EVAXION

Evaxion announces business update and third quarter 2024 financial results

October 31, 2024

COPENHAGEN, Denmark, October 31, 2024 - Evaxion Biotech A/S (NASDAQ: EVAX) ("Evaxion"), a clinical-stage TechBio company specializing in developing AI-Immunology™ powered vaccines, provides business update and announces third quarter 2024 financial results.

Business highlights (since last quarterly update)

Since the second quarter 2024 business update, we have continued to execute strongly on our strategy and plans with several major milestones achieved. Key highlights include:

- Significant expansion of the infectious disease vaccine development collaboration with MSD (tradename of Merck & co., Inc., Rahway, NJ, USA) in a transformative deal for Evaxion
- Continuously increasing external interest and several ongoing partnerships discussions covering both our platform and pipeline
- Strong progress in clinical and preclinical development with convincing phase 2 data presented for personalized cancer vaccine EVX-01 and preclinical Proof-of-Concept obtained for EVX-B2 mRNA Gonorrhea vaccine candidate
- Launch of improved AI-Immunology™ platform for vaccine antigen prediction
- Thomas Schmidt appointed as interim Chief Financial Officer

"We continued to make solid progress on our strategy execution in a busy third quarter and are very pleased to have achieved several important milestones across our company. The MSD agreement, which holds the potential to transform Evaxion over the coming years, and the groundbreaking EVX-01 phase 2 efficacy data, stand out among our many achievements. We continue to demonstrate our strong capabilities as a truly AI-based TechBio company and remain focused on advancing on-going partnerships as well as new partnership discussions, progressing the EVX-01 trial and carrying through preclinical studies as a basis for expanding our R&D pipeline," says Christian Kanstrup, CEO of Evaxion.

2024 Milestones

	Milestones	Target
EVX-B1	Conclusion of final MTA study with potential partner	Q1 2024 ✓
AI-Immunology™	Launch of EDEN™ model version 5.0	Mid 2024 (ECCB, September) ✓
EVX-B2-mRNA	EVX-B2-mRNA preclinical Proof-of-Concept obtained	Q3 2024 (18th Vaccine Congress, September) ✓
EVX-01	Phase 2 one-year readout	Q3 2024 (ESMO Congress, September) ✓
EVX-B3	Conclusion of target discovery and validation work in collaboration with MSD (tradename of Merck & Co., Inc., Rahway, NJ, USA)*	H2 2024 (✓)
Precision ERV cancer vaccines	Preclinical Proof-of-Concept obtained	H2 2024
Funding	Ambition for full year 2024 is to generate business development income or cash in equal to 2024 cash burn (excluding financing activities) of $14 million**	

* MSD option and license agreement on EVX-B2 and EVX-B3 supersedes this milestone
** See update on the business development income ambition below

Research & Development update

We maintain a high activity level in Research & Development (R&D) from both a preclinical and clinical perspective. This work yielded outstanding results in the third quarter, first and foremost with the presentation of encouraging one-year data from the ongoing phase 2 trial with our lead asset EVX-01, an AI-Immunology™ designed personalized cancer vaccine, in patients with advanced melanoma (skin cancer).

The data demonstrates 69% Overall Response Rate, reduction in tumor target lesions in 15 out of 16 patients, an immunogenicity rate of 79%, and a positive correlation between our AI-Immunology™ platform predictions and immune responses induced by the individual neoantigens in the EVX-01 vaccine (p=0.00013). The observed immunogenicity rate means that 79% of EVX-01's vaccine targets triggered a targeted immune response, which compares very favorably to what is seen with other approaches.

These clinical findings underscore the significant therapeutic potential of EVX-01 and are yet another validation of the AI-Immunology™ platform as a leading AI technology for fast and effective vaccine target discovery and design.

We were also successful in our preclinical research, obtaining Proof-of-Concept for novel mRNA Gonorrhea vaccine candidate EVX-B2. This was based on new data documenting that EVX-B2 mRNA triggers a targeted immune response that leads to the elimination of the gonorrhea bacteria. The same had earlier been shown for the protein-based version of EVX-B2, which is now part of our partnership with MSD. The mRNA data has been generated as part of our partnership with Afrigen Biologics.

Further to our pipeline, our R&D investments are also allocated to the continued improvement of our AI-Immunology™ platform. During the third quarter, we updated the platform with the launch of a new version of its EDEN™ AI prediction model. Among other improvements, the model can now predict toxin antigens, allowing for the development of improved bacterial vaccines. We expect this update to further solidify the strong interest seen in AI-Immunology™ from potential partners.

Business development income

Our strategy is based upon a multi-partner approach, making effective execution upon our business development plans crucial to our success. We were thrilled to sign the significantly expanded vaccine development collaboration with MSD during the third quarter. Further, we continue to see an increasing interest from potential partners and are excited by the current partnership opportunities both around existing pipeline assets as well as our AI-Immunology™ platform.

The agreement with MSD carries potential business development income of up to $10 million for 2025 on top of the $3.2 million upfront payment received in 2024. Based upon the current business development opportunities, we remain confident in our ability to execute upon our multi-partner strategy and bring in significant business development income.

Given that certain partnership discussions will be moving into 2025, we will - despite the strong interest - not be able to meet our 2024 ambition of generating business development income or cash in of $14 million. The discussions, having moved into 2025, will however support the generation of business development income for next year in addition to the potential up to $10 million from MSD.

Nasdaq dialogue

As communicated earlier, on May 7, 2024, we received a deficiency letter from Nasdaq Stock Market LLC (“Nasdaq”) for failure to maintain stockholders’ equity of at least $2.5 million, following which we presented a plan to Nasdaq to regain compliance. Nasdaq provided us until November 4, 2024, to evidence compliance based upon the plan submitted.

We remain committed to ensuring compliance with the Nasdaq minimum stockholder’s equity requirement and maintain our Nasdaq listing. This is to be pursued through increasing shareholder’s equity via a combination of business development income and capital markets activities. However, current equity market environment, the geopolitical uncertainties and timing of business development activities have to date impacted timing for the full required increase in shareholder’s equity.

We do not expect to have regained compliance by November 4, 2024, and therefore expect Nasdaq to send us a delisting notification after such date. We then plan to appeal the delisting determination and request a hearing on the matter, following which a new 180-day extension could be granted based on our plan to regain compliance.

We are in constructive dialogue with Nasdaq around this process, though we will not receive any guarantee that another 180-day extension will be granted before the anticipated hearing.

Third quarter 2024 financial results

Cash position as of September 30, 2024, was $4.6 million, as compared to $5.6 million as of December 31, 2023. The cash position as of September 30, excludes the $3.2 million upfront from the MSD agreement which was received in October. The Company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into March 2025.

Revenue of $3.0 million was recognized for the quarter ending September 30, 2024, as compared to nil for the quarter ending September 30, 2023. A minor proportion of this revenue derives from the existing EVX-B3 collaboration with MSD, while the majority relates to the newly signed option and license agreement with MSD.

Research and Development expenses were $2.6 million for the quarter ending September 30, 2024, as compared to $2.8 million for the quarter ending September 30, 2023. The decrease is primarily related to a reduced headcount.

General and Administrative expenses were $2.1 million for the quarter ending September 30, 2024, as compared to $2.9 million for the quarter ending September 30, 2023. The decrease was primarily due to a decrease in expenses to management remuneration following changes to executive management in 2023 and expenses related to this. In addition, various minor cost reductions related to overhead and professional fees are realized.

We generated a net loss of $1.9 million for the quarter ending September 30, 2024, or $(0.04) per basic and diluted share, as compared to a net loss of $5.7 million, or $(0.21) per basic and diluted share for the quarter ending September 30, 2023. The decreased loss was primarily driven by the recognized revenue and reduced general & administrative expenses.

Total equity amounts to $0.1 million as of September 30, 2024. Proceeds from the exercise of prefunded warrants amounted to $0.2 million for the quarter.

Evaxion Biotech A/S
Consolidated Statement of Financial Position Data (Unaudited)
(USD in thousands)

	Sep 30, 2024	Dec 31, 2023
Cash and cash equivalents	4,576	5,583
Total assets	15,185	12,889
Total liabilities	15,111	17,618
Share capital	8,732	5,899
Other reserves	106,245	99,946
Accumulated deficit	(114,903)	(107,860)
Total equity before derivative warrant liability	74	(2,015)
Effect from derivative liabilities from investor warrants	-	(2,714)
Total equity	74	(4,729)
Total liabilities and equity	15,185	12,889

Based on the Company's current cash position with an expected cash runway into March 2025, income from Business Development deals and/or further funding is required to mitigate the conclusion that there is significant doubt about the Company's ability to continue as a going concern. Please refer to the Form 20-F, filed March 27, 2024, for additional background on the Company.

Evaxion Biotech A/S
Consolidated Statement of Comprehensive Loss Data (Unaudited)
(USD in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	3,017	—	3,222	—
Research and development	(2,614)	(2,830)	(8,202)	(9,618)
General and administrative	(2,134)	(2,932)	(5,728)	(8,215)
Operating loss	(1,731)	(5,762)	(10,708)	(17,833)
Finance income	84	72	5,922	404
Finance expenses	(384)	(182)	(2,665)	(786)
Net loss before tax	(2,031)	(5,872)	(7,451)	(18,215)
Income tax benefit	96	194	513	613
Net loss for the period	(1,935)	(5,678)	(6,938)	(18,215)
Net loss attributable to shareholders of Evaxion Biotech A/S	(1,935)	(5,678)	(6,938)	(18,215)
Loss per share – basic and diluted	(0.04)	(0.21)	(0.13)	(0.66)
Number of shares used for calculation (basic and diluted)	55,255,329	27,659,878	51,905,948	26,754,440

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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 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.