Oculis Reports Q2 2024 Financial Results and Provides Recent Company Update

- Reported positive topline results for the Phase 2b RELIEF trial of OCS-02 (licaminlimab) paving the way for potentially the first precision medicine in Dry Eye Disease (DED)
- Phase 2 ACUITY trial of OCS-05 in acute optic neuritis (AON) is on track for topline readout in Q4 2024
- Pre-NDA meeting with U.S. Food and Drug Administration (FDA) completed in August for once daily OCS-01 for the treatment of post-operative inflammation and pain following ocular surgery; Providing a clear path forward for NDA submission in Q1 2025, while randomization in Phase 3 DIAMOND-1 and DIAMOND-2 trials in diabetic macular edema (DME) is on track
- Cash, cash equivalents and short-term investments of $131.2 million as of June 30, 2024 provides cash runway into the 2H 2026.

ZUG, Switzerland, August 27, 2024 -- 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 June 30, 2024, and provided an overview of the Company's progress.

Riad Sherif M.D., Chief Executive Officer of Oculis: "We made significant strides in advancing our innovative clinical programs this past quarter, demonstrating strong momentum and exceptional execution in our DIAMOND-1 and DIAMOND-2 trials with Oculis' lead asset, OCS-01, the first eye drop in Phase 3 for DME. Additionally, we were excited to announce the positive results from the Phase 2b RELIEF trial of OCS-02 (licaminlimab) in dry eye, which showed improvements in multiple regulatory sign endpoints and materially more profound results in patients with the TNFR1 genetic biomarker. These results are potentially paving the way for the first precision medicine in dry eye disease for this heterogeneous condition, where the current treatment approach mainly consists of "trial and error". We look forward also to the upcoming topline readout from the Phase 2 ACUITY trial in AON with OCS-05 in the fourth quarter of 2024, and to our anticipated first NDA submission with OCS-01 in post-ocular surgery in the first quarter of 2025."

Q2 2024 and Recent Highlights

Clinical Highlights

- OCS-01 for DME: Continued positive momentum in the randomization of patients for both Phase 3 DIAMOND trials with OCS-01 eye drop in DME. Patient enrollment through the end of June exceeded the Company's expectations and was at 35% and 23% for DIAMOND-1 and DIAMOND-2, respectively.
- OCS-02 (licaminlimab) in DED: Announced positive topline results of Phase 2b RELIEF trial evaluating OCS-02 (licaminlimab) for the treatment of signs in DED. Improvements in multiple regulatory efficacy sign endpoints were observed in full population and with rapid and materially more pronounced effects in the TNFR1 genetic biomarker population as identified in the prior successful Phase 2 symptoms trial. OCS-02 (licaminlimab)'s tolerability was excellent with drop comfort level reported similar to artificial tears. If approved, OCS-02 (licaminlimab) has the potential to transform the treatment paradigm in DED with a precision medicine approach.

- OCS-05 in AON: Completed enrollment in the Phase 2 ACUITY trial with OCS-05 in AON, and on-track for topline readout in Q4 2024 for its novel neuroprotective candidate with potential for neuro-ophthalmic diseases.

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.
- Snehal Shah, Pharm. D., was appointed as President of Research & Development strengthening the Company's R&D capabilities.
- Robert K. Warner, M.B.A. and Arshad M. Khanani, M.D., M.A., FASRS elected as members of the Board of Directors, bolstering its development and commercial expertise.
- Baruch D. Kuppermann, M.D., Ph.D. and Frank G. Holz, M.D., Ph.D. appointed as members of the Scientific Advisory Board, and working closely with senior management team as the Company advances both Phase 3 DIAMOND trials with OCS-01 eye drops in DME.

Presentations and Awards Highlights

- 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.
- Established the Ramin Tadayoni Award together with EURETINA in memory of the Company's late Chief Scientific Officer and a world-renowned retina expert.

Recent Updates and Upcoming Milestones

- Pre-NDA meeting conducted as planned in August 2024 to seek alignment with the FDA on the regulatory submission for once daily OCS-01 for the treatment of post-operative inflammation and pain following ocular surgery. FDA confirmed that the completed Phase 3 OPTIMIZE-1 trial, along with the completed Phase 2 SKYGGN trial and safety data from completed trials in ocular surgery and diabetic macular edema, are sufficient to support an NDA submission in Q1 2025. The Company will close the Phase 3 OPTIMIZE-2 trial due to a third-party administrative error which affected the conduct of the trial and prevents analysis of trial results. If approved, OCS-01 with its OPTIREACH® formulation would become the first once-daily, preservative-free steroid for treating inflammation and pain following ocular surgery.
- Topline readout for the Phase 2 ACUITY trial with OCS-05 is anticipated in the fourth quarter of 2024. The ACUITY trial is a randomized, double-blind, placebo-controlled, multi-center trial in France designed to evaluate the safety and tolerability of OCS-05, a novel serum glucocorticoid kinase-2 (SGK-2) activator and potentially neuroprotective candidate in AON. Enrollment is completed with 36 patients randomized. In addition to safety, an objective measurement of retinal thickness, as assessed by optical coherence tomography (OCT), will be evaluated as an exploratory efficacy endpoint. OCS-05 was granted orphan drug designation by FDA in the U.S. and by the European Medicine Agency (EMA) in Europe for AON, a disease characterized by acute inflammation and demyelination of the optic nerve, often affecting young adults, in which retinal thinning is directly associated with vision loss and permanent visual impairment. This study seeks to explore the potential neuroprotective benefits of OCS-05 on preserving retinal thickness in AON patients. To date there is no specific therapy approved for AON and unmet needs remain for therapies that can prevent vision loss after an acute episode of optic neuritis. In addition to AON, a neuroprotective treatment could have wide applicability in neuro-ophthalmic diseases where protecting neural

retina is key to preserving patients' sight such as glaucoma, geographic atrophy, diabetic retinopathy and also for other ophthalmic indications where other nerves are impacted like neurotrophic keratitis. Additionally, the Company is on track to complete an IND submission for OCS-05 in the U.S. by fall 2024.
- The Company is planning to consult with the FDA in Q1 2025 to discuss next steps for the OCS-02 (licaminlimab) program in DED.

Q2 2024 Financial Highlights

- **Cash position:** As of June 30, 2024, the Company had total cash, cash equivalents and short-term investments of CHF 117.9 million or $131.2 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 16.5 million or $18.2 million for the three-month ended June 30, 2024, compared to CHF 6.2 million or $6.9 million in the same period in 2023. The increase was primarily due to increases in clinical trial expenses related to the ongoing OCS-01, OCS-02 (licaminlimab) and OCS-05 clinical trials, including positive advancements in DIAMOND-1 and DIAMOND-2 Phase 3 DME trials.
- **General and administrative expenses** were CHF 6.3 million or $6.9 million for the three-month ended June 30, 2024, compared to CHF 4.8 million or $5.3 million in the same period in 2023. The increase was primarily due to increases in personnel costs as well as certain non-recurring non-capitalized transaction costs associated with the registered direct offering in April 2024.
- **Q2 Net loss** was CHF 20.8 million or $23.0 million for the second quarter ended June 30, 2024, compared to CHF 12.9 or $14.3 million in the second quarter of 2023. The increase was primarily driven by increases in clinical development expenses.
- **Q2 Year to date net loss** was CHF 36.9 million or $41.5 million for the six months ended June 30, 2024, compared to CHF 58.9 or $64.6 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, partially offset by increases clinical development costs and costs incurred to operate as a public company.
- **Q2 Year to date non-IFRS net loss** was CHF 36.9 million or $41.5 million, or CHF 0.96 or $1.08 per share, for the six months ended June 30, 2024, compared to CHF 24.0 million or $26.3 million, or CHF 1.03 or $1.13 per share, for the same period in 2023. The increase in non-IFRS net loss was primarily driven by increases in development expenses.

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 the six months ended June 30, 2023 total operating expenses.

Condensed Consolidated Statements of Financial Position (Unaudited)

(Amounts in CHF thousands)	As of June 30, 2024	As of December 31, 2023
ASSETS		
Non-current assets		
Property and equipment, net	249	288
Intangible assets	12,206	12,206
Right-of-use assets	1,465	755
Other non-current assets	178	89
Total non-current assets	**14,098**	**13,338**
Current assets		
Other current assets	5,329	8,488
Accrued income	1,383	876
Short-term financial assets	74,070	53,324
Cash and cash equivalents	43,852	38,327
Total current assets	**124,634**	**101,015**
TOTAL ASSETS	**138,732**	**114,353**
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	427	366
Share premium	340,046	288,162
Reserve for share-based payment	10,819	6,379
Actuarial loss on post-employment benefit obligations	(1,447)	(1,072)
Treasury shares	(10)	-
Cumulative translation adjustments	(297)	(327)
Accumulated losses	(236,712)	(199,780)
Total equity	**112,826**	**93,728**
Non-current liabilities		
Long-term lease liabilities	1,011	431
Long-term payables	-	378
Defined benefit pension liabilities	1,261	728
Total non-current liabilities	**2,272**	**1,537**
Current liabilities		
Trade payables	3,181	7,596
Accrued expenses and other payables	12,763	5,948
Short-term lease liabilities	327	174
Warrant liabilities	7,363	5,370
Total current liabilities	**23,634**	**19,088**
Total liabilities	**25,906**	**20,625**
TOTAL EQUITY AND LIABILITIES	**138,732**	**114,353**

Condensed Consolidated Statements of Loss (Unaudited)

(Amounts in CHF thousands, except per share data)	For the three months ended June 30,		For the six months ended June 30,	
	2024	2023	2024	2023
Grant income	245	250	467	479
Operating income	**245**	**250**	**467**	**479**
Research and development expenses	(16,465)	(6,198)	(27,321)	(12,346)
General and administrative expenses	(6,265)	(4,797)	(10,959)	(8,840)
Merger and listing expense	-	-	-	(34,863)
Operating expenses	**(22,730)**	**(10,995)**	**(38,280)**	**(56,049)**
Operating loss	**(22,485)**	**(10,745)**	**(37,813)**	**(55,570)**
Finance income	660	216	1,241	253
Finance expense	(87)	(17)	(128)	(1,297)
Fair value adjustment on warrant liabilities	1,370	(2,625)	(1,699)	**(2,203)**
Foreign currency exchange gain (loss), net	(267)	408	1,527	161
Finance result, net	**1,676**	**(2,018)**	**941**	**(3,086)**
Loss before tax for the period	**(20,809)**	**(12,763)**	**(36,872)**	**(58,656)**
Income tax expense	(30)	(114)	(60)	(236)
Loss for the period	**(20,839)**	**(12,877)**	**(36,932)**	**(58,892)**
Loss per share:				
Basic and diluted loss attributable to equity holders	(0.51)	(0.38)	(0.96)	(2.53)

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,	
	2024	2023	2024	2023
IFRS loss for the period	**(20,839)**	**(12,877)**	**(36,932)**	**(58,892)**
Non-IFRS adjustments:				
Merger and listing expense (i)	-	-	-	34,863
Non-IFRS loss for the period	**(20,839)**	**(12,877)**	**(36,932)**	**(24,029)**
IFRS basic and diluted loss attributable to equity holders	(0.51)	(0.38)	(0.96)	(2.53)
Non-IFRS basic and diluted loss attributable to equity holders	**(0.51)**	**(0.38)**	**(0.96)**	**(1.03)**
IFRS weighted-average number of shares used to compute loss per share basic and diluted	**40,535,173**	**33,565,542**	**38,567,675**	**23,274,136**

(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.

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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; 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; the timing or likelihood of regulatory filings and approvals; and the Company's expected cash runway are forward-looking. Certain clinical trial results presented in this press release are topline and preliminary and subject to change, as analysis is ongoing. These topline results may not be reproduced in subsequent patients and clinical trials. 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.