

EVAXION

Evaxion Announces Business Update and Third Quarter 2023 Financial Results

December 19, 2023

- Christian Kanstrup joined Evaxion as Chief Executive Officer in September
- Evaxion has launched its refined strategy with an increased focus on value realization via partnerships based upon the AI-Immunology™ platform
- Solid progress has already been seen on the refined strategy with two partnerships announced in Q3 and proof-of-principle for Evaxion's proprietary responder model based upon the AI-Immunology™ platform
- Cash and cash equivalents of \$2.6 million on September 30, 2023. On December 18, 2023, Evaxion priced a bridge financing round, expected to raise aggregate proceeds of approximately \$5.3 million. This private placement is expected to close on or around December 21, 2023, and will fund operations towards the end of March 2024, marking an important step in Evaxion's long-term funding strategy
- The ambition is to fund 2024 cash burn, excluding financing activities, with income from business development activities. Cash burn for 2024, excluding financing activities, is expected at the level of \$14 million (with Q1 cash burn being significantly higher than other quarters in 2024)

COPENHAGEN, Denmark, Dec. 19, 2023 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion" or the "Company"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, today provided a business update and announced its third quarter 2023 financial results.

Christian Kanstrup, Evaxion's CEO, reports, "It has been a great pleasure to join Evaxion, and the first three months have confirmed my belief in a world-class organization and business with strong potential for addressing significant unmet needs within cancer and infectious diseases. Our AI-Immunology™ platform offers unique opportunities in this connection. A key focus for the first months has been to refine the Evaxion strategy with a strong focus on execution and value realization.

"I am pleased to be able to share the refined strategy in a simple, straightforward overview below. The core of our strategy lies in our pioneering AI-Immunology™ platform, which has been continuously refined and validated over the past many years. This platform holds the potential for generating one new target every 24 hours, is delivery modality agnostic, and is easily adaptable to partner needs. Based on the unique multi-disciplinary capabilities built around our different AI prediction models, we focus on value realization via Targets, Pipeline and Responders. We have already seen substantial progress within each of these three areas: two partnerships announced within Targets and encouraging initial EVX-01 Phase 2 data showcase significant progress in our Pipeline. Within Responders, we have obtained proof-of-principle for our checkpoint inhibitor responder model.

"The refined strategy also means reduced focus on Evaxion-driven clinical trials, significantly reducing the cash burn. Combined with a stronger focus on value realization based upon our AI-Immunology™ platform, we have the ambition of being able to generate full-year 2024 business development income equal to our cash burn in 2024, excluding financing activities. We believe we are set for strong business execution based on our refined strategy."

The Evaxion Three-Pronged Strategy

Our Strategy: Three-Pronged Business Model Based on Our Leading AI-Immunology™ Platform, Pursued via a Multi-Partner Approach

The AI-Immunology™ Platform

- Design and development of personalized and precision vaccine candidates
- AI prediction models trained in cancer and infectious diseases
- Potential for one new target every 24 hours
- Platform is delivery modality agnostic
- Unique predictive capabilities
- Adaptability to partner needs
- Scalable to other therapeutic areas



Targets

Multi partner approach focused around single or multiple target discovery and validation agreements



Pipeline

Own development programs for select high value programs; bringing programs to major value inflection point



Responders

Harnessing our data and predictive capabilities to develop responder models

Christian Kanstrup continued, "I am also very pleased with the bridge financing round we just priced. It is an important element in our long-term financing strategy. The investor base in the round consists of existing investors, management, and the board of directors, as well as new investors. The largest new investor is MSD Global Health Innovation Fund (MSD GHI), the corporate venture capital arm of Merck & Co., Inc., Rahway, NJ, USA, accounting for some 25% of the private placement. I am looking very much forward to be working with the capable team from MSD GHI. We believe this financing round shows strong confidence in our future business outlook.

"We are also excited to see that the validation of the AI-Immunology™ platform has continued. The EDEN™ AI prediction model has been validated for B-cell antigen discovery across seven different pathogens and formed a central component of the two important partnerships Evaxion entered into during the third quarter. One of these partnerships brings together AI-discovered antigens and mRNA technology – a first in the Evaxion pipeline. EDEN™ and the T-cell epitope discovery model, RAVEN™, are pivotal components of the other partnership forged with a leading pharmaceutical company to discover and develop vaccines against a pathogen with high unmet medical need for which no vaccines are available. Evaxion plans to build on this momentum and leverage our AI-Immunology™ platform to pursue new partnerships for novel vaccine targets within infectious diseases.

"This quarter has also seen significant developments in our cancer portfolio and capabilities. A comprehensive clinical update on the EVX-01 Phase 2 trial shared at the SITC conference confirms the encouraging Phase 1 immune profile seen for our lead personalized cancer vaccine asset. This achievement solidifies our confidence in the potential AI-Immunology™ holds at becoming a new treatment paradigm for metastatic melanoma.

"Another truly exciting element in the AI-Immunology™ platform is the ObsERV™ model, which is unique to Evaxion and allows us to harness a new source of tumor-specific antigens in oncology patients. With ObsERV™, we hope to expand the therapeutic reach of personalized cancer vaccines to patients with high mutational burden tumors but low numbers of high-quality neoantigens and patients with low tumor mutational burden who would otherwise not qualify for many of the treatment options available today. One exciting possibility we are currently looking into is whether we could use ObsERV™ to identify shared cancer antigens in particular cancer subtypes. This would hold the promise to develop the first precision cancer vaccines targeting indications with no equivalent treatment option to date. Details on this principle were shared at ASH in December this year.

"With the recent development within cancer and infectious diseases, we have been seeing a further confirmation of our approach and are looking forward to discussing partnering opportunities across all parts of our strategy and associated with our three-pronged business model: Targets, Pipeline, and Responders."

Anticipated 2024 Milestones

- EVX-B1 – Conclusion of final MTA study with a potential partner, Q1, 2024
- AI-Immunology™ – Launch of EDEN™ model 5.0, mid-2024
- EVX-B2-mRNA – Preclinical proof-of-principle obtained, Q3-2024
- EVX-01 – Phase 2 one-year readout, Q3, 2024
- EVX-B3 – Conclusion of target discovery and validation work in collaboration with leading pharma, H2, 2024
- Precision ERV cancer vaccines – Preclinical proof-of-concept obtained, H2, 2024
- Value realization – Ambition for full year 2024 to generate business development income equal to 2024 expected cash burn of \$14 million (excluding financing activities)

Recent Events (July-December 2023)

Christian Kanstrup Leads Evaxion's AI Strategy as CEO

Evaxion appoints Christian Kanstrup as CEO, emphasizing his unique leadership and strategic development skills. Kanstrup's vision aims to harness the full potential of Evaxion's AI platform for therapeutic innovation.

Evaxion's EDEN™ Model Validated: Revolutionizing Vaccine Development

Evaxion shared data at the Vaccines Europe conference validating the EDEN™ model for bacterial vaccine discovery. This groundbreaking achievement emphasizes the models' ability to swiftly generate novel vaccine targets, offering a faster, cheaper, and lower-risk approach to vaccine development. CEO Christian Kanstrup and Founder Andreas Holm Mattsson highlight its potential impact on high unmet medical needs, signaling a paradigm shift in vaccine discovery.

Evaxion Initiates AI-Designed Vaccine Program EVX-B3 in Collaboration with Leading Pharmaceutical Partner

Evaxion Biotech launches EVX-B3, an AI-guided vaccine program, in collaboration with a leading pharmaceutical company. Leveraging Evaxion's EDEN™ and RAVEN™ AI models, the project aims to efficiently identify protective antigens against an undisclosed bacterial pathogen, addressing a critical global health concern. The collaborative effort highlights Evaxion's dedication to harnessing AI for innovative vaccine design.

Evaxion and Afrigen Join Forces for Gonorrhea mRNA Vaccine

Evaxion Biotech partners with Afrigen Biologics to develop an mRNA vaccine against gonorrhea, utilizing EDEN™-discovered targets. The collaboration, leveraging mRNA technology from the WHO and Medicines Patent Pool, aims to address the global medical need for a gonorrhea vaccine. Evaxion CEO Christian Kanstrup sees this collaboration as a strategic step to bring AI-designed vaccines to market, emphasizing the importance of identifying the right partners.

Evaxion's EVX-01 Phase 2 Trial Shows Promise in Personalized Cancer Treatment

Evaxion Biotech reports encouraging Phase 2 data for its personalized cancer vaccine, EVX-01, confirming earlier Phase 1 findings. Notably, a metastatic melanoma patient with initial progressive disease showed significant and continuous tumor reduction after EVX-01 treatment. CEO Christian Kanstrup highlights the potential of their AI-Immunology™ platform to revolutionize oncology.

Webinar: Evaxion Shares Insights on EVX-01 Phase 2 Clinical Data

Evaxion Biotech hosted an online webinar on November 8 featuring KOL Professor Adnan Khattak, one of the principal investigators of the EVX-01 Phase 2 clinical trial. The 30-minute event explores malignant melanoma, summarizes Phase 1 results, and details the Phase 2 update.

Evaxion Introduces AI Model for Predicting Cancer Immunotherapy Responses

Evaxion unveils its AI model at the Biomarkers & Precision Oncology Europe conference, aiming to predict patient responses to cancer immunotherapy. The model shows promise in enhancing outcomes and reducing healthcare costs, aligning with Evaxion's commitment to advancing the AI-Immunology™ Responders area.

Evaxion Unveils Innovative Precision Vaccine Concept for Hematological Malignancies

Evaxion announces a groundbreaking precision vaccine concept for hematological malignancies at the 65th American Society of Hematology (ASH) Annual Meeting. The use of AI-Immunology™ to target endogenous retroviruses represents a significant advancement, offering tailored vaccines for hematological malignancies. The upcoming oral presentation on December 9 signifies a major milestone in Evaxion's pursuit of innovative cancer solutions.

Third Quarter of 2023 Financial Results

- Cash position: as of September 30, 2023, cash and cash equivalents were \$2.6 million as compared to \$13.2 million as of December 31, 2022
- Research and Development expenses were \$2.9 million for the quarter ending September 30, 2023, as compared to \$4.1 million for the quarter ending September 30, 2022. The decrease was primarily due to a reduction in external costs
- General and administrative expenses were \$2.9 million for the quarter ending September 30, 2023, as compared to \$2.0 million for the quarter ending September 30, 2022. The increase was primarily due to increased external costs in connection with the current funding activities
- Net loss was \$5.9 million for the quarter ended September 30, 2023, or (\$0.21) per basic and diluted share, as compared to a net loss of \$5.9 million, or (\$0.24) per basic and diluted share for the quarter ended September 30, 2022

About EVAXION

Evaxion Biotech A/S is a pioneering TechBio company based upon its AI platform: AI-Immunology™. Evaxion's proprietary and scalable AI prediction models harness the power of artificial intelligence to decode the human immune system and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Based upon AI-Immunology™, Evaxion has developed a clinical-stage oncology pipeline of novel personalized vaccines and a preclinical infectious disease pipeline in bacterial and viral diseases with high unmet medical needs. Evaxion is committed to transforming patients' lives by providing innovative and targeted treatment options. For more information about Evaxion and its groundbreaking AI-Immunology™ platform and vaccine pipeline, please [visit our website](#).

Forward-Looking Statement

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 ongoing COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia and the Middle East; 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 US 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.

Financials

Evaxion Biotech A/S

Consolidated Statements of Financial Position Data (Unaudited)

(USD in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 2,605	\$ 13,184
Total assets	11,942	22,025
Total liabilities	14,676	13,722
Share capital	4,415	3,886

Other reserves	82,614	77,076
Accumulated deficit	(89,763)	(72,659)
Total equity	(2,734)	8,303
Total liabilities and equity	\$ 11,942	\$ 22,025

The number of shares sold through the ATM Program since September 30, 2023, amounts to 301,913 shares.

Evaxion Biotech A/S

Consolidated Statements of Comprehensive Loss Data (Unaudited) (USD in thousands, except per share data)

	Three months Ended September 30		Nine months Ended September 30	
	2023	2022	2023	2022
Research and development expenses	\$ 2,830	\$ 4,068	\$ 9,618	\$ 12,983
General and administrative expenses	2,932	2,015	8,215	5,756
Operating loss	(5,762)	(6,083)	(17,833)	(18,739)
Finance income	72	703	404	2,761
Finance expenses	(182)	(535)	(786)	(918)
Net loss before tax	(5,872)	(5,915)	(18,215)	(16,896)
Income tax benefit	194	175	613	599
Net loss for the period	\$ (5,678)	\$ (5,740)	\$ (17,602)	\$ (16,297)
Net loss attributable to equity holders of Evaxion Biotech A/S	\$ (5,678)	\$ (5,740)	\$ (17,602)	\$ (16,297)
Loss per share – basic and diluted	\$ (0.21)	\$ (0.24)	\$ (0.66)	\$ (0.69)
Number of shares used for calculation (basic and diluted)	27,659,878	23,894,684	26,754,440	23,489,206

Based on the Company's current cash position, including the bridge financing round expected to raise aggregate proceeds of approximately \$5.3 million, the Company has a cash runway towards the end of March 2024. Further funding is required and will be pursued through the Company's long-term funding strategy. Please refer to form 20-F, filed April 28, for additional background on the Company.

A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/16050912-bd9d-4e2a-bc01-9199b4e30b5f>