

EVAXION

Evaxion Biotech Announces Q3 2021 Financial Results and Provides Business Update

November 9, 2021

- Expect to close our follow-on public offering (FPO) of 3,942,856 ordinary shares represented by American Depositary Shares (ADSs) for gross proceeds of \$27.6 million before deducting underwriter fees and commissions and other offering expenses
- Data reported in early July 2021 from EVX-01 Phase 1/2a clinical trial 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 2021 from the EVX-02 clinical trial in adjuvant melanoma support advancing into a Phase 2b clinical trial

COPENHAGEN, Denmark, Nov. 09, 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 third quarter 2021 financial results and provided an operational update.

Lars Wegner, CEO of Evaxion, said: "Evaxion has continued to make very encouraging clinical progress in the third quarter of 2021, reporting data in July 2021 which we believe support advancing two of our lead programs into Phase 2b clinical trials. Phase 1/2a clinical trial data on our lead product candidate, 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 clinical trial for EVX-01 in melanoma by the end of 2021 in collaboration with Merck and initiate a Phase 2b clinical trial of EVX-02, in conjunction with our third product candidate, EVX-03, in Q2 2022. Our cash reserves of \$11.9 million as of the end of the third quarter, combined with the follow-on financing provide a solid financial foundation and will facilitate the continued development of our lead programs."

Operational and Business Highlights in Q3 2021

- Reported [new clinical data](#) in early July 2021 from Phase 1/2a clinical 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, for metastatic melanoma. Results from the combination therapy compares favorably to historical data from anti-PD-1 treatment alone. A Phase 2b clinical trial of EVX-01 is planned to start by the end of 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. We intend to submit a regulatory filing for a Phase 2b clinical trial of EVX-02 and EVX-03, in combination with anti-PD-1 in adjuvant melanoma in a three-arm trial, in the first half of 2022.

Events after the Reporting Period

- Announced clinical trial and supply agreement with subsidiaries of Merck & Co., Inc. (known as MSD outside of the United States and Canada) to evaluate the combination of Evaxion's cancer immunotherapy EVX-01 with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a new Phase 2b clinical trial in patients with metastatic melanoma
- Awarded this year's Enabling Technology Leadership Award in the artificial intelligence-enabled drug discovery industry by global research and consulting firm Frost & Sullivan
- Presentation at the Immuno UK 2021 conference held in London in October
- Announced pricing of our FPO on November 5, 2021, and expect to raise gross proceeds of \$27.6 million before deducting underwriting discounts and commissions and other offering expenses.

Expected milestones in 2021 & 2022

- Phase 2b Investigational New Drug (IND) / Clinical Trial Application (CTA) of EVX-01 in metastatic melanoma – H2 2021.
- Phase 2b IND / CTA filing for EVX-02 in combination with EVX-03 in adjuvant melanoma – H1 2022.
- Phase 1a IND / CTA filing for EVX-B1 for *S. aureus* in skin and soft tissue infections (SSTIs) – H2 2022.
- First viral candidate selected from RAVEN platform – H2 2022.

Third Quarter 2021 Financial Results

- Cash position: As of September 30, 2021, cash and cash equivalents were \$11.9 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 deducting underwriting discounts and commissions, but before offering expenses.
- Research and Development expenses were \$4.4 million for the quarter ended September 30, 2021, compared to \$3.0 million for the same period in 2020. The increase of \$1.4 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 \$1.5 million for the quarter ended September 30, 2021, compared to \$1.7 million for the same period in 2020. The decrease of \$0.2 million was primarily related to higher share-based compensation in the period ended September 30, 2020 due to accelerated vesting period and sign-on warrants issued associated with the IPO.
- Net loss was \$5.3 million for the quarter ended September 30, 2021 or (\$0.27) loss per basic and diluted share, compared to \$4.0 million, or (\$0.26) loss per basic and diluted share, for the same period in 2020.

Guidance

- We expect the net proceeds from our IPO and FPO combined with our existing cash reserves will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from September 30, 2021.

Webcast and Conference Call

Evaxion will host a webcast and conference call today, November 9, at 8:30 a.m. EST.

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

US: 877-407-0792

International: +1-201-689-8263

Conference ID: 13723544

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)

	Sep 30, 2021	Dec 31, 2020
Cash and cash equivalents	\$ 11,944	\$ 5,834
Total assets	24,116	11,965
Total liabilities	7,466	4,927
Share capital	3,132	2,648
Other reserves	55,658	31,669
Accumulated deficit	(42,140)	(27,279)
Total equity	16,650	7,038
Total liabilities and equity	\$ 24,116	\$ 11,965

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Consolidated Statements of Comprehensive Loss Data (Unaudited)

(USD in thousands, except per share data)

	Three Months Ended Sep 30		Nine months Ended Sep 30	
	2021	2020	2021	2020
Research and development expenses	\$ 4,417	\$ 2,966	\$ 13,429	\$ 8,046
General and administrative expenses	1,495	1,719	4,684	3,872
Operating loss	(5,912)	(4,685)	(18,113)	(11,918)
Finance income	288	100	1,293	122
Finance expenses	(51)	(3)	(843)	(7)
Net loss before tax	(5,675)	(4,588)	(17,663)	(11,803)
Income tax benefit	425	578	1,501	1,054
Net loss for the period	\$ (5,250)	\$ (4,010)	\$ (16,162)	\$ (10,749)
Net loss attributable to equity holders of Evaxion Biotech A/S	\$ (5,250)	\$ (4,010)	\$ (16,162)	\$ (10,749)
Loss per share – basic and diluted	\$ (0.27)	\$ (0.26)	\$ (0.86)	\$ (0.71)
Number of shares used for calculation (basic and diluted)	19,198,668	15,289,477	18,759,108	15,219,517



Source: Evaxion Biotech