

EVAXION

Fourth quarter and full year 2022 financial results and business update

April 27, 2023

- Evaxion presented promising data from its Phase 1/2a clinical trial of EVX-02 in patients with late-stage melanoma at the 2023 AACR meeting
- EVX-03, a DNA-based personalized cancer vaccine, is expected to have a CTA filing in Q3 2023 and start a Phase 1 trial in solid tumor patients in Q4 2023
- Recent collaborations with Pantherna Therapeutics GmbH (utilizing PIONEER™) and ExpreSion Biotechnologies ApS (utilizing RAVEN™) highlight the broad utility of Evaxion's differentiated AI platforms, which now includes the new ObsERV™ AI technology, which is designed to identify patient-specific viral targets from endogenous retroviruses (ERVs) known to be overexpressed in certain tumors
- \$13 million in cash and equivalents as of December 31, 2022 is expected to fund operations into December 2023
- Evaxion to host a webcast and conference call today, April 27 at 8:30 am EDT

COPENHAGEN, Denmark, April 27, 2023 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies, announced today the fourth quarter and full-year 2022 financial results and provided a business update.

"Evaxion made excellent progress across its core AI technologies for vaccine target discovery in 2022 and early 2023, validated through the progress in the pipeline," said Per Norlén, Chief Executive Officer of Evaxion. "Looking back on our accomplishments, I'd like to highlight the initial proof-of-concept clinical trials in melanoma for EVX-01 and EVX-02, developed using our PIONEER™ artificial intelligence (AI)-platform, and our next-generation immuno-oncology candidate, EVX-03, scheduled to begin clinical testing in Q4 2023. We also announced another proprietary AI technology, ObsERV™, targeting endogenous retroviruses (ERVs), which is planned to be incorporated into our personalized cancer vaccines. Over the last six months, as we have refined our development strategy and business focus, re-aligned our organization and extended our cash runway, I am grateful to the outstanding work of the team and remain impressed by the strength of Evaxion's core AI-science."

Per concluded, "We recently reported promising clinical results from the Phase 1/2a EVX-02 study in melanoma at the 2023 annual meeting for the American Association for Clinical Research (AACR). Looking ahead to the rest of the year, we plan to report final Phase 1/2a results and interim Phase 2 data from the EVX-01 program in melanoma. In addition, we intend to initiate recruitment in a Phase 1 study with EVX-03 in Q4 2023. We look forward to inform the investment community and our key stakeholders with further updates on our progress throughout the year."

Pipeline Updates

Technology advances:

Novel ObsERV™ technology -- In March 2023, Evaxion reported the discovery of a novel new source of antigens for personalized cancer immunotherapy, based on endogenous retroviruses (ERVs). The AI-enabled technology has the potential to make "cold" tumors responsive to immunotherapy, which has the potential to broaden the patient population for immunotherapy significantly.

Novel mRNA vaccine delivery collaboration with Pantherna -- In February 2023, Evaxion and Pantherna announced promising mRNA vaccine data. The preclinical data demonstrated that tumor neoantigens identified by Evaxion's AI PIONEER™ platform could drive a strong immune response and lead to complete inhibition of tumor growth when delivered using Pantherna's proprietary mRNA platform.

Program Overview

EVX-01 (1st generation, Peptide based vaccine, Phase 2 in melanoma) – The ongoing single-arm, multi-center trial ([NCT05309421](#)) is evaluating EVX-01 for the treatment of adults with metastatic melanoma in combination with the [PD-1 inhibitor/checkpoint inhibitor/CPI], KEYTRUDA®.

- The Company plans to present a full read-out of the previous Phase 1/2a study in 12 patients at the American Society for Clinical Oncology (ASCO) Annual Meeting in June 2023, in which interim data demonstrated clinical response in six out of the first nine patients.
- The Phase 2 study, initiated in September 2022, is expected to enroll up to 20 patients and report interim data in Q4 2023.

EVX-02 (2nd generation, DNA-based vaccine, Phase 1/2a in melanoma) – The single-arm, open-label study ([NCT04455503](#)) evaluated EVX-02 in combination with the CPI, nivolumab, in patients with advanced melanoma who had undergone complete surgical resection and were at high risk for recurrence.

- Data presented at the 2023 AACR meeting showed that all 10 patients who completed the full course of dosing with the EVX-02/CPI combination were relapse-free during the 12-month study period. The treatment also produced neoantigen-specific long-lasting T-cell immune responses involving both CD4+ and CD8+ T-cells. The EVX-02/CPI treatment combination was well tolerated, and only mild EVX-02-associated adverse events (AEs) were observed.

EVX-03 (3rd generation, DNA-based vaccine, Phase 1 study expected to begin in Q4 2023) – EVX-03 is a DNA-based personalized cancer immunotherapy that combines patient-specific neoantigens with personalized ERVs. Bringing these personalized antigens together into a single plasmid construct, armed with a genetic immune adjuvant, will enable Evaxion to develop an immunotherapy with the potential for inducing a robust and patient-specific immune response and for increased efficacy.

- A clinical trial authorization (CTA) filing with the European Medicines Agency to evaluate the combination of EVX-03 and a CPI is anticipated to be filed in Q3 2023 and the Phase 1 study is anticipated to begin in Q4 2023 in patients with solid tumors.

Infectious diseases programs: based on Evaxion's EDEN™ and RAVEN™ technologies

Technology advances:

EVX-B1 (*S. aureus*, preclinical) – Evaxion has demonstrated significant protection from *S. aureus* infection in both sepsis and skin infection models. The next step for this partnering-ready program is IND-enabling toxicology studies.

EVX-B2 (*N. gonorrhoeae*, preclinical) – In June 2022, Evaxion announced gonorrhea as a new bacterial vaccine candidate for *N. gonorrhoeae*. In September 2022, Evaxion announced that the Company, in collaboration with the UMass Chan Medical School, had received a grant from the U.S. National Institutes of Health (NIH) for the development of a lead vaccine candidate.

EVX-V1 (Cytomegavirus/CMV, preclinical) – In December 2022, Evaxion and ExpreS²ion initiated the discovery phase of a joint research collaboration to develop a next generation CMV vaccine candidate that elicits both cellular and humoral antibody responses; this phase will be jointly funded until 2025. After that, the parties could expand the research collaboration into a Development and Commercialization agreement.

Expected milestones in 2023

- Q2 2023 - Full readout EVX-01 Phase 1/2a – to be presented at ASCO in June 2023
- Q4 2023 - Report interim results from EVX-01 Phase 2 trial
- Q4 2023 - Initiate patient recruitment in a Phase 1 study for EVX-03

Full Year 2022 Financial Results

- Cash position: As of December 31, 2022, cash and cash equivalents were \$13.2 million as compared to \$32.2 million as of December 31, 2021. This along with capital raised in Q1 2023 of \$4.2 million, is anticipated to be sufficient to fund operations into December 2023.
- Research and Development expenses were \$17.1 million for the year ended December 31, 2022 as compared to \$19.6 million for the year ended December 31, 2021. The decrease was primarily related to a decrease in spending on clinical trials, net of grant income and preclinical product candidates countered by an increase in employee-related costs.
- General and Administrative expenses were \$8.2 million for the year ended December 31, 2022 compared to \$6.3 million for the year ended December 31, 2021. The increase was primarily related to professional fees incurred by the corporate functions as a listed company.
- Net loss was \$23.2 million for the year ended December 31, 2022 or (\$0.98) loss per basic and diluted share as compared to \$24.5 million, or (\$1.26) loss per basic and diluted share for the year ended December 31, 2021.

Based on the Company's current cash position, with a cash runway until beginning of December and the need for further funding, our auditors EY have provided an emphasis of matter in their auditors report that there exists substantial doubt about the Company's ability to continue as a going concern.

Webcast and Conference Call

Evaxion will host a webcast and conference call today, April 27, at 8:30 am EDT.

To dial in for the conference call, please use the following details:

- US: 877-407-0792
- International: +1-201-689-8263
- Conference ID: 13727933

Alternatively to access the audio webcast, please visit the events page of Evaxion's website at: <https://evaxion-biotech.com/news-and-events/events/default.aspx>

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. Evaxion's proprietary and scalable AI technologies decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of product candidates, including three personalized cancer immunotherapies. It is located in Hørsholm, Denmark and is listed on the Nasdaq New York stock exchange. For more information, please visit: www.evaxion-biotech.com.

Source: Evaxion Biotech

Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "target," "believe," "expect," "hope," "aim," "intend," "may," "might," "anticipate," "contemplate," "continue," "estimate," "plan," "potential," "predict," "project," "will," "can have," "likely," "should," "would," "could," and other words and terms of similar meaning identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including, but not limited to, risks related to: our financial condition and need for additional capital; our development work; cost and success of our product development activities and preclinical and clinical trials; commercializing any approved pharmaceutical product developed using our AI platform technology, including the rate and degree of market acceptance of our product candidates; our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; government regulation; protection of our intellectual property rights; employee matters and managing growth; our ADSs and ordinary shares, the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on our business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia; and other uncertainties affecting our business operations and financial condition. For a further discussion of these risks, please refer to the risk factors included in our most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. We do not assume any obligation to update any forward-looking statements except as required by law.

Evaxion Biotech A/S

Consolidated Statements of Financial Position Data (Unaudited)

(USD in thousands)

	Dec 31, 2022	Dec 31, 2021
Cash and cash equivalents	\$ 13,184	\$ 32,166
Total assets	22,025	40,163
Total liabilities	13,722	7,726
Share capital	3,886	3,755
Other reserves	77,076	79,114
Accumulated deficit	(72,659)	(50,432)
Total equity	8,303	32,437
Total liabilities and equity	\$ 22,025	\$ 40,163

Evaxion Biotech A/S

Consolidated Statements of Comprehensive Loss Data (Unaudited)

(USD in thousands, except per share data)

	Three Months Ended Dec 31		Twelve months Ended Dec 31	
	2022	2021	2022	2021
Research and development expenses	\$ (4,073)	\$ (6,154)	\$ (17,056)	\$ (19,583)
General and administrative expenses	(2,452)	(1,567)	(8,208)	(6,251)
Operating loss	(6,525)	(7,721)	(25,264)	(25,834)
Finance income	70	746	2,831	2,039
Finance expenses	(590)	(72)	(1,508)	(915)
Net loss before tax	(7,045)	(7,047)	(23,941)	(24,710)
Income tax benefit	173	(1,323)	772	178
Net loss for the period	\$ (6,872)	\$ (8,370)	\$ (23,169)	\$ (24,532)
Net loss attributable to equity holders of Evaxion Biotech A/S	\$ (6,872)	\$ (8,370)	\$ (23,169)	\$ (24,532)
Loss per share – basic and diluted	\$ (0.29)	\$ (0.39)	\$ (0.98)	\$ (1.26)
Number of shares used for calculation (basic and diluted)	24,082,247	21,671,312	23,638,685	19,493,143