.5 million, or CHF 1.64 or $1.83 per share, for the year ended December 31, 2023, compared to CHF 38.7 million or $40.5 million, or CHF 11.32 or $11.86 per share, for the year ended December 31, 2022. The increase in non-IFRS net loss was primarily driven by increases in clinical development expenses, G&A expenses related to operating as 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 net loss for the full year 2023, and non-IFRS net loss per common share for the same period. 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 year ended December 31, 2023. The resulting non-cash foreign exchange impact of such reclassification amounted to CHF 5.0 million or $5.7 million for the year ended December 31, 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.

Consolidated Statements of Financial Position

(Amounts in CHF thousands)	**As of December 31, 2023**	**As of December 31, 2022**
ASSETS		
Non-current assets		
Property and equipment, net	288	365
Intangible assets	12,206	12,206
Right-of-use assets	755	758
Other non-current assets	89	74
Total non-current assets	**13,338**	**13,403**
Current assets		
Other current assets	8,488	2,959
Accrued income	876	912
Short-term financial assets	53,324	-
Cash and cash equivalents	38,327	19,786
Total current assets	**101,015**	**23,657**
TOTAL ASSETS	**114,353**	**37,060**
EQUITY AND LIABILITIES		

Shareholders' equity		
Share capital	366	39
Share premium	288,162	10,742
Reserve for share-based payment	6,379	2,771
Actuarial loss on post-employment benefit obligations	(1,072)	(264)
Treasury shares	-	(1)
Cumulative translation adjustments	(327)	(300)
Accumulated losses	(199,780)	(110,978)
Total equity	**93,728**	**(97,991)**
Non-current liabilities		
Long-term lease liabilities	431	491
Long-term financial debt	-	122,449
Long-term payables	378	-
Defined benefit pension liabilities	728	91
Total non-current liabilities	**1,537**	**123,031**
Current liabilities		
Trade payables	7,596	3,867
Accrued expenses and other payables	5,948	8,011
Short-term lease liabilities	174	142
Warrant liabilities	5,370	-
Total current liabilities	**19,088**	**12,020**
Total liabilities	**20,625**	**135,051**
TOTAL EQUITY AND LIABILITIES	**114,353**	**37,060**

Consolidated Statements of Loss

(Amounts in CHF thousands, except per share data)	**For the three months ended December 31,**		**For the years ended December 31,**	
	2023	**2022**	**2023**	**2022**
Grant income	185	214	883	912
Operating income	**185**	**214**	**883**	**912**
Research and development expenses	(8,029)	(6,889)	(29,247)	(22,224)
General and administrative expenses	(4,340)	(4,438)	(17,487)	(11,064)
Merger and listing expense	-	-	(34,863)	-
Operating expenses	**(12,369)**	**(11,327)**	**(81,597)**	**(33,288)**
Operating loss	**(12,184)**	**(11,113)**	**(80,714)**	**(32,376)**
Finance income	656	56	1,429	126
Finance expense	(12)	(1,323)	(1,315)	(6,442)
Fair value adjustment on warrant liabilities	1,207	-	(3,431)	-
Foreign currency exchange gain (loss), net	(2,179)	3,183	(4,664)	49
Finance result, net	**(328)**	**1,916**	**(7,981)**	**(6,267)**
Loss before tax for the period	**(12,512)**	**(9,197)**	**(88,695)**	**(38,643)**
Income tax benefit (expense)	13	14	(107)	(55)
Loss for the period	**(12,499)**	**(9,183)**	**(88,802)**	**(38,698)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.34)	(2.62)	(2.97)	(11.32)

Reconciliation of Non-IFRS Measures (Unaudited)

(Amounts in CHF thousands, except per share data)

	For the years ended ended December 31,		
	2023	**2022**	**2021**
IFRS loss for the period	**(88,802)**	**(38,698)**	**(18,552)**
Non-IFRS adjustments:			
Merger and listing expense (i)	34,863	-	-

Merger Sub 2 reclassification from equity to foreign exchange loss [ii]	4,978	-	-
Non-IFRS loss for the period	**(48,961)**	**(38,698)**	**(18,552)**
IFRS basic and diluted loss attributable to equity holders	(2.97)	(11.32)	(5.84)
Non-IFRS basic and diluted loss attributable to equity holders	**(1.64)**	**(11.32)**	**(5.84)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**29,899,651**	**3,417,521**	**3,175,340**

(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 is a global biopharmaceutical company (Nasdaq: 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, a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED) and for non-infectious anterior 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. Headquartered in Switzerland and with operations in the U.S., Oculis' goal is to deliver life-changing treatments to 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 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, including the timing of completing enrolment in the RELIEF trial, topline results for OPTIMIZE-2 and ACUITY trials and IND status for OCS-05; 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.