Oculis Reports Q1 2024 Financial Results and Provides Company Updates

May 8, 2024

- Clinical programs progressing as planned with initiation of second OCS-01 Phase 3 DIAMOND-2 trial in Diabetic Macular Edema (DME) and completion of enrollment in OCS-02 (licaminlimab) Phase 2b RELIEF trial in Dry Eye Disease (DED); RELIEF topline results anticipated in Q2 2024
- Completed $59 million registered direct equity offering and concurrent listing on Nasdaq Iceland Main Market in April 2024, extending cash runway into the second half of 2026
- Strengthened executive leadership team and U.S. presence with the appointments of accomplished and seasoned professionals as President of Research & Development and Chief Human Resources Officer

ZUG, Switzerland, May 08, 2024 (GLOBE NEWSWIRE) -- 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 three-month period ended March 31, 2024, and an overview of the Company's progress.

Riad Sherif, M.D., Chief Executive Officer of Oculis: "We delivered a very successful first quarter and made significant strides toward achieving our strategic goals. The strong support from new and existing investors enabled a $59 million financing and dual listing on Nasdaq in Iceland in addition to the U.S. Furthermore, the continued advancement of our late-stage pipeline in Q1 and the strengthened leadership team with the appointments of Snehal and Virginia position us well for the future. I look forward to providing an update on the anticipated RELIEF Phase 2b clinical readout in DED with OCS-02 before the end of the quarter, and on other key milestones as the year progresses."

Q1 2024 and Recent Highlights

Clinical Highlights

- Initiated the second Phase 3 DIAMOND-2 trial in DME with OCS-01, an OPTIREACH® formulation of high concentration dexamethasone eye drop. The two ongoing Phase 3 52-week trials, DIAMOND-1 and DIAMOND-2, started as planned in December 2023 and February 2024, respectively.
- Rapidly completed patient enrollment for the DED Phase 2b RELIEF trial of OCS-02 (licaminlimab). Licaminlimab is a TNFα inhibitor developed as an eye drop with a proprietary antibody fragment technology specifically designed to treat ocular inflammations. The trial, initiated in November 2023, evaluates the efficacy and safety of OCS-02 (licaminlimab) vs. vehicle in signs of DED, and further explores its potential benefit in patients with a certain genotype.

Corporate Highlights

- Raised gross proceeds of $59 million in an oversubscribed registered direct offering, with participation from new Icelandic institutional and existing investors. Concurrently, the Company listed on the Nasdaq Iceland Main Market in addition to Nasdaq Global Market in the U.S.
- Leadership appointments:
  - Snehal Shah, Pharm. D., an industry veteran and accomplished regulatory and ophthalmology development professional, appointed as President of Research & Development.
  - Virginia R. Dean, a seasoned HR executive, appointed as Chief Human Resources Officer.

Events & Presentations Highlights

- Hosted an R&D Day on February 28, 2024, to review key clinical programs: OCS-01 Phase 3 DIAMOND program in DME and OCS-02 (licaminlimab) Phase 2b RELIEF trial in DED, featuring 10 leading experts in retina and anterior segments, with over 100 participants.
- Presented the Phase 3 OPTIMIZE-1 positive results with OCS-01 for treating inflammation and pain following cataract surgery at the 2024 American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting.

Upcoming Clinical Milestones
The Company continues to advance its innovative and differentiated pipeline and planned clinical development programs including:

- The Phase 2b RELIEF trial evaluating topical anti-TNFα OCS-02 (licaminlimab) efficacy and safety in signs of DED, on track with topline readout anticipated in the second quarter of 2024.
- The second Phase 3 OPTIMIZE-2 trial evaluating OCS-01 as a once-daily eye drop for the treatment of inflammation and pain following cataract surgery, with topline readout anticipated in the fourth quarter 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.
- The Phase 2 ACUITY trial designed to evaluate the safety and tolerability of OCS-05, a serum glucocorticoid kinase-2 (SGK-2) activator and potentially neuroprotective candidate, in acute optic neuritis (AON), with topline readout anticipated in the fourth quarter of 2024. The Company also aims to complete an IND submission for OCS-05 in the U.S. in 2024.

Q1 2024 Financial Highlights

- **Cash position:** As of March 31, 2024, the Company had total cash, cash equivalents and short-term investments of CHF

79.9 million or $88.7 million, compared to CHF 91.7 million or $108.9 million as of December 31, 2023. The decrease in cash position reflects the execution of planned development activities as well as routine business operations. With the addition of the recent $59 million registered direct equity offering, the Company's cash, cash equivalents and short-term financial assets are expected to fund operations into the second half of 2026.

- **Research and development expenses** were CHF 10.9 million or $12.4 million for the three-months ended March 31, 2024, compared to CHF 6.1 million or $6.6 million for the same period in 2023. The increase was primarily due to higher clinical trial costs during the first quarter of 2024 due to ongoing DIAMOND-1, DIAMOND-2, OPTIMIZE-2, RELIEF and ACUITY clinical trials.
- **General and administrative expenses** were CHF 4.7 million or $5.4 million for the three months ended March 31, 2024, compared to CHF 4.0 million or $4.4 million for the same period in 2023. The increase was primarily due to higher expenses related to operating a public company and personnel-related costs.
- **Q1 Net loss** was CHF 16.1 million or $18.4 million, or CHF 0.44 or $0.50 per share, for the quarter ended March 31, 2024, compared to CHF 46.0 or $49.7 million, or CHF 3.57 or $3.86 per share, for the first quarter of 2023. The decrease was primarily due to the non-recurring merger and listing expenses recognized during the first quarter of 2023, offset by higher research and development expenses, and the non-cash fair value adjustment on outstanding warrants in the first quarter of 2024.
- **Q1 Non-IFRS net loss** was CHF 16.1 million or $18.4 million, or CHF 0.44 or $0.50 per share, for the quarter ended March 31, 2024, compared to CHF 11.2 million or $12.1 million, or CHF 0.87 or $0.94 per share, for the same period in 2023. The increase in non-IFRS net loss was primarily driven by increases in research and development expenses and the non-cash fair value adjustment on outstanding warrants.

Non-IFRS Financial Information

This press release contains financial measures that do not comply with IFRS Accounting 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 non-cash expense CHF 34.9 million or $38.2 million in the first quarter of 2023 total operating expenses.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of March 31, 2024	As of December 31, 2023
ASSETS		
Non-current assets		
Property and equipment, net	259	288
Intangible assets	12,206	12,206
Right-of-use assets	719	755
Other non-current assets	87	89
Total non-current assets	**13,271**	**13,338**
Current assets		
Other current assets	4,371	8,488
Accrued income	1,138	876
Short-term financial assets	55,572	53,324
Cash and cash equivalents	24,361	38,327
Total current assets	**85,442**	**101,015**
TOTAL ASSETS	**98,713**	**114,353**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	367	366
Share premium	288,387	288,162
Reserve for share-based payment	7,520	6,379
Actuarial loss on post-employment benefit obligations	(1,072)	(1,072)
Cumulative translation adjustments	(296)	(327)
Accumulated losses	(215,873)	(199,780)
Total equity	**79,033**	**93,728**
Non-current liabilities		
Long-term lease liabilities	411	431
Long-term payables	378	378

Defined benefit pension liabilities	738	728
Total non-current liabilities	**1,527**	**1,537**
Current liabilities		
Trade payables	1,174	7,596
Accrued expenses and other payables	8,358	5,948
Short-term lease liabilities	182	174
Warrant liabilities	8,439	5,370
Total current liabilities	**18,153**	**19,088**
Total liabilities	**19,680**	**20,625**
TOTAL EQUITY AND LIABILITIES	**98,713**	**114,353**

Condensed Consolidated Statements of Operations (Unaudited)

(Amounts in CHF thousands, except per share data)	**For the three months ended March 31,**	
	2024	**2023**
Grant income	222	229
Operating income	**222**	**229**
Research and development expenses	(10,856)	(6,148)
General and administrative expenses	(4,694)	(4,042)
Merger and listing expense	-	(34,863)
Operating expenses	**(15,550)**	**(45,053)**
Operating loss	**(15,328)**	**(44,824)**
Finance income	581	33
Finance expense	(41)	(1,279)
Fair value adjustment on warrant liabilities	(3,069)	422
Foreign currency exchange gain (loss), net	1,794	(243)
Finance result, net	**(735)**	**(1,067)**
Loss before tax for the period	**(16,063)**	**(45,891)**
Income tax expense	(30)	(124)
Loss for the period	**(16,093)**	**(46,015)**
Loss per share:		
Basic and diluted loss attributable to equity holders	(0.44)	(3.57)

Reconciliation of Non-IFRS Measures (Unaudited)

(Amounts in CHF thousands, except per share data)

	For the three months ended March 31,	
	2024	**2023**
IFRS loss for the period	**(16,093)**	**(46,015)**
Non-IFRS adjustments:		
Merger and listing expense (i)	-	34,863
Non-IFRS loss for the period	**(16,093)**	**(11,152)**
IFRS basic and diluted loss attributable to equity holders	(0.44)	(3.57)
Non-IFRS basic and diluted loss attributable to equity holders	**(0.44)**	**(0.87)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**36,621,162**	**12,879,944**

(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 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, 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.

OCS-01, OCS-02 and OCS-05 are investigational drugs and have not received regulatory approval for commercial use in any country.

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 the treatment of DME and inflammation and pain following ocular surgery; the potential of OCS-02 for treating 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 topline results for RELIEF, OPTIMIZE-2 and ACUITY trials; 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.