

EVAXION

Evaxion Biotech Announces Q2 2021 Financial Results and Provides Business Update

August 12, 2021

- Data reported in early July from EVX-01 clinical program showed a robust anti-tumor effect in combination with anti-PD-1 treatment for patients with metastatic melanoma, supporting advancement into a Phase 2b clinical trial
- Data also reported in early July from the EVX-02 clinical program in adjuvant melanoma support advancing into a Phase 2b clinical trial
- Product candidate EVX-B1 is progressing through preclinical development as planned
- Reported preclinical proof of concept for the Adaptive and Intelligent Vaccine for a Rapid Response against Corona Viruses (AICoV) program
- Cash reserves of \$18.8 million as of June 30, 2021 are expected to provide funding of key programs into 2022

COPENHAGEN, Denmark, Aug. 12, 2021 (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 to improve the lives of patients with cancer, bacterial diseases and viral infections, announced today the second quarter 2021 financial results and provided an operational update.

Lars Wegner, CEO of Evaxion, said: "Evaxion has made very encouraging clinical progress in the second quarter of 2021, reporting data in July which we believe support advancing both of our lead programs into Phase 2b trials. Phase 1/2a data on our lead program EVX-01 showed that 67% of the patients benefited from EVX-01 in combination with anti-PD-1 for the treatment of metastatic melanoma, compared to the historical data of only 40% benefiting from the check point inhibitor alone. In addition, EVX-02 showed T-cell activation in adjuvant melanoma and appeared to be well tolerated. We plan to initiate a Phase 2b trial for EVX-01 in melanoma in December 2021 and initiate a Phase 2b trial of EVX-02, in conjunction with our third program, EVX-03, in Q2 2022. We also reported preclinical proof of concept data for our RAVEN AI platform for vaccine design and development for viral infections, which we believe has the potential to make a significant contribution in addressing coronavirus infections and other viral diseases. Our cash reserves of \$18.8 million provide a solid financial foundation and will facilitate the continued development of these four lead programs."

Operational and Business Highlights in Q2 2021

- [Reported preclinical proof of concept data](#) in June for the Adaptive and Intelligent Vaccine for a Rapid Response against Corona Viruses (AICoV) program, supporting next-generation coronavirus vaccine technology. First-generation SARS-COV-2 vaccines are focused on the generation of neutralizing antibodies by B cells that bind to the spike protein of the virus and inhibit infection. Activation of T cells may help broaden the immune system's response to coronavirus and protect against mutations on the spike protein that have been shown to circumvent immunity. Early data demonstrate our RAVEN platform identifies novel immunogenic T-cell epitopes beyond just the spike protein. The proof-of-concept data show RAVEN's potential to rapidly support the design of novel SARS-COV-2 vaccines capable of tackling newly emerging coronavirus variants.
- EVX-03, a novel patient-specific therapy for multiple cancer indications and EVX-B1, a vaccine for the prevention of *Staphylococcus aureus* including MRSA, continue to progress as expected through preclinical and Chemistry, Manufacturing and Controls (CMC) development.
- [Presentation](#) in April at the 4th Neoantigen Summit Europe, described Evaxion's recent improvement in determining cancer neoepitopes through measurement and prediction of peptide-MHC (pMHC) complex stability. We believe this is a significant improvement over AI models trained on traditional mass spectrometry ligand data and the data have already proven valuable in improving our discovery and design of patient-specific neoepitopes used to derive our cancer therapies.
- Acceptance of [a scientific paper](#) by the International Conference on Machine Learning describing a novel predictive system based on deep probabilistic programming that enables the rapid conversion of sequence data into structural information on protein fragments, which we believe may be useful for drug and vaccine design.

Events after the Reporting Period

- Reported [new clinical data](#) in early July from Phase 1/2a trials of EVX-01 and EVX-02.
 - EVX-01, our peptide-based patient-specific cancer therapy, demonstrated anti-tumor effect in combination with anti-PD-1 treatment, a checkpoint inhibitor anticancer drug, for metastatic melanoma. Results from the combination therapy compares favorably to historical data from anti-PD-1 treatment alone. A Phase 2b trial of EVX-01 is planned to start in December 2021.
 - Preliminary data with EVX-02, our DNA-based patient-specific cancer therapy, demonstrated T-cell activation induced by EVX-02 and appeared to be well tolerated. A Phase 2b trial of EVX-02, in combination with EVX-03, our novel patient-specific therapy for multiple cancer indications, is planned to start in Q2 2022 as a combination therapy with anti-PD-1 in adjuvant melanoma.

Expected milestones in 2021 & 2022

- Phase 2b trial initiation of EVX-01 in metastatic melanoma – Q4 2021.
- Phase 2b trial regulatory filing for EVX-02 in combination with EVX-03 in adjuvant melanoma – Q2 2022.
- Phase 1a trial regulatory filing for EVX-B1 for *S. aureus* in skin and soft tissue infections (SSTIs) – H2 2022.
- First viral candidate selected from RAVEN platform – Q1 2022.

Second Quarter 2021 Financial Results

- Cash position: As of June 30, 2021, cash and cash equivalents were \$18.8 million compared to \$5.8 million as of December 31, 2020. On February 9, 2021, we closed our IPO raising net proceeds of \$27.9 million after underwriting discounts and commissions, but before offering expenses.
- Research and Development expenses were \$5.1 million for the quarter ended June 30, 2021, compared to \$2.6 million for the same period in 2020. The increase of \$2.5 million was primarily related to increased spending, net of grant income, for ongoing development utilizing our AI platforms, preclinical product candidates, and clinical trials. In addition, employee-related costs increased due to higher headcount.
- General and Administrative expenses were \$1.9 million for the quarter ended June 30, 2021, compared to \$1.4 million for the same period in 2020. The increase of \$0.5 million was primarily related to increases in overhead and professional fees related to the expansion of our corporate function.
- Net loss was \$6.8 million for the quarter ended June 30, 2021 or (\$0.36) loss per basic and diluted share, compared to \$3.6 million, or (\$0.24) loss per basic and diluted share, for the same period in 2020.

Guidance

- Evaxion's current cash position of \$18.8 million is expected to be sufficient to fund key clinical programs into 2022.

Webcast and Conference Call

Evaxion will host a webcast and conference call today, August 12, at 8:30 a.m. EDT.

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

US: 877-407-0792

International: +1-201-689-8263

Conference ID: 13722183

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 AI-immunology™ platform company decoding the human immune system to discover and develop novel immunotherapies to treat cancer, bacterial diseases and viral infections. Based on its proprietary and scalable AI-immunology core technology, Evaxion is developing a broad pipeline of novel product candidates which currently includes three patient-specific cancer immunotherapies, two of which are in Phase 1/2a clinical development. In addition, Evaxion is advancing a portfolio of vaccines to prevent bacterial and viral infections currently in preclinical development.

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 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 Form 20-F for the year ended December 31, 2020 and the Company's other reports filed with, or submitted 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.

Evaxion Biotech A/S

Consolidated Statements of Financial Position Data (Unaudited)

(USD in thousands)

	June 30, 2021	Dec 31, 2020
Cash and cash equivalents	\$ 18,799	\$ 5,834
Total assets	27,657	11,965
Total liabilities	5,828	4,927
Share capital	3,132	2,648
Other reserves	56,168	31,669
Accumulated deficit	(37,471)	(27,279)
Total equity	21,829	7,038
Total liabilities and equity	\$ 27,657	\$ 11,965

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Consolidated Statements of Comprehensive Loss Data (Unaudited)

(USD in thousands, except per share data)

	Three Months Ended June 30		Six months Ended June 30	
	2021	2020	2021	2020
Research and development expenses	\$ 5,111	\$ 2,570	\$ 9,004	5,080
General and administrative expenses	1,915	1,372	3,197	2,153
Operating loss	(7,026)	(3,942)	(12,201)	(7,233)
Finance income	33	6	1,005	22
Finance expenses	(495)	--	(792)	(4)
Net loss before tax	(7,488)	(3,936)	(11,988)	(7,215)
Income tax benefit	669	296	1,076	476
Net loss for the period	\$ (6,819)	\$ (3,640)	\$ (10,912)	\$ (6,739)
Net loss attributable to equity holders of Evaxion Biotech A/S	\$ (6,819)	\$ (3,640)	\$ (10,912)	\$ (6,739)
Loss per share – basic and diluted	\$ (0.36)	\$ (0.24)	\$ (0.59)	\$ (0.44)
Number of shares used for calculation (basic and diluted)	19,198,668	15,184,152	18,535,685	15,184,152



Source: Evaxion Biotech