

EVAXION

Evaxion Announces Third Quarter 2022 Financial Results and Business Update

November 14, 2022

- *Per Norlén, M.D., PhD. joined Evaxion as Chief Executive Officer in October*
- *Enrollment of the first patient in our global Phase 2b clinical trial of EVX-01*
- *Increased strategic focus on clinical lead oncology assets and partnering*
- *Cash and cash equivalents of \$17.9 million sufficient to fund operations into mid-2023*

COPENHAGEN, Denmark, Nov. 14, 2022 (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 its third quarter 2022 financial results and provided an operational and business update.

Per Norlén, CEO of Evaxion, said: "Evaxion continues to advance its drug development pipeline, reaching an important milestone in the third quarter with the enrollment of the first patient in our global Phase 2b clinical trial of EVX-01, our personalized cancer immunotherapy for the treatment of patients with metastatic melanoma. Going forward, we intend to further increase our focus on our clinical lead oncology assets within personalized cancer immunotherapy."

Operational and Business Highlights in the Third Quarter of 2022

Enrolled the first patient in the global Phase 2b clinical trial of EVX-01 for the treatment of melanoma.

In the Company's first Phase 2b clinical trial, Evaxion is evaluating the efficacy and safety of EVX-01 in adults with metastatic melanoma. The trial is being conducted globally at clinical sites across the US, Europe, and Australia in collaboration with Merck & Co., Inc. Patients enrolled in the Phase 2b clinical trial will receive standard-of-care treatment along with KEYTRUDA® in combination with EVX-01. Evaxion is responsible for the conduct of the trial, and Merck will supply the required KEYTRUDA®. The Company anticipates interim topline data readout in the second half of 2023.

Announced an increased strategic focus on clinical lead oncology assets and partnering. Evaxion intends to further increase its focus on its clinical lead oncology product candidates, EVX-01 and EVX-02/03, to bring them to clinical proof of concept followed by out-licensing. Additionally, the Company plans preclinical partnering of its early-stage programs under its infectious disease platforms. This was announced by the Company's new Chief Executive Officer, Per Norlén, who emphasized the importance of prioritizing the Company's activities in the current market. As previously announced by the Company, the EVX-01 program recently started to enroll patients in the global Phase 2b trial in metastatic melanoma. At the same time, the Phase 1/2a trial of the DNA-based EVX-02 is progressing as planned, with data readout currently expected by mid-2023. The next-generation DNA vaccine, EVX-03, builds on EVX-02 and holds the potential for even stronger results due to an integrated mechanism that boosts the immune system. The Company plans to submit a regulatory filing of EVX-03, following EVX-02 data, which may allow Evaxion to advance EVX-03 faster to clinical proof of concept. Regarding the Company's early programs for infectious diseases, such as our *Staphylococcus aureus* vaccine, the Company aims to develop these in partnerships rather than bringing them into clinical development by itself.

Announced NIH Grant for Research Collaboration with UMass Chan Medical School to develop EVX-B2 gonorrhea vaccine product candidate. Evaxion announced a discovery project (EVX-B2) to create a gonorrhea vaccine based on the Company's artificial intelligence (AI) platform, EDEN. Chief Scientific Officer at Evaxion, Birgitte Rønø, states that the scientific collaboration with UMass Chan and the grant from NIH further reinforces Evaxion's capabilities within AI-based vaccine design and allow the Company to fast-track the development of a gonorrhea vaccine candidate.

A published peer-reviewed article in Future Oncology on Phase 2b trial design for EVX-01. Evaxion published an article in Future Oncology focusing on the Phase 2b trial design of EVX-01. This trial is designed so that the patients may continue treatment with Evaxion's immunotherapy, even if the standard-of-care treatment changes. With this new and innovative trial design, Evaxion expands the patients' otherwise limited treatment opportunities.

Events after the Reporting Period

Per Norlén, M.D., PhD. succeeded Lars Wegner, M.D., as Chief Executive Officer

Dr. Norlén is a board-certified physician and associate professor in clinical pharmacology with more than 20 years in the biotech sector. The last 12 years have been in executive leadership roles. He brings a wealth of experience from being CEO of listed drug development companies. He has a proven business development track record, including major out-licensing deals with biotech and Pharma.

Expected Milestones in the Fourth Quarter of 2022

- Selection of the first viral candidate from our RAVEN platform.

Expected Milestones in the First Half of 2023

- Clinical readout of Phase 1/2a clinical study to evaluate EVX-02 in patients with resectable melanoma.

Third Quarter 2022 Financial Results

- Cash position: As of September 30, 2022, cash and cash equivalents were \$17.9 million compared to \$32.2 million as of December 31, 2021. The decrease in cash and cash equivalents during the first nine months of 2022 was primarily attributable to an increase in our operating expenses for the first nine months of 2022, partially offset by the proceeds received from the first tranche of our loan from the European Investment Bank.
- Research and Development expenses were \$4.1 million for the three months that ended September 30, 2022, compared to \$4.4 million for the same period in 2021. The decrease was primarily due to lower external costs related to clinical trials.
- General and Administrative expenses were \$2.0 million for the three months ending September 30, 2022, compared to \$1.5 million for the same period in 2021. The increase was primarily due to an increase in fees associated with the expansion of our business as a listed company.
- Net loss was \$5.7 million for the three months ended September 30, 2022, or (\$0.24) loss per basic and diluted share as compared to \$5.3 million, or (\$0.27) loss per basic and diluted share for the three months ended September 30, 2021.

Guidance

- We expect our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into mid-2023.

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. With our proprietary and scalable AI technology, we decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of novel product candidates, including three patient-specific cancer immunotherapies. It is located in Hørsholm, Denmark, with 70 employees.

For more information

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Source: Evaxion Biotech

Forward-looking statement

This announcement contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this announcement regarding the Company's future operations, plans and objectives are forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this announcement about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "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 or the negative thereof. 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 associated with the Company's financial condition and need for additional capital; risks associated with the Company's development work; cost and success of the Company's product development activities and preclinical and clinical trials; risks related to commercializing any approved pharmaceutical product developed using the Company's AI platform technology, including the rate and degree of market acceptance of the Company's product candidates; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; risks associated with the Company's inability to enter into partnerships; risks related to government regulation; risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's ADSs and ordinary shares, risks associated with the pandemic caused by the coronavirus known as COVID-19 and the emergence and prevalence of COVID-19 variants, such as the Delta and Omicron variant and certain related variants such as the Omicron BA.4 and BA.5 variants, risks associated with the invasion of the Ukraine by Russia and other risks and uncertainties affecting the Company's business operations and financial condition.

Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the risks described in the "Risk Factors" section included in the Company's Annual Report on Form 20-F filed on March 31, 2022 and the Company's current and future reports filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements contained in this announcement speak only as of the date hereof, and except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Consolidated Statements of Financial Position Data (Unaudited)

(USD in thousands)

	Sep 30, 2022	Dec 31, 2021
Cash and cash equivalents	\$ 17,853	\$ 32,166
Total assets	27,446	40,163
Total liabilities	13,898	7,726
Share capital	3,864	3,755
Other reserves	75,444	79,114
Accumulated deficit	(65,760)	(50,432)
Total equity	13,548	32,437
Total liabilities and equity	\$ 27,446	\$ 40,163

Evaxion Biotech A/S

Consolidated Statements of Comprehensive Loss Data (Unaudited)

(USD in thousands, except per share data)

	Three Months Ended Sep 30		Nine months Ended Sep 30	
	2022	2021	2022	2021
Research and development expenses	\$ 4,068	\$ 4,417	\$ 12,983	\$ 13,429
General and administrative expenses	2,015	1,495	5,756	4,684
Operating loss	(6,083)	(5,912)	(18,739)	(18,113)
Finance income	703	288	2,761	1,293
Finance expenses	(535)	(51)	(918)	(843)
Net loss before tax	(5,915)	(5,675)	(16,896)	(17,663)
Income tax benefit	175	425	599	1,501
Net loss for the period	\$ (5,740)	\$ (5,250)	\$ (16,297)	\$ (16,162)
Net loss attributable to equity holders of Evaxion Biotech A/S	\$ (5,740)	\$ (5,250)	\$ (16,297)	\$ (16,162)
Loss per share – basic and diluted	\$ (0.24)	\$ (0.27)	\$ (0.69)	\$ (0.86)
Number of shares used for calculation (basic and diluted)	23,833,694	19,198,668	23,468,653	18,759,108

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Source: Evaxion Biotech