

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report
Commission file number: 001-39950

Evaxion A/S

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)
Dr. Neergaards Vej 5F, DK-2970 Hørsholm, Denmark
(Address of principal executive offices)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
American Depositary Shares, each representing fifty ordinary shares, nominal value DKK 0.25 per share	EVAX	The Nasdaq Stock Market LLC
Ordinary Shares, nominal value of DKK 0.25 per share*		The Nasdaq Stock Market LLC*

*Not for trading, but only in connection with the registration of American Depositary Shares on the Nasdaq Stock Market LLC representing such Ordinary shares pursuant to requirements of the U.S. Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. The number of outstanding shares as of December 31, 2025, was:

Title of each class	Number of Shares Outstanding at December 31, 2025
Ordinary share, nominal value DKK 0.25 per share (including shares underlying American Depository Shares)	417,010,756

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer

Accelerated Filer
Emerging growth company

Non-accelerated Filer

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued
by the International Accounting Standards Board

Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Auditor Firm ID	1757
Auditor Name	EY Godkendt Revisionspartnerselskab
Auditor Location	Copenhagen, Denmark

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Certain Definitions

Unless otherwise indicated and except where the context otherwise requires, references in this annual report on Form 20-F to:

- References to “we”, “us”, the “company”, or “Evaxion”, or similar terms in this annual report on Form 20-F shall mean Evaxion A/S and, as the context requires, its subsidiaries
- “ADSS” are to our American Depositary Shares, each of which represents fifty ordinary shares of Evaxion A/S;
- “ADRs” are to the American depositary receipts that evidence our ADSs;
- “Exchange Act” are to the United States Securities Exchange Act of 1934, as amended;
- “FDA” are to the United States Food and Drug Administration;
- “Evaxion,” the “Company,” “we,” “us” and “our” refer to Evaxion A/S and our wholly owned subsidiaries;
- “Group” are to the consolidated entities of Evaxion A/S, Evaxion Biotech Australia Pty Ltd and Evaxion Biotech, Inc.;
- “IND” are to Investigational New Drug Application;
- “Ordinary shares” are to our ordinary shares, each of DKK 0.25 nominal value;
- “SEC” are to the United States Securities and Exchange Commission;
- “Securities Act” are to the Securities Act of 1933, as amended;
- “\$,” “USD,” “US\$” and “U.S. dollar” are to the United States dollar; and
- “DKK,” “Krone,” and “Kroner” are to the Danish Krone

Presentation of Financial Information

This annual report contains our audited consolidated financial statements as of December 31, 2025, and 2024, and for the years ended December 31, 2025, and 2024 (our “audited consolidated financial statements”), prepared in accordance with IFRS accounting standards, as issued by the International Accounting Standards Board (IASB).

Our financial information is presented in our presentation currency, U.S. Dollar (USD). Our parent Company’s functional currency is the Danish Krone (DKK). Certain Danish Krone amounts in this annual report have been translated solely for convenience into USD at an assumed exchange rate of DKK 6.3527 per \$1.00, which was the official exchange rate of such currencies as of December 31, 2025, rounded to four decimal places, as reported by Denmark’s National bank.

Foreign currency transactions are translated into our functional currency, DKK, using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized as financial income or financial expenses in the statements of comprehensive loss. Non-monetary items in foreign currency, which are measured at cost at the statements of financial position date, are translated into our functional currency, DKK, using the exchange rates at the date of the transaction. Such DKK translated amounts are not necessarily indicative of the amounts of DKK that could have been purchased with the underlying currency being exchanged into DKK at the dates indicated.

Assets and liabilities in our functional currency are translated to our presentation currency, USD, at the exchange rate applicable on December 31, 2025. Income and expenses in our functional currency are translated to USD at the average exchange rate, which corresponds to an approximation of the exchange rates prevailing on each individual transaction date. Translation differences arising in the translation to presentation currency are recognized in other comprehensive income. Such USD amounts are not necessarily indicative of the amounts of USD that could have been purchased upon exchange of DKK at the dates indicated.

We have made rounding adjustments to some of the figures contained in this annual report. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them.

Trademarks, Service Marks and Tradenames

This annual report includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this annual report appear without the and TM symbols, but the absence of those references is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks and tradenames to the fullest extent under applicable law. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

Special Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Many of the forward-looking statements contained in this annual report can be identified by the use of forward-looking 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 similar expressions that are predictions of or indicate future events and future trends, although not all forward-looking statements contain these identifying words.

Forward-looking statements appear in several places in this annual report and include, but are not limited to, statements regarding intent, belief or current expectations. Forward-looking statements are based on the current beliefs and assumptions of the management of Evaxion and on information currently available to such management. While the management of Evaxion believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments will be as anticipated. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section “Item 3. Key Information - D. Risk Factors” in this annual report. These risks and uncertainties include factors relating to:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- Our AI approach to the discovery of product candidates is novel and unproven, and we rely on our in-house propriety AI platform and capabilities in a highly competitive environment;
- our ability to enter in partnerships which is a key element of our refocused strategy;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;
- our and our collaborators’ ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- our and our collaborators’ ability to commercialize our product candidates, if approved;
- the pricing and reimbursement of our investigational medicines, if approved;
- the rate and degree of market acceptance of our investigational medicines;
- the amount of and our ability to use our net operating losses, or NOLs, and research and development credits to offset future taxable income;
- our ability to manage our development and expansion;
- regulatory developments in the United States, Europe, Australia and other foreign countries;
- our ability to manufacture our product candidates with advantages in turnaround times or manufacturing cost;
- our ability to implement, maintain and improve effective internal controls;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a foreign private issuer;
- adverse effects on our business condition and results for operation from general economic and market conditions and overall fluctuations in the United States and international equity markets, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine and other global conflicts such as ongoing in the Middle East; and
- other risk factors discussed under “Item 3. Key Information - D. Risk Factors”.

Our actual results or performance could differ materially from those expressed in, or implied by, any forward-looking statements relating to those matters. Accordingly, no assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what impact they will have on our results of operations, cash flows or financial condition. Except as required by law, we are under no obligation, and expressly disclaim any obligation, to update, alter or otherwise revise any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

Summary of Material Risks Associated with Our Business

The principal risks and uncertainties affecting our business include the following:

- We are a clinical stage TechBio company, and all our product candidates remain in preclinical and clinical development. As a result, we currently have no recurring revenue and may not achieve commercial revenue for an extended period, if at all;
- we have a limited operating history, and no vaccine has been approved using our technology, and none may ever be approved;
- we are dependent upon successfully concluding partnerships to advance our product candidates to monetize our assets;
- we have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future;
- we will require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, scale back or cease our product development activities or any other or all operations;
- we will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations;
- we are substantially dependent on the success of product candidates, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized;
- clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter substantial delays in our clinical studies. Furthermore, results of earlier studies and trials may not be predictive of results of future trials;
- interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- pharmaceutical product development is inherently uncertain, and there is no guarantee that any of our product candidates will receive marketing approval;
- competition in the biotechnology and pharmaceutical industries is intense and our competitors may discover, develop or commercialize products faster or more successfully than us. If we are unable to compete effectively our business, results of operations and prospects will suffer;
- the effects of the invasion of Ukraine by Russia, the resulting conflict and retaliatory measures by the global community have created global security concerns, including the possibility of expanded regional or global conflict, which have had, are likely to continue to have, short-term and likely longer-term adverse impacts on Ukraine and Europe and around the globe, which could adversely affect our business and results of operations. The same applies to other global conflicts such as the ongoing conflict in the Middle East;
- our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any;
- the regulatory approval processes of the U.S. Food and Drug Administration, the European Medicines Agency and comparable authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed;
- our future partners, if any, may not be able to obtain regulatory approval for products, if any, derived from our product candidates under applicable United States, European and other international regulatory requirements
- our future partners, if any, may not be able to obtain regulatory approval for products, if any, derived from our product candidates under applicable United States, European and other international regulatory requirements.
- even if products derived from our product candidates receive regulatory approval, such products may not gain market acceptance and our future partners, if any, may not be able to effectively commercialize them.
- if we are not successful in developing our product candidates and our future partners, if any, are not successful in commercializing any products derived from our product candidates, our ability to expand our business and achieve our strategic objectives will be impaired.
- we rely on third-parties to manufacture preclinical, clinical and commercial supplies of our products, product candidates and their components. In addition, we rely on third-parties in the conduct of significant aspects of our preclinical studies and clinical trials, and we intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements and/or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.
- our future partners, if any, may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management and/or shipping, and/or all of which could materially adversely affect our business operations.

- certain of our product candidates may be uniquely manufactured for each patient and we and/or our future partners may encounter difficulties in production, particularly with respect to the scaling of manufacturing capabilities.
- if our and our future partners', if any, efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- we may be involved in lawsuits to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or otherwise violate such third party's intellectual property.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 20-F, including our consolidated financial statements and the related notes, as well as in other documents that we file with the United States Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3.A. Reserved

3.B. Capitalization and Indebtedness

Not applicable.

3.C. Reasons for the Offer and Use of Proceeds

Not applicable.

3.D. Risk Factors

Our business faces significant risks. You should carefully consider all the information set forth in this annual report and in our other filings with the SEC, including the following risk factors which we face, and which are faced by our industry. Our business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. This annual report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and other materials we file or furnish with the SEC. See "[Special Note Regarding Forward-Looking Statements](#)" above.

Risks Related to our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future, which makes it difficult to assess our future viability. We have not generated significant revenue and may never be profitable.

We have incurred net losses every year since our inception in 2008. As of December 31, 2025, we had an accumulated deficit of \$126.2 million. In 2025, MSD (tradename of Merck & Co., Inc., Rahway, NJ, USA) licensed Evaxion's vaccine candidate EVX-B3 for a cash payment of \$7.5 million, and Evaxion is eligible for future development, regulatory and sales milestone payments as well as royalties on net sales, however we may never generate significant revenue and may never become profitable.

Our operations have been funded primarily through equity financings, convertible debt, and private and governmental grants, and, most recently our partnership with Merck. We have devoted substantially all financial resources to research and development, including preclinical and clinical activities and the advancement of our AI-Immunology™ platform. The magnitude and timing of our future losses will depend on our ability to secure additional funding through equity or debt financings, asset sales, collaborations, including recent and potentially future out-licensing arrangements and grants.

We believe that the costs associated with late-stage clinical development, regulatory approval, and commercialization of our product candidates exceed the resources of all but large biopharmaceutical companies. Accordingly, our strategy is to engage in partnerships with such companies, deriving value from both our platform and pipeline. Our AI-Immunology™ platform enables us to partner on target discovery, candidate design and development agreements, whilst through our pipeline we aim to be advancing select high value programs into preclinical and early clinical development, retaining value and leveraging multidisciplinary capability base. Although we have entered into one partnership, we may be unable to secure additional partnerships on acceptable terms, or at all. As a result, no late stage or pivotal clinical trials for our product candidates have commenced under any partnership arrangement, and even if such trials begin in the near term, it will be several years, if ever, before any product candidate is ready for commercialization.

Even if our future partners obtain regulatory approval, our revenue will depend on the size of the approved markets, the achievement of development and commercial milestones, the level of upfront and other payments, reimbursement by third-party payors, and market acceptance and share. We may never achieve profitability.

Our ability to generate revenue and achieve profitability depends on our and our partners ability to successful development, regulatory approval, and commercialization of our product candidates, which may never occur.

We expect to continue incurring significant expenses and operating losses, including as we:

- advance our preclinical and clinical programs;
- continue investing in our AI-Immunology™ platform to enhance predictive capabilities and identify novel vaccines targets;
- generate preclinical evidence to support our partnership strategy;
- attract and retain qualified personnel;
- make milestone or other payments under in-license agreements; and
- maintain, protect, defend, enforce and expand our intellectual property portfolio.

Our ability to generate future revenues from our potential commercialization partnerships depends heavily on our success in:

- Leveraging our AI-Immunology™ platform, completing research and preclinical development, and securing partnerships pharmaceutical and biotech and pharmaceutical companies to conduct clinical development, trials, regulatory approval and commercialization of our immuno-oncology and infectious disease product candidates
- negotiating favorable terms in any future partnership agreements;
- maintaining relationships with third-party manufacturers capable of supplying adequate quantities and qualities of products and services to support our clinical development;
- enabling our current and future partners, if any, to obtain market acceptance and reimbursement for approved products;
- support our partners' commercial launches, if any;
- responding to competitive technological and market developments;
- implementing additional internal systems and infrastructure;
- maintaining, defending, protecting, enforcing and expanding our intellectual property rights.

Our operating results may fluctuate significantly, making future results difficult to predict. A failure to meet expectations could cause the market price of the ADSs to decline.

Our financial condition and operating results have fluctuated in the past and will continue to vary from period to period due to numerous factors, many of which are outside our control. These factors include:

- delays or failures in advancement of existing or future product candidates into preclinical studies or clinical trials;
- setbacks in development of our AI-Immunology™ platform;
- failure to secure new partnerships critical to our strategy;
- the ability of future partners, if any, to manufacture and commercialize our product candidates;
- our ability to manage growth effectively;
- outcomes of research programs, preclinical studies, clinical trials, and regulatory processes conducted by us or our partners;
- exclusivity terms and other conditions in partnership agreements;
- obligations to fund development of our product candidates;
- continued operating losses for the foreseeable future;
- risks associated with international operations, including multi-site clinical trials;
- reliance on third-party manufacturers for consistent supply of products and product candidates;
- our ability to integrate our programs into clinical workflows and treatment regimens;
- timely and accurate financial reporting;
- dependence on key management and personnel;
- our and our partners' ability to obtain, maintain, defend and enforce our intellectual property rights and prevent infringement or misappropriation;
- competitive advantages held by existing or potential competitors, including access to capital and critical intellectual property;
- our ability to raise additional capital to support operations;
- our partners' ability to raise capital to support development and commercialization activities;
- business interruptions, including power outages, strikes, terrorism, pandemics or natural disasters;
- the effects of climate change on our operations;
- geopolitical instability, including conflicts in the Ukraine and the Middle East; and
- our ability to utilize net operating loss carryforwards.

Given these factors and others described in this Form 20-F, the financial projections included herein should not be relied upon as indicative of future performance.

We will need substantial additional financing to achieve our goals, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, other collaborations and licensing arrangements, or a combination of these approaches. In any event, we will require additional funding to achieve our goals. We may seek additional capital if market conditions are favorable, if needed for continuing our operational activities or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for our development activities.

Our future funding requirements, both near and long term, will depend on many factors, including, without limitation:

- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our product candidates;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our future partners, if any;
- the number and characteristics of any technology that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, the TGA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement,
- misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical scale manufacturing activities by third parties sufficient to support all of our current and future programs.
- the effects of climate change on the global economy and our business; and
- the effects of the continued conflict between Russia and the Ukraine and in the Middle East region on the global economy and our business.

To date, we have financed our operations primarily through the sale of equity securities, the EIB loan and from private and governmental grants and we cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient upfront fees, milestone payments and royalty revenues from our agreements with existing and future partners, if any, to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, sales of assets, out-licensing arrangements, and other product development arrangements.

We cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all. Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all.

The amount of NOLs and research and development credits and our ability to use the same to offset future taxable income may be subject to certain limitations and uncertainty.

In Denmark, we have accumulated corporate tax losses carryforwards; however, we have not recognized deferred tax assets related to these losses for IFRS reporting purposes. While Danish NOLs generally do not expire, they are subject to review and possible adjustment by the Danish tax authorities. In addition, under current Danish tax laws, significant changes in our ownership structure and business could further limit the amount of NOLs that may be used to offset taxable income in any given year. We may also generate NOLs in other jurisdictions where we have subsidiaries.

We may be unable to utilize a significant portion of our NOLs or tax credits in Denmark, or other jurisdictions. Tax rules governing the timing and recognition of income and expenses are complex and subject to interpretation, and our tax position may be challenged by the tax authorities. If any such challenge is successful, our NOLs or credits could be reduced, or we could be required to pay material taxes in one or more periods. Moreover, our ability to use our NOLs and credits depends on our ability to generate taxable income. We have incurred significant losses since inception and expect to continue to incur losses for the foreseeable future, and we cannot predict if or when we will generate sufficient taxable income to utilize these carryforwards.

In addition, we will require substantial additional financing to achieve our business objectives. If we are unable to obtain such financing on acceptable terms, or at all, we may be required to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

We will need to develop our company, and we may encounter difficulties in managing this development, which could disrupt our operations.

As of December 31, 2025, we had 45 full-time equivalent employees. As we advance our product pipeline, partnerships and becoming a public company, we expect our operations to continue to grow. To support our growth, we will need to expand and improve our management, operational, legal, compliance, and financial systems, and hire, retain, and train additional qualified personnel. At the same time, management may need to devote significant time and attention to these efforts, which could reduce its focus on day-to-day operations.

We are a developing TechBio company pursuing multiple technologies, platforms, and product candidates across several therapeutic areas and diseases. Managing development activities across these areas requires substantial expertise, coordination, and resources. Because our resources are limited, we may not be able to effectively manage multiple development efforts at the same time or attract and retain the personnel needed to do so. If we are unsuccessful, we could experience operational errors, weaknesses in our internal infrastructure, legal or regulatory compliance issues, loss of business opportunities, employee turnover, and reduced productivity.

In addition, the requirements of being a Nasdaq-listed company, together with limited liquidity in the capital markets, may increase our costs and divert financial resources away from the development of our product candidates. If we fail to manage our growth effectively, our expenses may increase faster than expected, our ability to generate revenue could be impaired, and we may not be able to execute our business strategy. As a result, our financial performance, competitive position, and ability to develop our product candidates could be adversely affected.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

Our business exposes us to risks that may not be fully covered by insurance. We do not maintain insurance for all potential risks, and we may not be able to continue to obtain or maintain insurance on acceptable terms or with sufficient coverage. Any insurance we do carry may not be adequate to cover all losses or liabilities we may incur.

If any of our product candidates are approved for marketing, we would expect to obtain additional insurance covering commercial activities. However, such coverage may not be available in sufficient amounts or on commercially reasonable terms, or at all. If our losses exceed our insurance coverage, or if a claim is not covered, our financial condition and results of operations could be materially harmed.

We could face substantial liabilities in the event of contamination, injury, or other adverse events, including fines or damages that exceed our available resources. In addition, such events could result in the suspension of clinical trials or regulatory approvals, which could delay or prevent the development and commercialization of our product candidates.

Operating as a public company has also increased the cost of director and officer liability insurance. We may be required to accept higher premiums, reduced coverage, or lower policy limits, or we may be unable to obtain coverage on acceptable terms. As a result, it could become more difficult for us to attract and retain qualified directors and members of management.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Disruptions affecting banks or other financial institutions, including liquidity shortages, defaults, or failures, have in the past and could in the future cause broader market instability. Even concerns or rumors about such events could reduce confidence in the financial system and limit access to liquidity.

Although we hold our cash and cash equivalents at multiple financial institutions, our ability to access these funds could be impaired if any of those institutions experience financial distress or failure. In addition, instability in U.S. or international financial markets could make financing more difficult or expensive to obtain, including through higher interest rates, more restrictive terms, or reduced availability of credit.

If we are unable to access our cash or secure financing on acceptable terms, our ability to fund operations could be negatively affected. This could limit our ability to pay operating expenses, meet contractual obligations, or comply with applicable wage and employment laws, and could materially harm our business, financial condition, and liquidity.

Inflation could adversely affect our business and results of operations.

Rising inflation increases the cost of labor, materials, services, and other inputs needed to operate and grow our business. If we are unable to manage these higher costs or obtain needed resources on reasonable terms, our financial condition and results of operations could be adversely affected.

Inflation, geopolitical developments, and global supply chain disruptions may also contribute to economic uncertainty and higher interest rates. As a result, obtaining additional financing may become more difficult, more expensive, or more dilutive. If we are unable to effectively respond to these conditions, our financial condition, results of operations, and cash flows could be materially harmed.

Risks Related to Our Business and Industry

Our AI approach to the discovery of product candidates is novel and unproven, and we may never develop products of commercial value. If we or our future partners are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We are leveraging our AI-Immunology™ platform to create a pipeline of vaccine candidates for cancer treatment and for preventing bacterial and viral infectious patient populations that have not been adequately served by existing approaches. Together with future partners, if any, we aim to design and conduct efficient clinical trials with a potentially higher likelihood of success. We also intend to out-license identified targets or product candidates earlier in development and to partner on target discovery.

While we believe that applying our AI-Immunology™ platform may enable more efficient drug discovery process than conventional methods, our approach is both novel and unproven. As a result, the cost, timing, and likelihood of success in developing product candidates, whether by us or future partners, are highly uncertain. Our efforts may not lead to the discovery and development of commercially viable medicines.

We may also be incorrect in our understanding of how product candidates affect the diseases of our targeted patient populations, which could limit the utility or perceived utility of our approach. In addition, the number of patients who meet our defined criteria for study and treatment may be smaller than expected, which could hinder our or our partners' ability to conduct clinical trials and reduce the potential market size for any successfully commercialized product.

Our approach may not yield the clinical benefits, development efficiencies, higher success rates, or cost reductions we anticipate. If our platform does not perform as expected, we may be unable to attract additional partners, advance new drug candidates as quickly or cost-effectively as planned, or enable our future partners to commercialize our product candidates as originally expected.

Our AI approach may fail to identify or enable the development of additional product candidates, which could materially harm our business, financial condition, results of operations, and prospects.

Drug discovery efforts using our AI platform technologies may not successfully identify compounds with commercial value or therapeutic utility. Although our AI-Immunology™ platform may initially appear promising in identifying potential product candidates, it may ultimately fail to generate viable candidates for clinical development or commercialization for several reasons, including:

- we may be unable to identify additional product candidates suitable for preclinical and clinical development or attractive to potential partners. If we cannot identify such candidates or secure partnerships, our ability to advance product candidates and generate future revenue could be impaired, materially harming our financial condition and adversely affecting the market price of the ADSs;
- compounds identified through our AI-Immunology™ platform may not demonstrate adequate efficacy, safety or tolerability in preclinical studies or clinical trials;
- potential product candidates may later be found to have harmful side effects or other characteristics that make them unlikely to receive regulatory approval or achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive;
- a product candidate may not be manufacturable at acceptable cost, quality, or speed; or
- we or our future partners, if any, may be unable to scale manufacturing of personalized therapies to a commercial level.

We may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for our AI-Immunology™ platform.

Our business depends on sophisticated computer systems and software, and many of the underlying technologies evolve rapidly. We must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There is no assurance that we will be able to develop, acquire, enhance, deploy, or integrate new technologies, that such technologies will meet our needs or achieve expected performance, or that we will do so as quickly or efficiently as our competitors. Significant technological change could render our AI-Immunology™ platform obsolete.

Our continued success depends on our ability to adapt to emerging technologies, manage and process increasing volumes of data, and improve the performance of our AI-Immunology™ platform in response to evolving patient populations. We may encounter difficulties that delay or prevent the design, development, testing, and introduction of advanced versions of our platform, which could limit our ability to identify new product candidates. Any such failures could materially adversely affect our operating results and financial condition.

Our product candidates may not function as intended, may cause undesirable side effects, or may have other properties that delay or prevent regulatory approval, limit the commercial profile of any approved product, or result in significant negative consequences following marketing approval, any of which could materially harm our business, financial condition, results of operations, and prospects.

As with most biological and vaccine products, our product candidates may cause side effects or adverse events that range in severity from mild reactions to life-threatening events or death, and in frequency from rare to common. The risk of adverse events is especially acute in the oncology, where patients often have advanced disease, compromised immune systems, and concurrent therapies. Undesirable side effects or unacceptable toxicities could cause us, our future partners, or regulatory authorities to interrupt, delay or halt clinical trials and could lead to more restrictive label or the delay or denial of regulatory approval by the regulatory authorities. Clinical trial results may also reveal side effects with unacceptable severity or prevalence.

If unacceptable side effects arise in the development of our product candidates, we, our future partners, regulatory authorities, ethics committees, the institutional review boards (IRBs), or a Data Safety Monitoring Board (DSMB) could suspend or terminate our clinical trials. Regulatory authorities may also require us or our future partners to cease clinical trials or deny approval for one or more indications. Treatment-related side effects could also impair patient recruitment, reduce patient retention, or lead to product liability claims.

Side effects may also be improperly recognized or managed by the treating medical personnel. We expect that we or our future partners may have to train clinical and commercial medical personnel to understand and manage the safety profiles of our product candidates. Inadequate training could result in patient injury or death. Any of these events could materially adversely affect our business, financial condition, results of operations, and prospects.

Monitoring the safety of patients receiving our product candidates is challenging, which could adversely affect our and our partners' ability to obtain regulatory approval and commercialize our product candidates.

In our ongoing and planned clinical trials, we rely on academic medical centers and hospitals experienced in assessing and managing toxicities. However, these centers may still face challenges in observing patients managing adverse events, including issues related to personnel turnover, inexperience, shift changes, or limited staff coverage. Such challenges could lead to more severe or prolonged toxicities or even patient deaths, which could lead us, our future partners, or regulatory authorities to delay, suspend, or terminate one or more of our clinical trials, and could jeopardize regulatory approval. We also expect the centers administering our product candidates, if approved, may encounter similar difficulties.

Medicines used to manage adverse side effects of our product candidates may not adequately control such effects and could negatively impact treatment outcomes. The use of these medicines may increase as new physicians and centers begin administering our product candidates.

Even if our future partners advance one or more of our product candidates into late-stage clinical trials, such trials will likely involve a limited number of subjects and limited exposure periods. As a result, adverse effects may only become apparent when a significantly larger patient population is treated. Clinical trials may also be insufficient to fully assess the long-term safety of our product candidates over multiple years.

If any of our product candidates receive marketing approval and undesirable side effects are later identified, significant negative consequences could result, including:

- regulatory authorities withdrawing approval of products derived from our product candidates;
- required product recalls or changes to administration protocols;
- additional restrictions on marketing or manufacturing processes;
- mandated labeling changes, including boxed warnings or contraindications;
- requirements to implement a Risk Evaluation and Mitigation Strategy (REMS), or provide Medication Guide;
- product liability claims against us or our future partners;
- reduced competitiveness of products derived from our product candidates; and
- damage to our reputation.

Any of these events could prevent our future partners from achieving or maintaining market acceptance of the particular product candidate, even if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates generally prove to be unsafe, our AI platform technologies and product pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Preclinical development is inherently uncertain, and our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our partners' ability to obtain regulatory approvals or commercialize these programs and could materially harm our business, financial condition, results of operations and prospects.

A portion of our pipeline remains in preclinical development, and these programs may be delayed or may not progress into the clinic. We intend to out-license targets identify and preclinical programs to future partners, however due to our financial position and challenging capital market conditions, we may have to earlier out-license targets and programs to future partners than we otherwise would have done, if we had funds to mature them further. We may be unable to enter into any such out-licensing arrangements for current or future targets, which could prevent us from advancing these programs in a timely manner or at all. We may also be unable to identify new targets, and even if we do, we may not be able to secure out-licensing arrangements for them, limiting our ability to develop these programs.

Before we or our future partners, if any, can initiate clinical trials, extensive preclinical studies must be completed, including IND-enabling Good Laboratory Practice toxicology studies to support planned IND submission with regulatory authorities. We or our future partners must also complete substantial chemistry, manufacturing, and controls (CMC) work, such as generating yield, purity and stability data, to support these filings. CMC activities for new categories of medicines require complex manufacturing processes and analytical development, which are uncertain and lengthy. We have previously encountered challenges scaling up our manufacturing, and similar issues may arise in the future.

We or our future partners, if any, may also face difficulties identifying appropriate buffers and storage conditions to ensure adequate shelf life for preclinical or clinical batches. If new batches must be produced due to insufficient shelf life, the commencement or completion of preclinical studies or clinical trials may be delayed.

We cannot predict the timing or outcome of our preclinical studies, nor can we be certain that the regulatory authorities will accept the results of these studies or our proposed clinical development plans. As a result, we may be unable to submit INDs or similar applications on the expected timelines, if at all, and submission of such applications may not result in authorization to begin clinical trials.

Conducting research, clinical trials, and commercializing our product candidates internationally exposes us to significant risks that could materially harm our business, financial condition, results of operations, and prospects.

We expect that, if approved, our product candidates will be commercialized globally by future partners. Operating across multiple jurisdictions subjects us and our future partners to numerous additional risks, including:

- **Regulatory complexity**, including differing requirements for clinical trials, marketing approvals, data privacy, and the use of artificial intelligence;
- **Trade and economic risks**, such as changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- **Logistical challenges** in manufacturing, storing, and shipping product candidates across borders;
- **Import/export restrictions** and compliance with customs regulations;
- **Macroeconomic and political instability**, including inflation, recessions, and regional conflicts;
- **Compliance obligations** under tax, employment, immigration, and labor laws for employees working internationally;
- **Taxation risks**, including payroll withholding and other local tax obligations;
- **Currency fluctuations**, which may increase operating costs and reduce revenues;
- **Operational difficulties**, including staffing and managing foreign operations and addressing labor unrest in certain jurisdictions;
- **Reimbursement and pricing variability**, including differing payor systems, governmental price controls, and patient self-pay regimes;
- **Anti-corruption and compliance exposure**, including potential liability under the U.S. Foreign Corrupt Practices Act and similar laws in Denmark, Australia, and other jurisdictions;
- **Intellectual property enforcement challenges**, particularly in countries with weaker IP protections;
- **Supply chain vulnerabilities**, including raw material shortages or disruptions in manufacturing capabilities abroad; and
- **Business interruptions** from geopolitical events (such as the Russia-Ukraine war and the Israel-Gaza conflict), climate change, natural disasters, cybersecurity attacks, and pandemics.

These and other risks associated with our international operations and collaborations may materially impair our ability to achieve or maintain profitable operations.

Interim, preliminary, or top-line data from studies or those of our future partners, may differ materially from final results, which could adversely affect our business, financial condition, results of operations, and prospects.

From time to time, we or our future partners may announce interim, preliminary, or top-line data from preclinical studies or clinical trials. These data are subject to significant risks and uncertainties, including:

- **Incomplete datasets:** Interim results may change materially as additional data become available or as patient enrollment continues.
- **Assumptions and estimates:** Analyses often rely on assumptions, estimations, and calculations that may later prove inaccurate once full data are reviewed.
- **Audit and verification:** Preliminary data remains subject to audit and verification procedures, which may result in material differences from previously reported figures.
- **Regulatory interpretation:** Authorities may interpret data differently or disagree with our analyses, potentially affecting approvability or commercialization.
- **Disclosure limitations:** Public disclosures typically summarize extensive datasets. Information we deem immaterial or appropriate to omit may later be viewed as significant by investors, regulators, or other stakeholders.

Consequently, interim or preliminary data should be interpreted with caution until final, verified results are available. If top-line data differs from actual outcomes, or if regulators or others disagree with our conclusions, our ability to obtain approvals and commercialize product candidates could be materially harmed.

Results of preclinical studies and clinical trials may not predict outcomes in later trials, which could delay or prevent regulatory approval of our product candidates.

Positive results in preclinical studies and early clinical trials do not guarantee success in subsequent trials. Many biotechnology and pharmaceutical companies have experienced significant setbacks in later-stage trials despite encouraging early data, often due to unforeseen safety or efficacy issues, including previously unreported adverse events. We and our future partners, if any, may encounter similar challenges.

Our preclinical studies may not accurately predict human responses. Product candidates may exhibit different chemical, biological and pharmacological properties in patients than in preclinical models or interact with human biological systems in unexpected or harmful ways. Even after advancing through early trials, candidates may fail to demonstrate the desired safety or efficacy in later stages. Consequently, even if we complete clinical trials, results may be insufficient to obtain regulatory approval.

Our clinical trials may identify significant adverse events or an unfavorable safety profile, which could delay or terminate development, prevent regulatory approval, or limit market acceptance of our product candidates.

Clinical development of medicines is characterized by a high rate of attrition. Product candidates often fail to demonstrate acceptable safety or efficacy in later-stage trials despite promising early results. Many biopharmaceutical companies have experienced setbacks due to lack of efficacy or unacceptable safety profiles, and we or our future partners may face similar challenges. Most product candidates that enter clinical trials are never approved, and there is no assurance that any of our current or future trials will succeed or support further development.

Some of our product candidates may require co-administered with other investigational or approved therapies, which could introduce additional, unpredictable side effects. If significant adverse events occur, we or our future partners may face difficulties recruiting or retaining trial participants, may be required to suspend or terminate trials, or may abandon development of one or more candidates. Regulatory authorities, ethics committees, or institutional review boards may impose clinical holds or terminate trials at any time if they believe participants face unacceptable risks.

Even if adverse events do not preclude marketing approval, an unfavorable benefit-risk profile could limit physician adoption and patient acceptance compared to alternative therapies. Any of these developments could materially harm our business, financial condition, results of operations, and prospects.

We and/or our future partners may be unable to develop or obtain approval for companion diagnostics required for certain product candidates, which could delay or prevent their commercialization.

Some of our product candidates may require companion diagnostic tools to identify appropriate patients. Regulatory authorities generally require approval or clearance of a companion diagnostic concurrently with approval of the therapeutic product. For certain indications, companion diagnostics often undergo rigorous premarket approval processes, which can take several years. Similarly, in many jurisdictions, companion diagnostics must meet specific technical and safety requirements and undergo lengthy conformity assessments before they can be marketed.

For personalized immunotherapies, regulators may require development and approval of a companion diagnostic as a condition of product approval. Additional approvals may also be required for use of the same diagnostic with other therapeutic candidates. We have limited experience in developing or commercializing companion diagnostics and expect to rely heavily on third parties for these activities. Companion diagnostics are regulated as medical devices and require separate regulatory approvals prior to use with our therapies.

If we or our partners fail to develop or obtain timely approval of required companion diagnostics, or experience delays in doing so, we may be unable to identify appropriate patients for clinical trials or commercialization. This could require additional investment, delay clinical development, and materially impact our ability to obtain regulatory approval for affected product candidates.

Regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results, which could delay or prevent approval of our product candidates.

For certain diseases we may target, there are few or no approved pharmacologic therapies, and limited precedent for clinical trial design. Developing therapies for these indications may require novel endpoints, which could increase trial complexity, duration, and cost. Even if we achieve pre-specified endpoints, regulators may determine that these endpoints are not sufficiently validated or clinically meaningful. Furthermore, trial results may be unpredictable or inconsistent with traditional efficacy measures, and regulators may give overriding weight to secondary endpoints or safety considerations, even where primary endpoints are met.

Regulatory authorities also assess benefit-risk profiles and may conclude that efficacy results do not outweigh safety concerns. Any such determination could delay, limit, or prevent approval of our product candidates and materially harm our business, financial condition, results of operations, and prospects.

Regulatory authorities may disagree with our and/or our future partners' regulatory and development plans or fail to approve of our product candidates, which could delay or prevent commercialization.

Even if clinical trial results appear compelling, there is no assurance that our regulatory strategy will be accepted or that our submissions will be sufficient to obtain approval in any jurisdiction. Regulatory authorities may require additional studies, impose conditions such as post-marketing commitments, or change approval standards over time, particularly if new therapies become available for the same indications.

Our product candidates could fail to receive regulatory approval for many reasons, including:

- Regulatory authorities may disagree with the design, conduct, or interpretation of our clinical trials;
- We may be unable to demonstrate that our product candidates are safe and effective for their intended indications;
- Clinical trial results may not meet required statistical significance or may be impacted by patient population heterogeneity;
- We may be unable to show that the benefits of our product candidates outweigh their risks;
- Data from preclinical or clinical studies may be deemed insufficient to support approval;
- Manufacturing facilities used by us or our partners may fail to meet regulatory standards; and
- Approval policies or regulations may change in ways that render our data inadequate.

Even if accelerated or conditional approval is granted, regulators may require post-marketing studies to confirm clinical benefit and may withdraw approval if these studies fail. Any of these outcomes could materially harm our business, financial condition, results of operations, and prospects.

We and/or our future partners may not be able to initiate additional clinical trials on expected timelines, and regulatory authorities may not permit us or our future partners to proceed.

The timing of new clinical trials depends on successful completion of preclinical, clinical, and manufacturing activities. We cannot assure that applications to commence trials will be accepted by regulatory authorities or that trials will begin as planned. Even if regulators initially agree with our trial design, they may later impose changes or additional requirements. Furthermore, issues may arise during trial conduct that result in suspension or termination.

Any delays or inability to obtain authorization to initiate trials could increase development costs, postpone regulatory submissions, and materially impact our ability to advance product candidates.

We and/or our future partners if any, may be unable to obtain orphan drug designation or the associated benefits, including market exclusivity, which could reduce potential revenue.

We may seek orphan drug designation for certain product candidates in various jurisdictions. Orphan designation can provide benefits such as financial incentives, fee reductions, and periods of market exclusivity following approval. However, these benefits are subject to strict eligibility criteria and may be lost or limited under certain circumstances.

Even if we obtain orphan designation, exclusivity may not prevent competition. Different drugs with distinct active ingredients may be approved for the same condition, and regulators may allow competing products if they are deemed clinically superior or if supply of the original product is insufficient. Orphan designation does not shorten development timelines, accelerate regulatory review, or guarantee approval. Additionally, regulators may revoke designation if they determine that the original request was materially defective.

There is no assurance that we will obtain orphan drug designation for any product candidate, or that we will maintain the associated benefits. Loss or failure to secure these benefits could materially impact our ability to compete and reduce potential revenue.

We and/or our future partners may seek breakthrough therapy or fast-track designation for certain product candidates, but may not obtain them, and even if granted, such designations may not accelerate development or approval or increase the likelihood of marketing authorization.

In some jurisdictions, expedited pathways such as breakthrough therapy, fast-track, or conditional approval may be available for products intended to treat serious or life-threatening conditions and address significant unmet medical needs. These designations can provide opportunities for enhanced regulatory interaction and, in some cases, eligibility for priority review. However, such designations are granted at the discretion of regulatory authorities, and there is no guarantee that any of our product candidates will qualify.

Even if granted, expedited designations do not guarantee faster development, shorter review timelines, or ultimate approval. Regulators may later determine that a product no longer meets the criteria for designation or may withdraw the designation. Expedited pathways also do not eliminate the need to demonstrate safety, efficacy, and quality to regulatory standards.

Failure to obtain or maintain these designations, or to realize their intended benefits, could delay development and approval of our product candidates and materially impact our business, financial condition, results of operations, and prospects.

In January 2023, we received Fast Track Designation for our EVX-01 product candidate, to be used in combination with pembrolizumab (KEYTRUDA) for the treatment of patients with unresectable melanoma. Even though we have received this Fast Track Designation and even if we receive Fast Track Designation, for any of our other product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We expect some of the product candidates will be regulated as biologics in the United States and elsewhere and therefore may face competition from biosimilars sooner than expected.

The Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We and/or our future partners, may be unable to obtain regulatory approval for our product candidates in international markets, and delay or denial could materially harm our business, financial condition, results of operations, and prospects.

Approval in one jurisdiction does not guarantee approval elsewhere. To market our product candidates internationally, we must comply with varying regulatory requirements in each country, which often involve additional testing, validation, and administrative review. Clinical trials conducted in one jurisdiction may not be accepted by regulators in others, and approval processes can differ significantly, creating uncertainty and potential delays.

Seeking approval in multiple jurisdictions may require additional preclinical or clinical studies, increasing cost and timelines. We have no product candidates approved in any market and limited experience securing approvals internationally. Failure to obtain and maintain regulatory approvals, or delays in doing so, would reduce our target market and prevent us from realizing the full commercial potential of our products.

Even if our product candidates receive regulatory approval, they will remain subject to ongoing regulatory obligations and continued review, which may result in significant additional costs, restrictions, or penalties.

Regulatory approval does not eliminate ongoing compliance requirements. Authorities may impose restrictions on indications, marketing, or require costly post-approval studies and surveillance. We or future partners must monitor and report adverse events, maintain product specifications, and obtain approval for certain changes to labeling, manufacturing processes, or distribution. Promotional activities are also subject to strict regulation.

Failure to comply with these requirements could result in severe consequences, including:

- Warning letters or enforcement actions;
- Civil or criminal penalties and monetary fines;
- Suspension or withdrawal of approvals or licenses;
- Clinical trial holds or terminations;
- Refusal to approve pending applications or supplements;
- Product seizures or recalls; and
- Restrictions on entering supply or government contracts.

Any investigation or enforcement action could require significant resources and harm our reputation, limiting potential commercialization and revenue generation.

If our products cause serious adverse events, undesirable side effects, or unexpected characteristics, trials may be delayed, suspended, or terminated. Even if unrelated to the product, such events could impair patient recruitment and completion of trials. Regulators may require us to cease development or deny approval if safety concerns cannot be resolved. Post-approval, authorities may mandate risk management programs, such as controlled distribution systems, extensive monitoring, or patient education measures, which could increase costs and complexity.

If new safety issues emerge after approval, regulators may:

- Suspend or withdraw approvals;
- Require additional warnings or labeling changes;
- Mandate new clinical trials or changes in administration;
- Impose recalls or distribution restrictions; or
- Trigger litigation and reputational harm.

Manufacturing facilities also remain subject to ongoing inspections and compliance with good manufacturing practices. Previously unknown product or facility issues could lead to recalls, production halts, or other restrictions.

Any of these developments could materially harm our business, financial condition, results of operations, and prospects.

If we and/or our future partners, are unable to discover, develop, and commercialize additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives will be limited.

A key element of our strategy is to discover and, through partners, develop and commercialize new product candidates across multiple therapeutic areas. We plan to leverage our AI-Immunology™ platform to engage in drug and target discovery efforts, exploring potential collaborations for the development of new product candidates, and potentially in-licensing delivery technologies. We may also out-license potential new product candidates to future partners, if any, that have their own delivery technology. Furthermore, we may enter co-development or other partnership arrangements based on our AI-Immunology™ platform without preclinical or clinical studies including but not limited to responder models.

Identifying new product candidates requires substantial technical, financial and human resources, and there is no assurance they will succeed. Even if we identify product candidates, we or our partners may fail to develop and commercialize them for reasons including:

- Our platform may not successfully identify viable candidates;
- Competing technologies may render our candidates obsolete;
- Candidates may be subject to third-party intellectual property rights;
- Further studies may reveal safety concerns or lack of efficacy;
- Manufacturing challenges may prevent production at scale or acceptable cost; and
- Approved products may fail to gain acceptance among patients, clinicians, or payors.

If we are unsuccessful in discovering, developing and, through our future partners, commercializing additional products, our potential for growth may be impaired.

Government funding constraints or disruption affecting regulatory authorities could delay product development, review, and approval, materially impacting our business.

The ability of regulatory authorities to review and approve new products depends on adequate funding, staffing, and operational stability. Budget reductions, inability to retain personnel, policy changes, or failure to collect user fees can slow review timelines. Political processes governing agency funding are inherently unpredictable, and disruptions, such as government shutdowns or organizational changes, may impair normal regulatory functions.

Such disruptions could delay the initiation or completion of clinical trials, review of applications, or approval of new products. They may also affect agencies that fund research or regulate public markets, limiting our ability to raise capital. Any prolonged inability of regulatory authorities to perform their functions could significantly delay development and commercialization of our product candidates, adversely affecting our business, financial condition, results of operations, and prospects.

Future pandemics, epidemics, or outbreaks of infectious disease could materially disrupt our operations and adversely affect our business.

Our business depends on uninterrupted clinical development, manufacturing, and supply chain activities, many of which rely on third parties such as CDMOs, CROs, shippers, and other vendors. A future pandemic or similar public health crisis could significantly disrupt these operations, leading to delays in clinical trials, interruptions in manufacturing, and increased costs.

Potential impacts include:

- Delays or interruptions in clinical trial activities, including site initiation, patient recruitment, enrollment, monitoring, and data collection;
- Pauses in patient dosing or trial enrollment due to health concerns or resource constraints;
- Disruptions in global supply chains, including shortages of raw materials, shipping delays, and increased costs;
- Reduced availability of manufacturing slots or critical components due to competing demand for healthcare products;
- Staffing shortages among our employees or third-party service providers due to illness or restrictions;
- Increased cybersecurity risks and communication challenges from remote work arrangements;
- Regulatory delays caused by reduced agency operations or prioritization of emergency approvals.

These disruptions could result in missed development timelines, increased expenses, and inability to meet strategic objectives. Any prolonged impact could materially harm our business, financial condition, results of operations, and prospects.

Russia's invasion of Ukraine and ancillary developments may have an adverse effect on our business.

The ongoing conflict in Ukraine and related geopolitical tensions have created global security and economic uncertainty, which may result in supply chain disruptions, increased costs, and delays in research and clinical trial activities. We rely on global networks of contract research organizations and clinical trial sites for patient enrollment and study execution. Any interruption in these activities could require us to seek alternative suppliers or trial sites at additional expense and delay development timelines.

In addition, geopolitical instability has contributed to volatility in global financial markets, which may impair our ability to raise capital on favorable terms or at all. Prolonged or escalating conflicts could further disrupt operations, increase costs, and materially harm our business, financial condition, results of operations, and prospects.

Global and regional economic, political, health, climate, and other conditions could adversely affect our business.

Our operations and financial performance may be negatively impacted by global or regional instability, including armed conflicts, terrorism, civil unrest, trade disputes, pandemics, natural disasters, cybersecurity threats, and climate-related events. Such disruptions can lead to volatility in financial markets, supply chain interruptions, and increased costs.

Potential impacts include:

- Delays in clinical trial enrollment, site availability, and patient access;
- Interruptions in manufacturing and supply chain activities;
- Temporary closures of facilities operated by us or our suppliers;
- Trade restrictions, tariffs, sanctions, or export controls affecting critical materials or technologies;
- Increased difficulty in raising capital on acceptable terms;
- Regulatory delays or changes in approval timelines.

Events such as geopolitical conflicts, global health crises, and climate-related disasters are inherently unpredictable, and we cannot anticipate all potential consequences. Any of these developments could materially harm our business, financial condition, results of operations, and prospects.

Risks Related to the Manufacturing of Our Product Candidates and Future Pipeline

We and/or our future partners, may encounter significant challenges in manufacturing, product release, shelf life, testing, storage, supply chain management, or shipping. Any such difficulties, whether experienced by us, our partners, or third-party manufactures, could delay the supply of materials for clinical trials or approved products.

Early-stage development involves limited product knowledge, and our personalized immunotherapies and novel delivery technologies present unique complexities. Potential risks include:

- Difficulties scaling production, equipment failures, or raw material quality issues;
- Insufficient product stability or shelf life, requiring reformulation or resupply for clinical trials;
- On-demand manufacturing challenges for personalized therapies, impacting timely supply;
- Process changes during development that affect product specifications or stability, leading to lot failures and trial delays;
- Cross-contamination risks in multi-product facilities or during pharmacy preparation;
- Contaminated or adulterated raw materials and consumables;
- Dependence on novel raw materials or excipients that may not scale for commercial supply, creating shortages or failures;
- Single-source supply risks for critical components;
- Manufacturing disruptions due to resource constraints, labor disputes, supply chain interruptions, geopolitical instability, climate-related events, or pandemics.

Continuous process improvements may require extended stability testing, delaying trials. Transportation conditions could also compromise product quality, necessitating formulation changes and adding cost and complexity. Custom or novel manufacturing equipment introduces additional risk of malfunction or performance issues.

Any of these factors could result in delays, increased costs, wasted inventory, or inability to meet clinical and commercial supply requirements, materially harming our business, financial condition, results of operations, and prospects.

We expect to rely on external manufacturers, and any inability to produce sufficient quantities or comply with regulatory requirements could materially harm our business.

Manufacturing is critical for all of our product candidates and must comply with current good manufacturing practices (cGMP) and other regulatory standards. We expect to rely on external contract development and manufacturing organizations (CDMOs) and potentially future partners for production. For personalized immunotherapies, advance stockpiling is not feasible, making timely and reliable manufacturing essential.

If our CDMOs or partners experience difficulties—such as issues with product release, stability, testing, storage, supply chain management, or shipping—our clinical programs could be delayed or suspended, and we may incur significant costs to resolve these problems. Facilities used by CDMOs and partners are subject to regulatory inspections and must meet strict compliance standards. Failure to meet these requirements could result in enforcement actions, withdrawal of approvals, or the need to secure alternative manufacturing arrangements, which would be costly and time-consuming.

Additional risks include resource constraints, labor disputes, cybersecurity breaches, climate-related disruptions, and geopolitical instability. Any such event could jeopardize our ability to supply products for clinical trials or commercial use, materially impacting our business, financial condition, results of operations, and prospects.

We face regulatory and operational risks related to physical and digital infrastructure at manufacturing facilities operated by external service providers or future partners.

We expect to rely on CDMOs and potentially future partners for manufacturing, some of which may use highly digitized systems to improve efficiency. While beneficial, these systems introduce additional risks, including equipment malfunctions, system incompatibility, and cybersecurity breaches. Any such failure could disrupt manufacturing operations, delay supply of drug substances or products, and require costly remediation or transition to alternative facilities.

As our development and commercial needs grow, we may need to establish additional manufacturing capabilities or expand to new locations. This expansion could lead to regulatory delays and require significant investment in construction, personnel recruitment, and infrastructure upgrades. Changes in manufacturing processes may also necessitate modifications to facilities, adding further cost and complexity.

Any disruption in manufacturing capacity—whether due to infrastructure failures, regulatory delays, or operational challenges—could materially harm our ability to develop, produce, and commercialize our product candidates, adversely affecting our business, financial condition, results of operations, and prospects.

Our product candidates depend on the availability of key raw materials, which may not be obtainable on acceptable terms or at all.

Certain product candidates require specialized raw materials, some of which are produced by small suppliers with limited resources and experience supporting commercial-scale operations. These suppliers may be unable to consistently meet our specifications or respond effectively to unexpected events such as contamination or regulatory inspections. We often do not have long-term contracts with all suppliers, and we may be unable to secure such agreements on favorable terms or at all.

In addition, some raw materials are sourced from a single supplier or a small number of suppliers. These suppliers may cease operations, be acquired by competitors, or otherwise become unavailable. Transitioning to new suppliers can involve lengthy lead times, qualification processes, and additional costs, which could delay manufacturing and clinical development. Supply shortages or failures could negatively impact production yields, increase expenses, and materially harm our ability to meet development timelines or commercial demand.

Our product candidates are sensitive to shipping and storage conditions and may be subject to loss or damage.

Our product candidates require strict temperature control and handling during storage and transportation. Any deviation from required conditions could compromise product integrity, leading to loss of material or delays in clinical or commercial supply. These risks may result in increased costs, interruptions in development timelines, and could materially impact our ability to deliver product candidates for trials or approved use.

We are subject to extensive regulatory oversight for manufacturing and reliance on the manufacturing facilities of CDMOs or future partners introduces significant risks if they do not meet regulatory requirements.

All manufacturing for our product candidates, whether for clinical trials or commercial sale, is subject to stringent regulatory requirements, including current good manufacturing practices (cGMP). We do not operate our own manufacturing facilities and rely on CDMOs or future partners to produce our product candidates. These facilities must meet regulatory standards and are subject to inspection at any time. Failure to comply with cGMP or other applicable requirements could result in delays, increased costs, or inability to supply product.

Poor control of manufacturing processes can lead to quality failures, impacting supply and delaying clinical timelines. Risks include:

- Critical deviations in manufacturing processes;
- Facility or equipment failures;
- Product or facility contamination;
- Ineffective change management for processes or equipment;
- Raw material failures due to supplier non-compliance;
- Inadequate corrective or preventive actions; and
- Defective components or consumables.

Regulatory authorities may require extensive documentation and conduct inspections before approving clinical trials or marketing applications. Deficient inspection outcomes could delay development or commercialization. Even if approvals are granted, there is no assurance that CDMOs or future partners can consistently produce to required specifications or scale production to meet demand. Lot failures or product recalls could necessitate additional trials, increase costs, and delay launches.

Further risks include shortages of qualified personnel, operational errors, or intentional misconduct by employees or contractors. CDMOs may also face regulatory issues unrelated to our products, which could affect their ability to supply us. Non-compliance could result in sanctions, including clinical holds, fines, injunctions, license revocations, product seizures, recalls, and criminal penalties.

Our reliance on third parties for manufacturing and raw materials may adversely affect our ability to conduct clinical trials, secure approvals, and commercialize products on a timely and competitive basis, materially harming our business, financial condition, results of operations, and prospects.

Risks Related to the Commercialization of Our Pipeline

We rely on future partners to further develop our product candidates in late-stage clinical trials and to commercialize our product candidates. Successful commercialization depends on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates.

We expect to rely on future partners to complete late-stage development and commercialize our product candidates, if approved. The success of commercialization will depend significantly on whether government authorities, private insurers, and other third-party payors provide coverage and adequate reimbursement at levels that make our products accessible and commercially viable. Failure to secure favorable coverage or reimbursement could limit market adoption and materially reduce potential revenue.

Pricing and reimbursement for innovative therapies, including personalized and genetic medicines, are highly uncertain. Many jurisdictions require formal pricing and reimbursement approvals, which may occur after marketing authorization and can involve lengthy delays or result in prices that are not commercially attractive. In some countries, governments impose strict price controls or implement cost-containment measures that reduce reimbursement levels. Increasing global efforts to curb healthcare costs, through legislation, importation initiatives, bulk purchasing, and transparency requirements, may further limit pricing flexibility.

Even where coverage is granted, reimbursement levels may not allow partners to achieve sufficient returns on investment. Additionally, evolving healthcare policies, managed care trends, and legislative changes may increase pricing pressure and create barriers to market entry for new products.

Any inability to obtain or maintain adequate reimbursement or pricing approvals could significantly impair commercialization efforts, reduce revenue potential, and materially harm our business, financial condition, and prospects.

We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving our goals. Most of our competitors have significantly greater resources than we do, and we may not be able to compete successfully.

The pharmaceutical and biotechnology markets are intensely competitive and subject to rapid technological change. Numerous companies, academic institutions, and research organizations are developing products for the same indications we target. Many competitors have:

- Greater financial, technical, and human resources;
- More extensive experience in clinical development, regulatory approvals, manufacturing, and commercialization;
- Established products or candidates in late-stage development; and
- Strategic collaborations with leading companies and institutions.

Our product candidates may face competition from approved therapies and new entrants that could be more effective, safer, less expensive, or better marketed. Large pharmaceutical companies and specialized immunotherapy firms, many with significant resources and partnerships, represent formidable competitors.

If our product candidates are approved, competition will depend on factors such as safety, efficacy, ease of administration, pricing, reimbursement, manufacturing capacity, and intellectual property protection. Competitors may develop superior products or secure advantageous collaborations, making our products obsolete or noncompetitive before we recover development costs.

Failure to compete effectively could materially harm our business, financial condition, results of operations, and prospects.

Market opportunities for certain of our product candidates may be limited due to the rarity of the disease or limited to those patients who are ineligible for or have failed prior treatments and may be small. Therefore, we must be able to successfully identify trial participants and achieve a significant market share to maintain profitability and growth.

The FDA often approves new cancer immunotherapies initially only for use by patients with relapsed or refractory advanced cancer, or new bacterial vaccines initially only for use by patients with certain advanced diseases. We expect our future partners will initially seek approval of certain of our product candidates in this context. Subsequently, we would expect our future partners, to seek approval in earlier lines of treatment and potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy. Prior to any such approvals, we and our future partners, may have to conduct additional clinical trials. In the future, we may also develop product candidates for the treatment of rare diseases.

Our estimates of disease prevalence may prove inaccurate, and the actual number of eligible patients may be lower than expected. Even if approved products achieve meaningful market share, limited patient populations may prevent us from reaching profitability without securing approvals for additional indications.

We do not intend to establish a marketing and sales organization and as a company, we have no marketing, sales, or distribution capabilities. We expect to rely on future partners and other third parties, which may not successfully commercialize our product candidates.

We currently have no sales, marketing, or distribution infrastructure and have not designed our preclinical studies or clinical trials with commercialization considerations in mind. We do not intend to establish an internal marketing or sales organization and have no experience in marketing pharmaceutical products. If any of our product candidates are approved, we expect to rely on future partners and other third parties to commercialize them in the United States, Europe, and other jurisdictions.

Our ability to generate revenue will depend on the success of these third parties. We may be unable to enter into collaboration or distribution agreements on favorable terms, or at all. Even if we secure such arrangements, our partners may not commit sufficient resources to effectively market and sell our products. As a result, product sales may not reach levels necessary to sustain our business.

We will compete against companies with established and well-funded marketing and sales operations. Without the support of capable third parties, we may be unable to compete successfully, which could materially and adversely affect our business, financial condition, and results of operations.

Our future profitability depends on the ability of our future partners to successfully commercialize products globally, which exposes us to additional risks and uncertainties.

If any of our product candidates are approved, our future profitability will depend in part on the ability of our future partners to penetrate markets worldwide. Commercialization in international markets involves significant risks and uncertainties, including:

- obtaining marketing authorizations from regulatory authorities in each country;
- complying with complex and evolving regulatory, tax, accounting, labor, and other legal requirements;
- reduced protection for intellectual property rights;
- differing medical practices and market acceptance;
- import and export licensing requirements;
- governmental controls, trade restrictions, or changes in tariffs;
- economic weakness, inflation, or political instability in certain regions;
- production shortages due to disruptions in raw material supply or manufacturing capabilities;
- longer accounts receivable collection periods and shipping lead times;
- language and cultural barriers;
- foreign currency exchange rate fluctuations;
- varying reimbursement, pricing, and insurance regimes; and
- interpretation of contractual provisions under local laws in the event of disputes.

Our future partners may have limited experience managing these challenges. Failure to effectively address these risks could limit or prevent market penetration of any products developed using our technologies, materially reducing their commercial potential and our revenues.

Even if our future partners obtain regulatory approval, our products may not achieve market acceptance, which would limit commercial success.

Even if our future partners obtain regulatory approval for our product candidates, the resulting products may not gain sufficient acceptance among physicians, patients, hospitals, cancer treatment centers, and other members of the medical community to achieve commercial success. Market acceptance will depend on the medical community, patients, and third-party or governmental payors recognizing immunotherapies, including any prophylactic vaccines we may develop, as medically useful, cost-effective, and safe. Ethical, social, or legal concerns regarding genetic research could also lead to additional regulations that restrict or prohibit certain products or processes we use.

The degree of market acceptance of any approved products will depend on numerous factors, including:

- perceived efficacy and advantages over alternative treatments;
- ability to offer competitive pricing;
- prevalence and severity of side effects, including limitations or warnings in approved labeling;
- adverse effects associated with checkpoint inhibitors or other combination therapies;
- convenience and ease of administration;
- restrictions on use with other medications;
- willingness of patients to try new therapies and physicians to prescribe them;
- strength of marketing and distribution support and timing of competitive product launches;
- publicity regarding our products or competing treatments; and
- adequacy of third-party insurance coverage or reimbursement and patients' willingness to pay out-of-pocket.

Even if a product demonstrates favorable efficacy and safety in clinical trials, actual market acceptance will not be known until after launch. Efforts by us or our future partners to educate physicians, payors, and patients may require significant resources and may not succeed, particularly given the complexity and novelty of our programs compared to conventional technologies.

Commercial success also depends on adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, and access to managed care organizations. Healthcare reform measures or other cost-containment initiatives could reduce reimbursement levels or require additional post-marketing studies to demonstrate cost-effectiveness, increasing costs and diverting resources. If adequate coverage and reimbursement are not available, market acceptance and commercial success would be adversely affected.

In addition, any approved products will be subject to ongoing regulatory obligations, including submission of safety and other post-marketing reports, and compliance with current good manufacturing practices (cGMP) and good clinical practices (GCP) for any post-approval trials. Previously unknown safety issues, such as unexpected adverse events, could arise post-approval. Compliance with these requirements is costly, and any failure to comply or identification of new safety concerns could materially harm our business, financial condition, and results of operations.

Coverage and reimbursement may be limited or unavailable, which could adversely affect the commercial viability of our product candidates.

The commercial success of any product candidates that receive regulatory approval will depend significantly on the availability of coverage and adequate reimbursement from third-party payors, including government healthcare programs such as Medicare and Medicaid, managed care organizations, and commercial insurers. There is substantial uncertainty regarding the coverage and reimbursement status of any approved products, particularly because our product candidates represent novel approaches to cancer treatment and infectious disease prevention. As a result, we cannot accurately predict potential revenue from any approved products.

Patients typically rely on third-party payors to cover all or part of the costs of treatment. Obtaining coverage and reimbursement is critical to market acceptance and is often a time-consuming and costly process. Third-party payors determine coverage and reimbursement based on factors such as whether the product is:

- a covered benefit under the health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- not considered experimental or investigational.

Even if coverage is obtained, reimbursement rates may be insufficient to enable hospitals or physicians to adopt the product, or may require patient co-payments that are prohibitively high. In some cases, separate reimbursement for the product may not be available, and providers may only be reimbursed for the procedure in which the product is used. Additionally, revisions to reimbursement systems, such as changes to the Medicare Physician Fee Schedule or Outpatient Prospective Payment System, could reduce payments and negatively impact private payor rates, further limiting adoption.

Coverage and reimbursement policies vary widely among markets and payors, and favorable coverage by one payor does not guarantee similar decisions by others. In international markets, pricing of biologics is often subject to governmental control, and negotiations can be lengthy. Some jurisdictions require cost-effectiveness studies comparing new products to existing therapies, while others impose profit controls or allow cross-border imports from lower-priced markets, exerting downward pressure on pricing. These factors create significant barriers to market entry and may delay or limit commercialization.

We expect downward pressure on pharmaceutical pricing and reimbursement to continue globally. Coverage policies and reimbursement rates may change at any time, and even if favorable terms are initially obtained, they may be reduced in the future. If adequate coverage and reimbursement are not available, or if pricing restrictions significantly limit profitability, the marketability and commercial success of any approved products would be materially and adversely affected.

Healthcare reform and other legislative changes may increase the cost and complexity of obtaining marketing approval and commercializing our product candidates, and may impose pricing and reimbursement limitations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict post-approval activities, and adversely impact our ability to profitably commercialize any approved products. These measures may also affect the prices we or our future partners, if any, can charge.

In the United States, there has been increasing legislative and enforcement focus on drug pricing, particularly for specialty pharmaceuticals. Recent congressional inquiries and legislative proposals have sought to increase pricing transparency, reduce prescription drug costs, review manufacturer patient assistance programs, and reform government reimbursement methodologies. Some of these changes are subject to ongoing legal challenges, creating uncertainty regarding their implementation. Any reduction in reimbursement or other government programs may result in similar reductions from private payors. At the state level, legislatures have adopted laws aimed at controlling pharmaceutical costs, including price transparency requirements. Regional healthcare authorities and hospitals increasingly use competitive bidding to determine which products and suppliers will be included in their formularies.

Further, heightened scrutiny of the FDA's drug approval process by Congress could lead to delays in marketing approvals and impose more stringent labeling, post-marketing testing, and compliance requirements. These developments may increase costs and reduce the commercial viability of our product candidates.

Similar pricing and reimbursement reforms have been proposed or implemented in other jurisdictions, including the European Union, where healthcare delivery and pricing are primarily governed by national law. Budgetary constraints in most EU member states have resulted in strict pricing and reimbursement controls, and legislative developments may impose additional requirements that increase operating costs. In many countries, proposed pricing must be approved before a product can be marketed, and negotiations with authorities can be lengthy. Some jurisdictions require cost-effectiveness studies comparing new products to existing therapies, and reference pricing or parallel trade between low-priced and high-priced markets can further reduce prices. Historically, prices for products launched in the EU have been significantly lower than in the United States, and publication of discounts may create additional downward pressure.

We expect continued healthcare reform initiatives globally, which may impose more rigorous coverage criteria and downward pressure on pricing. These changes could materially reduce anticipated revenues, limit demand for our products, or render certain product candidates commercially nonviable. In some cases, we or our partners may determine that assets in early development cannot be advanced, or that collaboration programs are no longer economically feasible. Additionally, combination therapies, such as our personalized cancer vaccines administered with PD-1 or PD-L1 inhibitors, may become prohibitively expensive for payors, further limiting market potential.

We cannot predict the scope or timing of future healthcare reform measures. However, ongoing legislative and regulatory developments are likely to increase pricing pressure and compliance costs, which could materially and adversely affect our business, financial condition, and results of operations.

European Union drug pricing and reimbursement regulations may limit the commercial potential of our product candidates.

If our future partners obtain marketing approval for products derived from our product candidates in the European Union or other jurisdictions, they will be subject to local pricing and reimbursement regulations that could materially affect commercialization. In many countries, particularly in the European Union, biologic pricing is subject to governmental control, and negotiations with authorities can take considerable time after marketing approval. Market acceptance and sales will depend significantly on the availability of adequate coverage and reimbursement, which may be impacted by existing and future healthcare reform measures.

Outside the United States, proposed drug pricing often must be approved before a product can be marketed. Requirements vary widely by country. For example, European Union member states may restrict reimbursement under national health insurance systems and impose price controls or profit limitations. Reference pricing and parallel trade between low-priced and high-priced member states can further reduce prices. Some jurisdictions may require cost-effectiveness studies comparing our product candidates to existing therapies to obtain or maintain reimbursement or pricing approval. There is no assurance that favorable reimbursement or pricing arrangements will be available in any country with such controls.

Historically, prices for products launched in the European Union have been significantly lower than in the United States. Publication of discounts by payors or authorities may create additional downward pressure on prices within the country of publication and other countries. If pricing is set at unsatisfactory levels or reimbursement is unavailable or limited, revenues from sales by us or our future partners, if any, and the potential profitability of our product candidates in those markets would be materially and adversely affected.

Risks Related to Our Reliance on Third Parties

We will rely on third parties for significant aspects of our research and development, including preclinical studies and clinical trials, and expect to continue to do so. If these third parties fail to perform as required, our development programs could be delayed or harmed.

We currently rely, and expect to continue to rely, on third parties, including CROs, clinical data management organizations, medical institutions, clinical investigators, and future partners, to conduct various and significant elements of our clinical trials. We also depend on third parties for certain research and preclinical testing activities. If these parties fail to meet contractual obligations, comply with regulatory requirements, or adhere to agreed timelines, the development and regulatory approval of our product candidates could be delayed or impaired.

Our reliance on third parties reduces our control over these activities but does not relieve us of our regulatory responsibilities. We remain responsible for ensuring that our preclinical studies and clinical trials comply with applicable protocols, laws, and scientific standards, including Good Clinical Practice (GCP) requirements enforced by the FDA and comparable authorities. Failure to comply with GCP or other regulations could result in data being deemed unreliable, requiring additional trials, delaying approvals, and potentially subjecting us to enforcement actions, fines, or other penalties. Clinical trials must also use product candidates manufactured in compliance with current Good Manufacturing Practice (cGMP) standards. Noncompliance by us or our vendors could require repeating trials, significantly increasing costs and timelines.

Because we expect CROs to conduct all of our clinical trials, many critical aspects of our development programs, including trial conduct, timing, and data integrity, will be outside our direct control. Reliance on third parties also introduces risks such as:

- staffing shortages or turnover;
- failure to meet contractual obligations;
- regulatory compliance issues;
- financial distress or changes in priorities;
- conflicts of interest or relationships with competitors;
- human error; and
- cybersecurity breaches.

Any of these issues could lead to delays, increased costs, or compromised data integrity. If CROs fail to perform satisfactorily or if we cannot rely on their data, we may need to repeat or expand trials, delaying development and commercialization and requiring significant additional expenditures.

We also rely on third parties for transportation, storage, and distribution of clinical trial materials. Mishandling by vendors could damage products, delay trials or approvals, cause financial losses not covered by insurance, and harm our reputation.

Our dependence on third parties for critical development activities exposes us to risks that could materially and adversely affect our business, financial condition, and prospects.

Our existing collaborations and any future collaboration arrangements may not be successful, which could limit our ability to develop and commercialize our product candidates.

We have entered into collaborations under which our collaborators may provide funding and other resources for the development and potential commercialization of our product candidates. We intend to enter into additional collaborations to access funding, capabilities, and expertise. However, our existing collaborations and any future agreements may pose significant risks, including:

- future partners may not perform or prioritize their obligations as expected;
- clinical trials conducted under collaborations may not be successful;
- partners may discontinue development or commercialization based on trial results, strategic shifts, funding constraints, or external factors such as mergers or acquisitions;
- partners may delay trials, provide insufficient funding, stop trials, abandon product candidates, require reformulation, or repeat studies;
- partners could independently develop or collaborate on competing products they view as more commercially attractive;
- product candidates developed with us may compete with a partner's own pipeline, reducing their commitment to our programs;
- partners with marketing rights may not allocate sufficient resources to commercialization;
- disagreements over intellectual property, contract interpretation, or development priorities could lead to delays, termination, or costly litigation;
- partners may fail to maintain, protect, or enforce our intellectual property or misuse proprietary information, exposing us to litigation or invalidation risks;
- disputes may arise over ownership of intellectual property developed under collaborations;
- partners may infringe third-party IP, exposing us to liability;
- collaborations may be terminated for convenience, requiring us to raise additional capital to continue development;
- future collaborations may involve significant costs, equity dilution, or operational disruption; and
- competition for partners is intense, and negotiations are complex and time-consuming.

If collaborations do not result in successful development or commercialization, or if partners terminate agreements, we may not receive expected research funding, milestone payments, royalties, or other contingent payments. Loss of funding could delay development and require additional resources. Termination could also harm our reputation and make it more difficult to attract new partners. All risks related to product development, regulatory approval, and commercialization described in this annual report apply equally to activities conducted by our partners.

Our business depends on the successful development, regulatory approval, and commercialization of product candidates based on our AI-Immunology™ platform. Failure to achieve these objectives would materially harm our business.

Our ability to generate revenue and achieve profitability depends on the successful development, regulatory approval, and commercialization of product candidates derived from our AI-Immunology™ platform. We believe the cost and complexity of discovery, development, clinical testing, regulatory approval, and commercialization for the indications we target are very high. Accordingly, we intend to rely on partnerships with large biopharmaceutical and pharmaceutical companies to conduct late-stage development, clinical trials, regulatory submissions, and commercialization. While we have entered into early collaborations and intend to pursue additional partnerships, we may be unable to secure such arrangements on favorable terms, if at all.

Late-stage and pivotal clinical trials for our product candidates have not commenced, and even if initiated soon, it will likely be several years, if ever, before we or our future partners have a product ready for commercialization. The regulatory approval process is expensive, time-consuming, and uncertain. Neither we nor our future partners have obtained marketing approval for any product candidates, and it is possible that none will ever be approved. We have limited experience preparing and supporting regulatory submissions and expect to rely on future partners to manage these processes. To our knowledge, no personalized cancer immunotherapy of the type we are developing has been approved by the FDA, EMA, TGA, or any other regulatory authority.

Obtaining marketing approval requires extensive preclinical and clinical data demonstrating safety and efficacy, as well as detailed information on manufacturing processes and facility inspections. Regulatory authorities have broad discretion and may refuse to accept applications, require additional trials, or interpret data inconsistently, delaying or preventing approval. Even if approval is granted, it may be limited to narrower indications than requested, subject to restrictive labeling, or contingent on costly post-marketing studies, reducing commercial viability. Regulatory agencies may also impose Chemistry, Manufacturing, and Controls (CMC) requirements or identify deficiencies during pre-approval inspections, causing delays.

Changes in laws, regulations, or agency policies during development or review could further delay or prevent approval. Advisory committees or regulatory authorities may recommend non-approval or impose restrictions that limit market potential. Additionally, our preclinical studies and clinical trials have not been designed with specific commercialization considerations, which could impair the commercial prospects of any approved products.

If our future partners experience delays or fail to obtain regulatory approval, the commercial prospects for our product candidates will be harmed, and our ability to generate revenue from collaborations will be materially impaired.

If we are unable to establish collaborations on commercially reasonable terms, we may have to alter our research and development plans.

Our research and development programs and the potential commercialization of any product candidates will require substantial additional capital. We expect to continue seeking collaborative arrangements to access funding, capabilities, and expertise. However, we face significant competition for partnerships, and recent consolidation among large pharmaceutical companies has reduced the number of potential partners. Whether we enter into a collaboration will depend on factors such as the partner's resources and expertise, proposed terms, and their evaluation of risks and opportunities, including:

- the strength of our technology and trial results;
- likelihood of regulatory approval by the authorities;
- market potential for the product candidate;
- manufacturing and delivery complexities;
- competitive landscape; and
- prevailing industry and market conditions.

Potential partners may also consider alternative technologies or product candidates for similar indications that they view as more attractive. Existing agreements may restrict our ability to enter into future collaborations, and non-competition provisions could further limit our flexibility.

Collaboration negotiations are complex and time-consuming, and we may not secure agreements on acceptable terms, or at all. If we do enter into collaborations, we may be required to relinquish rights that reduce our potential profitability. If we cannot secure additional collaborations, we may need to curtail or delay research and development programs, reduce commercialization efforts, or fund these activities ourselves. Doing so would require significant additional capital, which may not be available on favorable terms, or at all.

We have entered into in-licensing arrangements and may enter into additional licensing arrangements in the future. If these arrangements fail to deliver expected benefits, our business could be adversely affected.

We have entered into license agreements, including with Statens Serum Institut (SSI) and PharmaJet, Inc., to obtain rights to intellectual property useful for pharmaceutical formulations and delivery devices. We may seek additional licenses in the future. Our ability to successfully develop and commercialize products based on in-licensed technology depends in part on the efforts of our licensors to prosecute, obtain, maintain, protect, enforce, and defend patent rights. Licensors may fail to secure or maintain patents, may choose not to enforce rights against infringers, or may pursue enforcement less aggressively than we would. Without adequate protection, competitors could develop substantially similar products, harming our competitive position.

We may also sublicense licensed rights to partners, and any impairment of these rights could reduce revenues or lead to termination of collaboration agreements. Disputes may arise with licensors regarding:

- scope of rights granted under the license;
- whether our technology infringes licensor IP outside the license;
- rights to sublicense IP to third parties;
- diligence obligations for development and commercialization;
- ownership of jointly developed IP; and
- priority of invention.

For example, SSI initiated legal proceedings in April 2022 claiming ownership of a patent application we filed related to a cancer treatment method using SSI's adjuvant. We disputed SSI's claim and settled the matter in June 2024, retaining all commercial rights without compensation to SSI.

We face the same risks with licensed IP as with IP we own. If we, our licensors, or co-owners fail to adequately protect, maintain, or enforce licensed IP, our ability to develop and commercialize products could be materially harmed, adversely affecting our business, financial condition, and prospects.

We rely on third parties to manufacture clinical supplies and will depend on them for commercial production. If they fail to perform, our development and commercialization efforts could be delayed or impaired.

We rely on third-party contract development and manufacturing organizations (CDMOs) to produce clinical supplies and process our product candidates. None of our product candidates have been manufactured at late-stage clinical or commercial scale, and our CDMOs or future partners may be unable to achieve such scale or create sufficient inventory to meet demand. We do not yet have reliable cost estimates for commercial manufacturing, and actual costs or rights to manufacture could materially affect the availability and commercial viability of our product candidates.

Our reliance on a limited number of third-party manufacturers exposes us to risks, including:

- difficulty identifying qualified manufacturers on acceptable terms, particularly given regulatory requirements for any replacement contractor;
- delays or inability to produce sufficient quantities of product candidates with the required quality for clinical or commercial needs;
- failure to execute manufacturing procedures appropriately;
- termination or non-performance by CDMOs, or their exit from the contract manufacturing business;
- lack of control over compliance with cGMP and other regulatory standards, which are enforced through periodic inspections by the regulatory authorities;
- potential loss of intellectual property rights to process improvements made by CDMOs;
- breaches or early termination of manufacturing agreements; and
- exposure to the same risks we would face if developing manufacturing capabilities internally.

Any of these risks could delay clinical trials, regulatory approvals, or commercialization, increase costs, or reduce potential revenues. We also rely on third parties to perform release testing before delivery to patients. If these tests are not properly conducted or data are unreliable, patient safety could be compromised, exposing us to liability and reputational harm.

We may rely on single-source suppliers for critical components and materials, which could expose us to supply disruptions and delays.

We and/or our future partners, if any, may depend on single-source suppliers for certain components, raw materials, and manufacturing processes required to develop and commercialize our product candidates. We cannot guarantee that these suppliers will remain in business, maintain sufficient capacity, or continue working with us. Suppliers could be acquired by competitors or other companies unwilling to support our programs. Reliance on single-source suppliers exposes us to risks such as supply disruptions, price increases, and late deliveries. Alternative sources are often limited, and establishing replacement suppliers could take substantial time and require regulatory approval.

If we must switch suppliers, manufacturing and delivery of our product candidates could be interrupted for an extended period. Replacement suppliers would need to be qualified and may require additional regulatory review, causing further delays. While we intend to maintain adequate inventory of critical components, any interruption or delay in supply, or inability to secure alternate sources at acceptable prices, could impair our ability to meet clinical or commercial demand.

FDA approval of our product candidates will also require review of individual components and manufacturing processes, including those of single-source suppliers. Our reliance on these suppliers may subject us to risks that could materially harm our business, including:

- delays in development timelines;
- supply interruptions due to operational changes or discontinuation;
- shipment delays caused by defects or variability in components;

- lack of long-term supply agreements;
- inability to obtain adequate supply on commercially reasonable terms;
- difficulty and cost of qualifying alternative suppliers;
- production delays related to regulatory qualification of new suppliers;
- prioritization of other customers by suppliers;
- reputational harm from defective components; and
- fluctuations in delivery due to changes in demand.

If any of these risks materialize, costs could increase significantly, and our ability—or that of our partners—to meet demand for our product candidates could be adversely affected.

Risks Related to Our Intellectual Property

If we cannot obtain, maintain, protect, defend and/or enforce the intellectual property rights covering our product candidates and technologies, we may not be able to compete effectively.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patents and other intellectual property rights protecting our current and future product candidates, proprietary technologies and their uses. We generally seek to protect our intellectual property position by filing and/or licensing patents or patent applications in the United States, Europe and other countries relevant for the commercialization of our product candidates and proprietary technologies.

While in some jurisdictions patent applications can be enforced through the issuance of a preliminary injunction, in general, our patent applications cannot be enforced against third parties practicing the technology claimed in our applications until grant of patent. Further, our patents or licensed patents can only be enforced to the extent that the issued claims cover third parties' activities in the countries in which they are performed.

We cannot be certain that the claims in any of our patent applications will be considered patentable by the governmental patent agencies in any jurisdiction. The standards that governmental patent offices use to grant patents are not always applied predictably or uniformly and can change. Each jurisdiction has their individual set of patent laws and processes, which may result in very different protection of our products, inventions and technologies. In certain countries, for example, methods for the medical treatment of humans are not patentable. Moreover, there are periodic changes in patent law and there is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, there can be no assurance that our current to future issued or licensed patents will adequately cover our product candidates or technology.

If we do not adequately obtain, maintain, protect, defend, and enforce our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could materially harm our business, financial condition, results of operations and prospects.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years.

The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner in all relevant jurisdictions.

It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity, or enforceability so that any patents may be challenged in the courts or patent offices. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable which could limit our ability to stop others from commercializing similar or identical products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Our ability to enforce our own and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases, we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable, which could harm our competitive position. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, even if the eventual outcome is favorable to us. Furthermore, because of the potentially substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during the course of litigation.

The risks and uncertainties for our business related to intellectual property include, from time to time, the following:

- compliance lapses with a number of procedural, documentary, fee payment and other provisions during the patent process, may result in abandonment or lapse of a patent or application;
- patent applications may never result in any patents being issued;
- patents we own (solely or jointly) or have in-licensed may be challenged, opposed, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- third parties may have designed around our patent claims or developed technologies that may be related or competitive to our product candidates or other technologies;
- successful oppositions to patents we own or in-license may deprive us of rights necessary for the feasible development and commercialization of our product candidates or technologies;
- because patent applications remain confidential for a period after filing, we cannot be certain we, our co-owners, or licensors, were the first to file any patent application relating to our product candidates, technologies, or their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an inter parties review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- governments in countries where we have patent rights, may decide to do compulsory licensing wherein patents are required to be made available to third parties at reduce rates;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing competitors a better opportunity to create, develop and market competing product candidates;
- we may not be able to develop inventions adequate for obtaining new patents to protect our future products and technologies; and
- competitors may perform research and development in countries where we lack enforceable patent rights and use the resulting information to commercialize competing products in our key markets

If we are unable to adequately obtain, maintain, protect, defend, and enforce our intellectual property rights, competitors may exploit our product candidates and proprietary technologies, eroding or eliminating our competitive advantage and materially harming our business, financial condition, results of operations, and prospects.

Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us or our future partners from developing and commercializing our product candidates.

Our business operates in new and evolving scientific fields where numerous patents and applications have been filed by various organizations and individuals. We own and in-license patents and applications covering technologies, formulations, methods, and delivery systems, including lipid nanoparticles (LNPs). If we, our co-owners, licensors, or future partners fail to obtain, maintain, protect, defend, or enforce these rights, our ability to develop and commercialize products could be materially harmed.

Competitors and other third parties have filed, and will continue to file, patent applications in the United States and in other jurisdictions. There is uncertainty regarding which patents will issue, their scope, and enforceability. We cannot predict whether our pending applications or those of our licensors will result in issued patents or whether issued claims will provide sufficient protection.

We, our co-owners, or licensors may become involved in patent disputes, including interference, opposition, reexamination, or post-grant review proceedings in the U.S., Europe, or other jurisdictions. For example, SSI previously initiated litigation over ownership of a patent application we filed; while that matter was settled in our favor, similar disputes could arise. Adverse outcomes in such proceedings could result in loss or narrowing of patent rights, invalidation of claims, or unenforceability, which could take years to resolve and materially impact our business.

The America Invents Act introduced procedures, such as inter partes review and post-grant review, that allow third parties to challenge patents more easily. We expect competitors and other entities, including non-practicing entities, to use these mechanisms against patents we own or in-license. Defending such challenges is costly, time-consuming, and uncertain, and even unsuccessful challenges could weaken our IP position.

Additionally, third parties may hold patents covering technologies or methods we or our partners need for development or commercialization. Licenses to such patents may not be available on commercially reasonable terms, or at all. If we cannot obtain necessary licenses, we may need to cease development, manufacturing, or commercialization of one or more product candidates, which would materially harm our business, financial condition, and prospects.

We may not be successful in obtaining, maintaining, protecting or enforcing the intellectual property rights necessary for our development programs, which could materially harm our business.

Our ability to identify, develop, and commercialize product candidates depends on securing and maintaining rights to intellectual property through owned and in-licensed patents and other proprietary rights. As our pipeline expands, additional product candidates may require intellectual property held by third parties, including specific formulations or processes. We may be unable to acquire or license these rights on reasonable terms, or at all. Licensing and acquisition of third-party IP is highly competitive, and larger, better-funded companies may have advantages in securing rights we consider critical.

For example, we collaborate with academic institutions under agreements that typically provide options to negotiate licenses for resulting IP. However, institutions may not honor these options, or we may fail to reach acceptable terms within required timeframes, allowing others to obtain rights that block our programs. Additionally, some of our patents and applications are co-owned with third parties. If we cannot secure exclusive rights to co-owned IP, co-owners may license their interests to competitors, and we may need their cooperation to enforce patents, which may not be forthcoming.

Third parties that view us as a competitor may refuse to license IP to us, or may demand terms that prevent an adequate return on investment. If we cannot obtain necessary rights or maintain, protect, defend, or enforce existing IP, we may need to abandon development of affected programs or product candidates, and our partners may need to abandon commercialization efforts. Any of these outcomes would materially harm our business, financial condition, and prospects.

The lifespans of our patents may not be sufficient to protect our product candidates and technologies.

Patents have a limited term, generally 20 years from the earliest non-provisional filing date, subject to payment of maintenance fees and annuities. While certain jurisdictions allow patent term extensions, even with such extensions, protection is time-limited. Once patents expire, competitors may use the underlying inventions to develop competing products and technologies.

Although U.S. patents may receive term adjustments for delays caused by the USPTO, these can be reduced or eliminated by applicant delays during prosecution. Given the lengthy timelines for development, clinical testing, and regulatory approval, patents covering our product candidates may expire before or shortly after commercialization. If patents we own or in-license expire, we cannot prevent others from using similar or identical technology, which could materially harm our competitive position, business, financial condition, and prospects.

If we do not obtain patent term extension and data exclusivity for our product candidates, our competitive position could be materially harmed.

Depending on the timing and specifics of FDA approval for any product candidates, certain U.S. patents may be eligible for limited term extensions under the Hatch-Waxman Amendments, which allow up to five years of additional protection to compensate for regulatory review delays. However, extensions cannot exceed 14 years from the date of product approval, and only one patent covering the approved drug, its use, or its manufacturing method may be extended.

We may fail to obtain extensions due to missed deadlines, lack of diligence during development or review, or failure to meet other requirements. Even if granted, the extension period or scope may be less than requested. If we cannot secure patent term extensions or data exclusivity, competitors may obtain approval for competing products shortly after our patents expire, which could materially harm our business, financial condition, and prospects.

If we fail to comply with our license agreements or lose rights to in-licensed intellectual property, our ability to develop and commercialize product candidates could be materially harmed.

We rely on licenses for certain intellectual property from third parties that are critical to the development and commercialization of our technologies and product candidates, and we expect to enter into additional license agreements in the future. Licensing arrangements are complex and may not provide exclusive rights in all fields of use or territories, which could allow competitors to develop and commercialize competing products.

In some cases, we do not control the prosecution, maintenance, enforcement, or defense of patents covering licensed technology, and even where we have such rights, they may require third-party input. Licensors may fail to properly maintain or enforce patents, or patents may be challenged, narrowed, invalidated, or held unenforceable. If licensors fail to protect licensed IP, or if we cannot secure cooperation to enforce rights, competitors could market similar products, harming our business.

Our license agreements impose obligations, including diligence, milestone and royalty payments, exclusivity provisions, and other covenants. Failure to comply, or a bankruptcy event, could give licensors the right to terminate agreements, eliminating our ability to develop or commercialize covered product candidates. Licensors may also conclude we have breached agreements, even if we disagree, and terminate rights. Renegotiating or reinstating licenses may not be possible on favorable terms, or at all. Termination or loss of exclusivity could allow competitors to seek regulatory approval and market similar products.

We face the same risks with licensed IP as with IP we own. If we, our licensors, or co-owners fail to adequately protect these rights, or if disputes impair our ability to maintain licenses on acceptable terms, we may be unable to develop product candidates or our partners may be unable to commercialize products, which would materially harm our business, financial condition, and prospects.

Our current proprietary position for certain product candidates depends upon our owned or in-licensed patent filings covering components of such product candidates, manufacturing-related methods, formulations and/or methods of use, which may not adequately prevent a competitor or other third party from using the same product candidate for the same or a different use.

Our proprietary position for certain product candidates relies on owned and in-licensed patents covering components, manufacturing methods, formulations, and methods of use. While composition-of-matter patents generally provide the strongest protection, we do not currently have issued claims in the U.S. or Europe covering the overall construct of our product candidates, and we cannot guarantee that future patents will provide such coverage.

Method-of-use and formulation patents offer narrower protection. Competitors may develop similar or identical products for indications outside the scope of our claims or create alternative formulations. Even if competitors do not promote off-label use for our patented indications, physicians or patients may do so, and such infringement is difficult to detect or enforce.

Additionally, competitors may rely on undisclosed know-how, such as proprietary manufacturing processes or tools. If they can demonstrate prior secret use, they may assert prior user rights under applicable laws, including U.S. defenses under 35 U.S.C. §273, allowing them to exploit technologies we later patent. In such cases, we may be unable to prevent commercial use of our patented technology in the U.S. or other jurisdictions.

These limitations could materially harm our ability to protect our product candidates and technologies, adversely affecting our competitive position, business, financial condition, and prospects.

Third-party intellectual property rights could prevent us or our partners from developing or commercializing our product candidates, and we may need to litigate or obtain costly licenses.

Because our product candidates are in early development and may undergo changes in formulation, manufacture, or use, we cannot be certain we are aware of all third-party intellectual property that could be relevant. Competitors and other third parties may hold patents, or pending applications that later issue, that cover aspects of our products or technologies. While U.S. law provides a "safe harbor" for activities related to FDA approval under 35 U.S.C. §271(e)(1), this exemption ends upon submission of a BLA or NDA. At commercialization, one or more third-party patents could cover our products or critical features of their manufacture or use.

If third-party patents or other IP rights cover, or are alleged to cover, our products, we may need to invalidate or design around such rights or obtain licenses. Litigation or licensing could be costly, time-consuming, and uncertain, and licenses may not be available on commercially reasonable terms or at all. Designing around patents may be prohibitively expensive or technically infeasible.

We may also fail to identify relevant patents or pending applications, as filings are typically confidential for 18 months after submission. Additionally, claims in pending applications can be amended over time, including through continuation or divisional filings, to cover aspects of our platforms or product candidates. We may not be aware of such amendments until it is too late to avoid infringement.

Any inability to secure necessary rights or resolve disputes could force us or our partners to cease development, manufacturing, or commercialization of one or more product candidates, materially harming our business, financial condition, and prospects.

We may be involved in costly and time-consuming intellectual property litigation, which could adversely affect our business.

We may need to initiate lawsuits or other proceedings to protect or enforce our intellectual property rights or those of our licensors, or to defend against claims that we infringe, misappropriate, or otherwise violate third-party rights. Such actions can be expensive, unpredictable, and time-consuming, and may divert management's attention from our operations.

If we assert patent rights against a third party, the defendant may challenge the validity or enforceability of our patents. Courts may find our patents invalid, unenforceable, or not infringed, which could result in the loss of patent protection for key product candidates. Similarly, third parties—including competitors and non-practicing entities—may claim that we infringe their patents covering materials, formulations, manufacturing processes, or methods of use. If a court determines that our technologies infringe third-party patents, we could face injunctions blocking development or commercialization unless we obtain licenses, which may not be available on commercially reasonable terms, or at all. Even if licenses are available, they may be non-exclusive, allowing competitors access to the same technology.

We may also be subject to interference, derivation, or opposition proceedings to determine priority of invention. An unfavorable outcome could require us to cease using certain technologies or obtain costly licenses. Defending litigation or administrative proceedings, even if successful, can result in substantial costs, operational delays, and reputational harm. Competitors with greater financial resources may withstand such litigation more effectively than we can.

In the event of an adverse judgment, we could be required to pay significant damages, including treble damages for willful infringement, attorneys' fees, and royalties, or redesign infringing products, which may be impractical. Litigation could also compromise confidential information through discovery and lead to negative publicity that adversely affects our stock price.

Additionally, certain collaboration agreements require us to indemnify partners for IP-related litigation costs, which could further increase our financial exposure. Any of these outcomes could materially harm our business, financial condition, and prospects.

Failure to comply with patent office requirements could result in loss of patent rights.

Obtaining and maintaining patent protection requires compliance with numerous procedural, documentary, and fee payment obligations imposed by patent offices worldwide. These include periodic maintenance, renewal, and annuity fees throughout the life of a patent or application. While we use internal systems and outside counsel to manage these requirements, we cannot guarantee full compliance. Inadvertent lapses may sometimes be cured by late fees, but in certain cases, non-compliance can result in abandonment or expiration of patents or applications, leading to partial or complete loss of rights.

We also rely on licensors to maintain and protect in-licensed intellectual property, and we cannot ensure they will meet these obligations. Loss of patent rights, whether owned or in-licensed, could allow competitors to market similar or identical products and technologies, materially harming our business, financial condition, and prospects.

Changes in patent laws could reduce the value of intellectual property and impair our ability to protect our products.

Our success depends on our ability to obtain, maintain, and enforce patents. Patent law is complex and subject to change, creating uncertainty in the biotechnology industry. For example, the America Invents Act transitioned the U.S. to a "first-inventor-to-file" system and introduced new procedures, such as inter partes review and post-grant review, which increase the cost and complexity of obtaining and defending patents. These changes, and their implementation, could materially affect our ability to secure and enforce patent rights.

Additionally, recent U.S. Supreme Court decisions have narrowed the scope of patent protection and weakened patent owners' rights, increasing uncertainty regarding the value of issued patents. Future legislative, judicial, or administrative changes in the U.S. or other jurisdictions could further alter patentability standards, enforcement mechanisms, or available remedies in unpredictable ways. Any such changes could materially harm our existing patent portfolio and our ability to obtain, maintain, protect, or enforce intellectual property rights, adversely affecting our business, financial condition, and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be materially harmed.

In addition to patents, we rely on trade secrets and confidentiality agreements to protect proprietary know-how, processes, and other elements of our discovery and development activities that are not covered by patents or are difficult to enforce through patents. However, trade secrets can be challenging to protect.

We seek to safeguard trade secrets and proprietary information through non-disclosure and confidentiality agreements with employees, consultants, CROs, CDMOs, advisors, and other third parties. We also require invention assignment agreements from employees and key consultants. Despite these measures, we cannot guarantee that all parties with access to our confidential information have executed such agreements or that these agreements will prevent unauthorized disclosure. Breaches may occur, and enforcing claims for misappropriation or unauthorized disclosure is costly, time-consuming, and uncertain. Courts in some jurisdictions may offer limited protection for trade secrets.

If competitors lawfully obtain or independently develop similar know-how, we cannot prevent them from using it to compete with us. Unauthorized disclosure of our trade secrets could eliminate any competitive advantage, materially harming our business, financial condition, and prospects.

We may be subject to claims of misappropriation of third-party confidential information or trade secrets, which could result in costly litigation and harm our business.

We have received confidential information from third parties during research collaborations and other industry interactions. Additionally, many of our employees, consultants, and advisors were previously employed by universities or biotechnology and pharmaceutical companies, including competitors. Although we seek to prevent the use of third-party confidential information or trade secrets in our work, we may face claims that we, or our personnel, have misappropriated or improperly disclosed such information.

If we fail to successfully defend against these claims, we could be required to pay damages and may lose valuable intellectual property rights or personnel. Even if we prevail, litigation could be costly, time-consuming, and disruptive to our operations. Such claims could materially harm our business, financial condition, and prospects.

We may be subject to claims challenging inventorship or ownership of our intellectual property, which could result in costly disputes and loss of rights.

We have been, and may in the future be, subject to claims that current or former employees, consultants, contractors, collaborators, or partners have rights in our patents or other intellectual property. Although we require agreements assigning IP to us, these agreements may not be executed by all contributors, may be breached, or may not be self-executing.

Conflicting obligations of individuals involved in developing our product candidates could lead to inventorship disputes.

If such disputes impair our ability to maintain licenses or exclusive rights, development and commercialization of our product candidates could be adversely affected.

Litigation may be necessary to resolve inventorship claims. If we fail to prevail, we could lose valuable IP rights or exclusive ownership, materially harming our business, financial condition, and prospects. Even successful defense could involve substantial costs and management distraction.

Additionally, laws governing employee inventions vary by jurisdiction. Most of our employees work in Denmark, where the Danish Act on Employee Inventions regulates ownership and compensation for employee-created inventions. Disputes under this law could require us to pay additional compensation or negotiate assignments, increasing costs and creating operational uncertainty.

Any of these outcomes could materially harm our business, financial condition, and results of operations.

We do not seek patent protection in all jurisdictions and may be unable to enforce our rights where protection is limited.

Filing, prosecuting, and defending patents worldwide is prohibitively expensive, and we do not pursue protection in every jurisdiction. Intellectual property laws in some countries provide less protection than those in Denmark or the United States, and enforcement mechanisms may be weak or unfavorable, particularly in certain developing countries. As a result, we may be unable to prevent third parties from using our technologies in jurisdictions where we lack patent protection or from exporting infringing products into markets where enforcement is limited.

Proceedings to enforce IP rights abroad can be costly, time-consuming, and uncertain, and may expose our patents to invalidation or narrow interpretation. Even if successful, remedies may be commercially insignificant. Many countries also have compulsory licensing laws or limit enforceability against government agencies, which could materially diminish the value of our patents. If we or our licensors are compelled to grant licenses or cannot enforce rights effectively, our competitive position could be impaired, materially harming our business, financial condition, and prospects.

If our trademarks and trade names are not adequately protected, our ability to build brand recognition could be impaired.

Our trademarks, trade names, and service marks, whether registered or unregistered, may be challenged, infringed, misused, or deemed generic. We may not be able to prevent competitors from adopting similar marks, which could cause market confusion and weaken our brand identity. Additionally, third parties may assert claims of trademark infringement against us, and defending such claims could be costly and disruptive.

Failure to establish and maintain strong brand recognition could limit our ability to compete effectively. Misuse of our trademarks by licensees or distributors, even under agreements intended to govern proper use, could diminish goodwill and jeopardize our rights. Efforts to enforce or protect our trademarks, trade names, and other proprietary rights may be costly, time-consuming, and ultimately ineffective, which could materially harm our business, financial condition, and prospects.

Intellectual property rights do not necessarily address all potential threats to our business or permit us to maintain any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain any competitive advantage we may have. The scope and effectiveness of such protection are inherently uncertain. For example:

- Competitors may develop personalized cancer immunotherapies, infectious disease products, or similar technologies that are not covered by our current or future patent claims.
- We, our co-owners, licensors, or future partners may not have been the first to invent or file patent applications for certain technologies.
- Pending patent applications may not result in issued patents, and issued patents may be challenged, invalidated, or rendered unenforceable.
- Competitors may independently develop similar or alternative technologies or replicate our technologies without infringing our patents.
- Competitors may conduct research in jurisdictions where we lack patent protection and use resulting data to launch competing products in key markets.
- We may fail to develop additional proprietary technologies that are patentable.
- Third-party patents could adversely affect our ability to develop or commercialize products.
- We may choose to maintain trade secrets rather than seek patent protection, which could allow third parties to patent similar intellectual property.

Any of these events could materially and adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Cybersecurity

We rely on information technology systems operated by us and, in the future, by our partners, vendors, contractors, and consultants. Any failure, interruption, or security breach of these systems could materially and adversely affect our business, financial condition, results of operations, and prospects. Security breaches, data loss, or other disruptions could compromise sensitive information, impede access to critical data, and expose us to liability.

Our internal systems and those of third parties are vulnerable to cybersecurity threats, unauthorized access, computer viruses, natural disasters, pandemics, terrorism, war, and failures of telecommunications or electrical infrastructure. A material system failure or breach could disrupt our operations, including development programs, and result in the loss or compromise of trade secrets, proprietary information, or critical data. For example, the loss of preclinical or clinical trial data could delay regulatory submissions and significantly increase costs to recover or reproduce such data. Because we operate multiple programs in parallel, a single breach could affect data integrity across numerous projects at different stages of development. In addition, any compromise of clinical trial participant personal data could subject us to civil fines and penalties under laws such as the EU General Data Protection Regulation (GDPR), U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), and other applicable privacy regulations.

Although we have not experienced any material system failures or security breaches to date, we cannot guarantee that unauthorized access or other incidents will not occur in the future. Any such event could harm our competitive position, delay development and commercialization of our product candidates, and materially and adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Government Regulation

Even if our future partners obtain regulatory approval for products derived from our product candidates, such products will remain subject to extensive and ongoing regulatory requirements. Failure to obtain or maintain regulatory approval, or to comply with these requirements, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Approved products are subject to continuing obligations regarding manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post-marketing studies, and submission of safety and efficacy data under U.S. federal and state laws and comparable foreign regulations. Holders of Biologics License Applications (BLAs) or New Drug Applications (NDAs), as well as manufacturing facilities, must comply with current Good Manufacturing Practice (cGMP) requirements and are subject to ongoing inspections by the FDA and foreign authorities. Compliance requires significant time, resources, and investment in manufacturing, quality control, and regulatory oversight.

Promotional activities are strictly regulated and must align with approved labeling; “off-label” promotion is prohibited. Changes to an approved product, its labeling, or manufacturing process generally require prior regulatory approval. Regulatory authorities may also mandate post-marketing studies to confirm safety and efficacy. Failure to complete such studies or negative outcomes could result in withdrawal of marketing approval.

If regulators identify previously unknown safety issues, manufacturing deficiencies, or improper marketing practices, they may impose restrictions or require product withdrawal. Noncompliance with regulatory requirements could result in:

- Warning letters;
- Civil or criminal penalties;
- Suspension or withdrawal of approvals;
- Clinical trial holds;
- Refusal to approve pending applications;
- Operational restrictions, including closure of manufacturing facilities; or
- Product seizures or recalls.

Government investigations of alleged violations could require significant resources and generate negative publicity. Any sanctions or loss of approval would adversely affect commercialization and revenue generation, and materially harm our business.

Regulatory policies may change, and new requirements may be introduced that delay or prevent approval of products derived from our candidates. We cannot predict future legislative or administrative actions in the United States, Europe, or other jurisdictions. If such actions limit regulatory operations, our business could be negatively impacted. Failure to adapt to evolving requirements or maintain compliance could result in loss of marketing approvals and prevent us from achieving or sustaining profitability.

We and our future partners may be subject, directly or indirectly, to extensive federal, state and foreign healthcare laws and regulations, including fraud and abuse laws, false claims statutes, and transparency requirements. Failure to comply with these laws could result in substantial civil or criminal penalties, exclusion from government programs, reputational harm, and other sanctions that could materially and adversely affect our business, financial condition, results of operations, and prospects.

If our future partners obtain FDA approval for products derived from our product candidates and commercialize them in the United States, our operations, directly or indirectly through prescribers, customers, and purchasers, will be subject to numerous laws, including:

- **Federal Anti-Kickback Statute**, which prohibits knowingly offering, paying, soliciting, or receiving remuneration to induce or reward referrals or purchases reimbursable under federal healthcare programs.
- **False Claims Act and related laws**, which prohibit knowingly presenting false or fraudulent claims for payment to government programs. Violations of the Anti-Kickback Statute and certain marketing practices, including off-label promotion, may implicate these laws.
- **HIPAA and HITECH**, which impose criminal and civil liability for healthcare fraud and establish privacy and security requirements for protected health information.
- **Federal Food, Drug, and Cosmetic Act and Public Health Service Act**, which govern drug and biologic approval, labeling, and marketing.
- **Physician Payments Sunshine Act**, which requires disclosure of payments and transfers of value to physicians and teaching hospitals.
- **State equivalents** of these laws, including marketing disclosure and privacy requirements, which vary significantly and complicate compliance.
- **Foreign Corrupt Practices Act**, which prohibits improper payments to foreign officials.
- **Similar laws in the EU and other jurisdictions**, including anti-bribery laws (e.g., U.K. Bribery Act) and transparency requirements for payments to healthcare professionals.

Violations of these laws may result in warning letters, fines, damages, imprisonment, exclusion from government programs, and restrictions on operations. In the EU, inducements to prescribe or purchase medicinal products are prohibited, and payments to physicians often require prior approval and public disclosure. Noncompliance may lead to reputational harm, administrative penalties, fines, or criminal sanctions.

Due to the complexity and breadth of these laws, and the limited scope of available safe harbors, certain business practices may be subject to challenge. Any failure to comply could materially and adversely affect our ability to operate, commercialize products, and achieve profitability.

We are subject to anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, “trade laws”) in the jurisdictions where we operate. Violations of these laws can result in severe civil and criminal penalties, including substantial fines, imprisonment, loss of trade privileges, debarment, tax reassessments, breach of contract claims, reputational harm, and other consequences that could materially and adversely affect our business, financial condition, results of operations, and prospects.

Trade laws generally prohibit companies and their employees, agents, and third-party partners, including CROs, CDMOs, consultants, contractors, and legal counsel, from authorizing, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything of value to or from public or private sector recipients. We have direct and indirect interactions with government officials and employees of government-affiliated hospitals, universities, and other organizations. We also plan to engage third parties to conduct clinical trials and obtain permits, licenses, intellectual property rights, and regulatory approvals. We could be held liable for the illegal or corrupt activities of our personnel, agents, or partners, even if we did not authorize or have prior knowledge of such conduct.

Any failure to comply with applicable trade laws could result in significant penalties and restrictions, materially harming our ability to operate and achieve our business objectives.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.

We process significant volumes of sensitive personal information, including employee, patient, and genetic data, and are subject to extensive and evolving privacy, data protection, and information security laws in the jurisdictions where we operate. These include the European Union General Data Protection Regulation (GDPR), U.S. federal and state privacy laws, and similar regulations globally. These laws govern the collection, use, storage, transfer, and other processing of personal data and impose strict requirements on controllers and processors, including special protections for health and genetic information and limitations on cross-border transfers. Legal requirements relating to data processing continue to evolve and may result in increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with these requirements may increase our operational costs, require changes to business practices, and impose contractual obligations that restrict our ability to collect, use, and disclose data. In some cases, compliance challenges could limit our ability to operate in certain jurisdictions. Enforcement practices remain uncertain, particularly regarding clinical trials and cross-border transfers following the Schrems II ruling, and may require additional assessments and safeguards. Failure to comply with applicable laws could result in significant administrative fines, civil or criminal penalties, private litigation, and reputational harm. Even allegations of non-compliance could be costly and disruptive.

Despite our security measures, our systems and those of our vendors may be vulnerable to cyberattacks, human error, or other incidents that could lead to unauthorized access, loss, or disclosure of personal data. Such events could interrupt critical operations, including clinical research, test result delivery, claims processing, and financial reporting, and expose us to liability under privacy and security laws, contractual obligations, and regulatory enforcement actions. We cannot guarantee that our policies and controls will fully comply with all applicable requirements as they evolve. Any failure or perceived failure to comply could materially adversely affect our business, financial condition, results of operations, and prospects.

If we, our future partners, if any, or our third-party suppliers fail to comply with environmental, health and safety and regulations, we could become subject to fines or penalties or incur costs that could materially harm our business, financial condition, results of operations, and prospects.

We and our future partners, if any, will become subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste. Although we expect to engage qualified third parties for waste disposal, we cannot eliminate the risk of contamination, injury, or accidental release. Any such event could result in liability for damages that may exceed our resources, as well as civil or criminal fines and penalties.

Compliance with current and future environmental, health, and safety requirements may require substantial expenditures and could impair research, development, or production activities. Failure to comply could result in significant fines, penalties, or other sanctions. While we maintain workers' compensation insurance for employee injuries, coverage may be inadequate for all potential liabilities. Any of these outcomes could materially adversely affect our business, financial condition, results of operations, and prospects.

Our business operations and relationships are subject to healthcare laws, and non-compliance could result in significant penalties.

We are subject to extensive healthcare laws and regulations, including those governing fraud and abuse, transparency, and other compliance obligations. These laws apply to our operations and to current and future arrangements with investigators, healthcare professionals, consultants, third-party payers, patient organizations, and customers. They may restrict how we structure business and financial relationships and how we research, market, sell, and distribute any approved products.

Ensuring compliance with these requirements will involve substantial costs. Government authorities may determine that our practices violate applicable statutes, regulations, or guidance. If we or any of our business partners fail to comply, we could face civil, criminal, or administrative sanctions, including fines, penalties, exclusion from government healthcare programs, and reputational harm. Defending against such actions can be costly and time-consuming, even if successful, and could divert significant resources. Any of these outcomes could materially adversely affect our business, financial condition, results of operations, and prospects.

General Risks Related to Our Business

Our ability to attract and retain key personnel is critical to our success.

Our future success depends on our ability to recruit, retain, and motivate highly qualified executive, scientific, and technical personnel, including experts in immuno-oncology, infectious diseases, and artificial intelligence. We are highly dependent on the continued service of our management and scientific teams, and the loss of any key individual could adversely affect our research, development, financing, and commercialization objectives. We do not maintain "key person" insurance on any employee.

We also rely on consultants, contractors, and advisors, who may have competing commitments that limit their availability. Failure to retain these individuals could delay our operations. Recruiting additional qualified personnel is critical and increasingly challenging due to intense competition among biotechnology and pharmaceutical companies and academic institutions. Adverse developments, such as negative publicity or setbacks in clinical trials, could further hinder our ability to attract talent. If we cannot retain or recruit key employees, consultants, or advisors, our business, financial condition, results of operations, and prospects could be materially adversely affected.

Product liability claims could result in significant costs and adversely affect commercialization of our current or future product candidates.

We face inherent product liability risks related to the clinical testing of our current and future product candidates and may face greater exposure if any products are commercialized. If we cannot successfully defend against claims that our product candidates caused injury, we could incur substantial liabilities. Even if claims lack merit, litigation could result in:

- decreased demand for our products;
- loss of revenue;
- significant monetary awards to patients or trial participants;
- high defense costs and diversion of resources;
- withdrawal of clinical trial participants; and
- reputational harm and negative publicity.

We maintain clinical trial and product liability insurance that we believe is adequate for our current programs; however, coverage may be insufficient or unavailable on commercially reasonable terms as our business expands. Large judgments have been awarded in similar cases involving drugs or medical treatments with unanticipated adverse effects. A successful product liability claim, or a series of claims, could materially adversely affect our business, financial condition, results of operations, and prospects.

Product recalls could harm our business and reputation.

Regulatory authorities, including the FDA, EMA, and similar agencies, have the authority to require the recall of commercialized products under certain circumstances, such as when a product presents an imminent or substantial hazard to public health. We or our manufacturers may also voluntarily initiate recalls due to manufacturing errors, design or labeling defects, or other deficiencies. For products developed using our AI-Immunology™ platform, a recall could delay or prevent commercialization of other products derived from the same technology until we demonstrate that the issue did not involve our platform.

Any recall, whether government-mandated or voluntary, would divert significant managerial and financial resources, harm our reputation, and negatively affect sales, if any. Recalls could materially adversely affect our business, financial condition, results of operations, and prospects.

Future acquisitions, joint ventures, partnerships or collaborations could involve significant risks and costs.

We may pursue acquisitions, joint ventures, partnerships, or collaborations to obtain complementary products, technologies, or businesses. These transactions could increase our operating expenses and cash requirements, require us to assume debt or contingent liabilities, or result in the issuance of dilutive securities. They may also involve risks such as:

- difficulties integrating operations, personnel, and intellectual property;
- diversion of management attention from existing programs;
- challenges retaining key employees and maintaining business relationships;
- uncertainties regarding the other party's prospects, products, or regulatory status; and
- inability to realize anticipated benefits or generate sufficient revenue to offset costs.

Acquisitions may also result in significant one-time expenses, amortization of intangible assets, and increased complexity in our operations. We may not identify suitable opportunities, and failure to do so could limit our ability to grow or access critical technologies. Any of these outcomes could materially adversely affect our business, financial condition, results of operations, and prospects.

Global climate change and ESG requirements could adversely affect our business.

Increasing stakeholder expectations regarding environmental, social and governance (ESG) matters, as well as physical and transition risks associated with climate change, may impact our market outlook, reputation, cost of capital, supply chain, and operational continuity.

Emerging ESG regulations and policy requirements could impose additional compliance obligations on us, our partners, and third parties on which we rely, potentially increasing costs and restricting operations. Physical effects of climate change, such as extreme weather events, may disrupt facilities and supply chains and drive higher operating expenses. Any of these factors could materially adversely affect our ability to achieve our business objectives and our financial condition, results of operations, and prospects.

Natural disasters or catastrophic events could disrupt our operations.

Our business and those of our partners and critical third-party providers are vulnerable to earthquakes, fires, extreme weather, terrorism, and other unforeseen events. If such events damage or render facilities unusable, we could face prolonged operational disruptions. We currently lack a comprehensive disaster recovery and business continuity plan, and some key suppliers operate from single locations, increasing their exposure to catastrophic events. Any significant disruption to our supply chain or facilities could delay clinical trials, impair development plans, and materially adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Ownership of ADSs

The market price of our ADSs has fluctuated significantly since our IPO in February 2021 and may continue to be highly volatile. Broad market and industry factors, particularly in the biopharmaceutical sector, often cause stock price volatility unrelated to a company's performance. As a result, ADS holders may be unable to resell their shares at or above the purchase price. Factors that may influence the price of our ADSs include:

- results of our preclinical studies and clinical trials or those of competitors;
- success or failure of competing products or technologies;
- announcements of acquisitions, partnerships, or collaborations;
- regulatory or legal developments in key markets;
- developments concerning intellectual property rights;
- recruitment or departure of key personnel;
- issuances or sales of our shares or ADSs by us or our shareholders;
- changes in financial estimates or analyst recommendations;
- variations in our financial results or those of comparable companies;
- expectations of additional financing;
- currency fluctuations and healthcare policy changes;
- general economic, industry, and geopolitical conditions, including conflicts in Ukraine and the Middle East; and
- developments in our pipeline programs.

If our operating results fall below investor or analyst expectations, the ADS price could decline substantially. Volatility in our ADSs may also lead to securities class action litigation, which could result in significant costs and divert management's attention. Any of these factors could materially adversely affect our business, financial condition, results of operations, and prospects.

An active and liquid market for the ADSs and our ordinary shares may not be sustained, which could harm the market price of the ADSs.

Although the ADSs are listed on the Nasdaq Capital Market, an active trading market for the ADSs may not be sustained. In the absence of an active trading market for the ADSs, investors may not be able to sell their ADSs at the desired price or at the time that they would like to sell. In addition, the market price of the ADSs in our follow-on offering was based on the closing price of the ADSs at the time of such follow-on offering, there is no guarantee that such price will be free from challenge by our existing shareholders based on allegations that it does not reflect the "market price" at which we are required by our articles of association and Danish law to sell our ordinary shares. Any such challenge could be time-consuming and costly and, if decided in a manner unfavorable to us, could result in liability to us and our directors, and could prevent any such offering from closing.

We incur significant costs as a public company, and face risks related to compliance with reporting and governance requirements.

As a public company, we are subject to extensive legal, accounting, and regulatory requirements, including those under U.S. federal securities laws, the Sarbanes-Oxley Act, SEC rules, and Nasdaq listing standards. Compliance has increased our costs and requires substantial management time and resources. These obligations include filing periodic reports, maintaining effective disclosure controls and internal control over financial reporting, and implementing corporate governance practices. We may not be able to produce timely and accurate financial statements or maintain compliance with Nasdaq listing requirements, and errors could require restatements.

Section 404 of the Sarbanes-Oxley Act requires us to assess the effectiveness of our internal control over financial reporting and, eventually, obtain auditor attestation. Achieving and maintaining compliance is costly and challenging and may require significant internal resources and external consultants. If we fail to comply or if our auditors cannot attest to the effectiveness of our controls, investor confidence in our financial reporting could decline, adversely affecting our share price.

We also face increased costs for director and officer liability insurance and may incur additional expenses as new regulations, including those under the Dodd-Frank Act, take effect. Shareholder activism and evolving governance standards could further increase compliance burdens. Any failure to meet these obligations could result in sanctions, penalties, or reputational harm and materially adversely affect our business, financial condition, results of operations, and prospects.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares and the ADSs less attractive to investors.

We are an “emerging growth company” under the JOBS Act, and we will remain an emerging growth company until the earliest of:

- the last day of the fiscal year in which our annual gross revenues exceed \$1.235 billion;
- the date we issue more than \$1 billion in nonconvertible debt over a three-year period;
- the date we become a large accelerated filer with a public float of at least \$700 million; or
- December 31, 2026, the fiscal year following the fifth anniversary of our IPO.

As an emerging growth company, we rely on exemptions from certain disclosure and governance requirements applicable to other public companies, including:

- no auditor attestation of internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced executive compensation disclosures;
- no mandatory advisory votes on executive compensation or golden parachute arrangements; and
- exemptions from certain PCAOB requirements.

We have taken advantage of these reduced reporting obligations and may continue to do so. Investors may find our ADSs less attractive as a result, which could reduce trading liquidity and increase volatility.

The JOBS Act also permits emerging growth companies to delay adoption of new or revised accounting standards under U.S. GAAP; however, because we report under IFRS, this provision does not apply.

Any perception that our reduced disclosures limit transparency could adversely affect the market for our ADSs and our ability to raise capital.

As a foreign private issuer, we are exempt from certain U.S. securities and Nasdaq requirements, which may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.

We qualify as a foreign private issuer under U.S. securities laws. As a result, we are permitted to follow Danish corporate governance practices instead of certain Nasdaq Listing Rules applicable to U.S. domestic issuers. For example, Nasdaq rules generally require a majority of independent directors and independent oversight of executive compensation, nominations, and governance matters. Danish law does not impose these requirements, and our board may in the future include fewer independent directors or choose not to maintain committees consistent with Nasdaq standards. We also follow home country practices regarding quorum requirements and shareholder approval for certain dilutive transactions, which may provide less protection than U.S. rules.

In addition, Danish law does not regulate proxy solicitation, and such practices are uncommon in Denmark, which differs from Nasdaq requirements. As a foreign private issuer, we are also exempt from certain U.S. proxy rules and may provide less information in our SEC filings than U.S. domestic issuers. These differences may limit the information and protections available to ADS holders and could make our ADSs less attractive to investors, potentially reducing liquidity and increasing volatility.

Failure to meet Nasdaq’s continued listing requirements could result in a delisting of our ADSs.

Our ADSs are listed on the Nasdaq Capital Market, and we must meet Nasdaq’s continued listing requirements, including minimum bid price, equity thresholds, and corporate governance standards. Failure to comply could result in delisting, which would likely reduce the liquidity and market price of our ADSs and impair investors’ ability to trade them. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not i) allow our ADSs to become listed again, (ii) stabilize the market price or iii) improve the liquidity of our ADSs, iv) prevent our ADSs from dropping below the Nasdaq minimum bid price requirement or v) prevent future non-compliance with the listing requirements of Nasdaq.

May 7, 2024, the Nasdaq notified us that the Company did not comply with Nasdaq Listing Rule 5550(b)(1) requiring a minimum equity of \$2.5 million.

November 11, 2024, we received a letter with a delisting determination from Nasdaq Stock Market, which the Company immediately appealed. February 14, 2025, Nasdaq confirmed that we had regained compliance after restoring equity above the minimum requirement through capital market activities.

We remain listed as fully compliant; however, any future failure to satisfy Nasdaq's requirements could result in delisting and materially adversely affect our business, financial condition, results of operations, and prospects.

As a foreign private issuer, we are exempt from certain U.S. securities rules and provide less frequent reporting.

We qualify as a foreign private issuer under the Exchange Act and, as such, are exempt from certain U.S. securities law requirements applicable to domestic issuers. These exemptions include:

- U.S. proxy solicitation rules;
- insider reporting (until March 2026) and short-swing profit liability under Section 16 of the Exchange Act; and
- requirements to file quarterly reports on Form 10-Q and current reports on Form 8-K.

Instead, we file annual reports on Form 20-F within four months after fiscal year-end, compared to 60–90 days for U.S. domestic issuers. We are also exempt from Regulation FD, which prohibits selective disclosure of material information.

As a result, holders of our ADSs may receive less information and fewer protections than shareholders of U.S. domestic companies, which could make our ADSs less attractive and reduce market liquidity.

Our status as a foreign private issuer allows us to adopt IFRS accounting principles, which are different than accounting principles under U.S. GAAP.

As a foreign private issuer, we prepare our financial statements in accordance with International Financial Reporting Standards (IFRS) as issued by the IASB, rather than U.S. GAAP. SEC rules do not require us to provide a reconciliation between IFRS and U.S. GAAP. IFRS differs in significant respects from U.S. GAAP, and investors who are not familiar with IFRS may misinterpret our financial information. This could affect the comparability of our financial statements to those of U.S. companies and may make our ADSs less attractive to some investors.

Loss of foreign private issuer status would increase our regulatory burden and cost.

We currently qualify as a foreign private issuer under U.S. securities laws, which exempts us from certain Exchange Act reporting and governance requirements applicable to U.S. domestic issuers. This status is reassessed annually as of the end of our second fiscal quarter. To maintain it, either (a) a majority of our shares must be held by non-U.S. residents, or (b) we must meet tests relating to management nationality, asset location, and business administration outside the United States. The SEC is currently considering revising the foreign private issuer test to make it even more stringent.

If we lose this status, beginning January 1 of the following year we would be subject to the more extensive reporting and governance requirements for U.S. domestic issuers, including accelerated filing deadlines, quarterly reports on Form 10-Q, current reports on Form 8-K, and additional proxy and insider reporting obligations. Compliance would significantly increase our legal, accounting, and administrative costs, make certain activities more time-consuming, and likely raise the cost of director and officer liability insurance. These changes could also make it more difficult to attract and retain qualified directors. Any of these outcomes could materially adversely affect our business, financial condition, results of operations, and prospects.

Holders of the ADSs may be subject to certain limitations on the transfer of the ADSs and the withdrawal of the underlying ordinary shares.

Our ADSs, which may be evidenced by American Depositary Receipts (ADRs), are transferable on the depositary's books; however, the depositary may close its transfer books at any time when deemed necessary to perform its duties. The depositary may refuse to deliver, transfer, or register ADSs when our books or its own are closed, or if required by law, regulation, or the deposit agreement.

Temporary delays in canceling ADSs and withdrawing underlying ordinary shares may occur, including when transfer books are closed for voting or dividend payments, or when fees, taxes, or charges remain unpaid. Withdrawals may also be restricted to comply with applicable laws or regulations. These limitations could affect holders' ability to transfer ADSs or access underlying shares when desired.

A significant portion of our total outstanding ordinary shares may be sold in the near future. The large number of shares eligible for sale or subject to rights requiring us to register them for sale could cause the market price of the ADSs to drop significantly, even if our business is performing well.

Sales of a substantial number of ordinary shares or the ADSs could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of the ADSs. We had 417,010,756 ordinary shares outstanding, corresponding to 8,340,215 ADSs outstanding if fully converted, as of December 31, 2025. To date, not all of the holders of outstanding ordinary shares have converted their ordinary shares to ADSs.

As of December 31, 2025, there were 141,860,674 warrants outstanding. If these warrants are exercised then an additional 141,860,674 ordinary shares, which are convertible into 2,837,213 ADSs, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ADSs could decline. Any sales of securities by these security holders could have a negative effect on the trading price of our ordinary shares and ADSs.

Additionally, on October 3, 2022, we entered into a Capital on Demand™ Sales Agreement, or the Sales Agreement, with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we may sell from time to time, at our option, ADSs representing ordinary shares through or to JonesTrading, as sales agent or principal. The ADSs are offered pursuant to a prospectus supplement, dated March 26, 2025, which was filed with the SEC on such date and our Form F-3 (Registration No. 333-285778), and a prospectus supplement, dated December 10, 2025, or the Prospectus Supplement. The prospectus supplement (this “Prospectus Supplement”) amends and supplements the information in the prospectus dated March 24, 2025 (the “Prior Prospectus”), filed with the Securities and Exchange Commission (the “SEC”) as part of our registration statement on Form F-3 (File No. 333-285778) (the “Registration Statement”), as previously supplemented by our prospectus supplement dated March 26, 2025 (together with the Prior Prospectus, the “Prospectus”).

Pursuant to the Prospectus Supplement, we may offer and sell the ADSs pursuant to the Prospectus Supplement having an aggregate offering price of up to \$45,527,824 of ADSs. Sales of the ADSs made pursuant to the Sales Agreement, are made by any method deemed to be an “at the market offering”, or ATM, as defined in Rule 415(a)(4) promulgated under the Securities Act. JonesTrading is not required to sell any specific number or dollar amount of ADSs but has agreed to use its commercially reasonable efforts to sell the ADSs from time to time, based upon our instructions, including any price, time or size limits or other customary parameters or conditions we may impose.

As the date of the Prospectus Supplement filing, the aggregate market value of our ordinary shares represented by ADSs held by non-affiliates (our “public float”), calculated in accordance with General Instruction I.B.5 of Form F-3 under the Securities Act of 1933, as amended, was approximately \$75.9 million, which was calculated based on 344,711,416 ordinary shares (which would be represented by 6,894,228 ADSs) outstanding and held by non-affiliates as of November 4, 2025, at a price of \$11.01 per ADS as of October 15, 2025, which was the highest closing price of the ADSs on The Nasdaq Capital Market within 60 days of the filing of this Prospectus Supplement.

The Prospectus Supplement was filed to amend the Prospectus to update our public float, and indicate that, because our public float was above \$75.0 million, we are no longer subject to the sales limitations of General Instruction I.B.5 of Form F-3 with respect to the Registration Statement of which the Prospectus, as amended by the Prospectus Supplement, forms a part.

Since the filing of the Registration Statement, we have sold \$4,472,175.80 of ADSs pursuant to the Sales Agreement. Accordingly, because we are no longer subject to the sales limitations of General Instruction I.B.5, we may offer and sell up to an additional \$45.52 million of ADSs pursuant to the Sales Agreement.

In addition, on July 31, 2023, we entered into a financing agreement with Global Growth Holding Limited (“GGH”), for the issuance of convertible notes into our ordinary shares represented by ADSs, DKK 0.25 nominal value, with each ordinary share represented by one ADSs. Pursuant to the agreement, we may elect to sell to GGH up to \$20.0 million in such notes on any business day over the 36 month term of the agreement. We have under certain circumstances the right, but not the obligation, to direct GGH to purchase tranches of up to \$0.7 million, subject to certain limitations and conditions set forth in the agreement. In connection with the agreement, we are obligated to pay GGH a commitment fee totaling \$1.1 million. At any time, GGH may, in its sole discretion, convert the notes into ordinary shares at specified conversion prices upon submission of a request for conversion by GGH to us. The financing agreement between us and GGH is subject to approval by the SEC through the date of this prospectus.

Sales of ADSs or our ordinary shares as restrictions end or pursuant to the above-described agreements or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult for holders of ADSs to sell the ADSs.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our securities.

Regulation Best Interest, adopted by the SEC, and FINRA's suitability requirements impose heightened standards on broker-dealers when recommending securities to retail and institutional customers. These rules require that recommendations be in the customer's best interest and based on a review of financial status, investment objectives, and other factors.

Because our ADSs may be considered speculative or low-priced, broker-dealers may be less willing to recommend them or make a market in our securities. This could reduce trading activity, limit liquidity, and adversely affect the market price of our ADSs.

Holders of the ADSs have limited voting rights compared to shareholders, which may affect the value of the ADSs.

Holders of ADSs are not treated as our shareholders unless they withdraw the underlying ordinary shares from the depository. As a result, ADS holders cannot directly vote ordinary shares and have only the rights provided under the deposit agreement. ADS holders may instruct the depository to vote the underlying shares, but we are not required to request the depository to solicit voting instructions. Even when instructions are solicited, ADS holders may not receive meeting information in time, and the depository is not obligated to act on unsolicited instructions. Consequently, ADS holders may not be able to exercise voting rights as effectively as if they held ordinary shares directly, which could affect the value of the ADSs.

Future issuance of ordinary shares or ADSs could cause dilution and depress the ADS price.

We may issue additional ordinary shares or ADSs in future financings or other transactions, potentially at prices below the current market price. Any such issuance would dilute existing shareholders and ADS holders and could adversely affect the market price of our ADSs. In addition, we may issue debt securities or equity instruments convertible into ordinary shares or ADSs, which could result in further dilution and downward pressure on the ADS price.

Raising additional capital may cause dilution, restrict operations, or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through public or private equity offerings, debt financings, collaborations, or licensing arrangements. Issuing equity or ADSs would dilute existing shareholders and could involve terms that adversely affect holders of ADSs. Incurring debt could increase fixed obligations and impose restrictive covenants limiting our ability to incur additional debt, acquire or license intellectual property, or operate freely.

If we raise funds through collaborations, licensing, or asset sales, we may be required to relinquish valuable rights to our technologies or product candidates or grant licenses on unfavorable terms. Any of these actions could materially adversely affect our business, financial condition, results of operations, and prospects.

Shareholder rights under Danish law differ from U.S. law and may provide less protection.

The rights of our shareholders under Danish corporate law and our articles of association differ in important respects from those typically available to shareholders of U.S. companies. For example:

- Danish law generally does not permit shareholders to inspect corporate records except in limited circumstances requiring support from at least 25% of voting shareholders, whereas Delaware law grants inspection rights to any shareholder.
- Shareholders of Danish companies generally cannot initiate derivative actions to enforce company rights, except in limited cases of director or management liability.
- A majority of shareholders may release directors or managers from liability, even for acts of negligence or bad faith, subject to certain exceptions.
- Danish law does not provide appraisal rights equivalent to those under U.S. law in connection with business combinations.
- Dividend distributions to foreign shareholders may be subject to non-refundable withholding tax, and Danish insolvency law may offer weaker creditor protections than U.S. law.
- Use of tax assets, such as accumulated tax losses, depends on generating taxable income and may be restricted by future changes in Danish tax law.

As a result of these differences, holders of ADSs may have fewer protections than shareholders of U.S. companies, which could affect the value of our ADSs.

Holders of our ordinary shares or ADSs may not be able to exercise pre-emptive rights and could be diluted.

Under the Danish Companies Act, our shareholders benefit from a pre-emptive subscription right on the issuance of ordinary shares for cash consideration only and not in the event of issuance of shares against non-cash contribution or debt conversion. Even the shareholders' pre-emptive subscription rights in the event of issuances of shares against cash payment may be disappplied by a resolution of the shareholders at a general meeting of our shareholders and/or the shares or ADSs may be issued on the basis of an authorization granted to the board of directors pursuant to which the board may disapply the shareholders' pre-emptive subscription rights. Such shares or ADSs may be issued above or at market value. In addition, a shareholder may not be able to exercise the shareholder's pre-emptive right on a timely basis or at all, unless the shareholder complies with the Danish Companies Act and applicable laws in the jurisdiction in which the shareholder is resident. Furthermore, the use of pre-emptive subscription rights in relation to future capital increases in our company can be restricted for United States residents according to United States securities law. As a result, the ownership interest of shareholders or ADS holders may be materially diluted in the event shares or ADSs are issued in the future. Shares or ADSs may be issued at a discount to market price in rights offerings provided that the resolution is approved by two-thirds of the votes cast and the share capital represented at the general meeting and in these cases a restriction on the ability to exercise pre-emptive rights may materially dilute the value of the ordinary shares or ADSs held by the shareholder or ADS holder in question.

Our shareholders have authorized our board of directors to issue securities, including in connection with (i) issues of new ordinary shares with preemptive rights for our existing shareholders at market price or at a discount price against cash payment, (ii) issues of new ordinary shares without preemptive rights for our existing shareholders at market price or at a discount price against cash payment, (iii) issues of warrants without preemptive rights for our existing shareholders at market price or at a discount price against cash payment, and (iv) issues of convertible loan notes without preemptive rights for our existing shareholders at market price against cash payment. The absence of pre-emptive rights for existing shareholders may cause dilution to such holders.

However, holders of the ADSs in the United States will not be entitled to exercise or sell pre-emptive subscription rights related to their ordinary shares, unless we register the pre-emptive subscription rights and the securities to which the pre-emptive subscription rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depository will not make rights available to ADS holders unless both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act.

Holders of ADSs may not receive distributions and could experience dilution.

If we offer our ordinary shareholders the option to receive dividends in cash or shares, the depository may require assurances that extending such an option to ADS holders does not trigger registration under the U.S. Securities Act. We are not obligated to file a registration statement or seek an exemption, and we may be unable to do so. As a result, ADS holders may be excluded from rights offerings or share-based dividend elections, which could dilute their ownership.

If rights are distributed to the depository and cannot be lawfully or practically sold, the depository may allow them to lapse, and ADS holders would receive no value for those rights.

United States holders of ADSs may face adverse tax consequences if we are classified as a passive foreign investment company (PFIC).

We may be treated as a PFIC for U.S. federal income tax purposes for any taxable year if (i) 75% or more of our gross income is passive income or (ii) 50% or more of the average value of our assets produce or are held to produce passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, certain gains from property sales, and foreign currency gains. For this determination, we are deemed to own our proportionate share of the assets and income of any entity in which we hold, directly or indirectly, more than 25% of the stock by value.

Our PFIC status is subject to complex factual and legal determinations, including interpretations of U.S. tax rules, and can only be assessed annually after the close of each taxable year. We have not determined whether we will be a PFIC for the current taxable year or any prior or future taxable year, and we have not sought, and will not seek, an IRS ruling or legal opinion on this matter. There is no assurance that we will not be classified as a PFIC.

If we are a PFIC for any year during which a U.S. holder owns ADSs, such holder may incur significant adverse U.S. federal income tax consequences. U.S. holders should consult their own tax advisors regarding our PFIC status and the related tax implications. See "Taxation—Certain Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

The Danish tax treatment of ADSs by the Danish tax authorities is uncertain.

The specific treatment of ADSs under Danish tax law is highly uncertain and not codified in law. The interpretation by the Danish tax authorities may have adverse effects on the taxation of investors. In the tax description contained herein we are assuming that the ADSs are to be treated as listed shares for Danish tax purposes. This is based on recent communications and tax rulings relating to similar structures from the Danish tax authorities which indicate that a holder of ADSs will be treated as holding listed shares in the company for Danish tax purposes. In the event that the holders of ADSs are not treated as holding listed shares in the company, it is likely that they will be treated as either holding unlisted shares or financial instruments for Danish tax purposes, which will impact the Danish tax treatment of the ADS holders, including in respect of the taxation of dividends paid to ADS holders. Furthermore, the communications and tax rulings from the Danish tax authorities indicate that the voting and economic rights attached to the underlying shares have been effectively transferred to the ADS holders and that they will therefore be considered as holding listed shares. In the event that the Danish tax authorities should rule differently with respect to the Company and the depository agreement with Bank of New York Mellon and not treat the ADS holders as holders of shares in the Danish company, then the depository bank may be considered the holder of the ordinary shares in the company for Danish tax purposes.

Claims of United States civil liabilities may not be enforceable against us.

We are incorporated under the laws of Denmark, and most of our assets and personnel are located outside the United States. As a result, it may be difficult for investors to serve process on us or our directors and officers within the United States or to enforce U.S. court judgments against them or us, including those based on U.S. securities laws.

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon United States securities laws, would not automatically be recognized or enforceable in Denmark. In order to obtain a judgment which is enforceable in Denmark, the party in whose favor a final and conclusive judgment of the United States court has been rendered will be required to file its claim with a court of competent jurisdiction in Denmark. Such party may submit to the Danish court the final judgment rendered by the United States court. If and to the extent that the Danish court finds that the jurisdiction of the United States court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the Danish court should, in principle, give binding effect to the judgment of the United States court, unless such judgment contravenes principles of public policy of Denmark. Danish courts are likely to deny the recognition and enforcement of punitive damages or other awards. Moreover, a Danish court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of United States courts in Denmark are solely governed by the provisions of the Danish Administration of Justice Act.

Based on these limitations, U.S. investors may not be able to enforce judgments obtained in U.S. courts against us or our directors, officers, or certain experts residing outside the United States.

Failure to meet our guidance or market expectations could adversely affect the market price of our ADSs.

From time to time, we may provide guidance regarding our expected financial or operational performance. Forecasting future results involves significant uncertainty, and our actual performance may differ materially from such guidance or market expectations. If our results fall short of guidance or investor expectations, the market price of our ADSs could decline significantly.

If securities or industry analysts do not publish research or reports about our business or if they publish negative evaluations of the ADSs, the market price of the ADSs and their trading volume could decline.

The trading market for our ADSs depends, in part, on research and reports published by securities and industry analysts. If analysts do not initiate or maintain coverage of our company, or if they downgrade our ADSs, issue negative or misleading reports, or if our results fail to meet their expectations, the market price and trading volume of our ADSs could decline. Loss of analyst coverage could also reduce our visibility in the market, further negatively impacting the ADSs' liquidity and price.

Our principal shareholders and executive management hold significant ownership and may exert substantial influence over shareholder decisions.

As of January 1, 2026, our executive management, directors, holders of 5% or more of our ordinary shares, and their affiliates beneficially owned approximately 20% of our outstanding voting securities. These shareholders can, individually or collectively, significantly influence matters requiring shareholder approval, including the election or removal of directors, amendments to our articles of association, changes to share capital, and approval of mergers, demergers, liquidations, or similar transactions.

This concentration of ownership may discourage or prevent unsolicited acquisition proposals or other transactions that ADS holders may consider favorable. It may also enable these shareholders to influence our management and strategic direction. Such control could affect the market price of our ADSs and limit opportunities for transactions that might otherwise benefit ADS holders.

We have broad discretion in the use of our funds and may not apply them effectively.

Our management has broad discretion in the use of our cash, cash equivalents, and investments, including proceeds from our IPO, follow-on offerings, and sales under our ATM program. We may allocate these funds in ways that do not improve our operating results or enhance the value of our ordinary shares or ADSs. Ineffective use of funds could result in financial losses, delay the development of our product candidates, and materially harm our business, financial condition, and prospects.

Pending their use, we may invest our cash and investments in ways that do not generate income or that result in a loss of value, which could further adversely affect our results.

We may not have sufficient funds to satisfy our obligations to the European Investment Bank upon the exercise of certain warrants.

In August 2020, we executed a loan agreement with the European Investment Bank (EIB), for a principal amount of €20.0 million, divided into three tranches of tranche 1 in the amount of €7.0 million, tranche 2 in the amount of €6.0 million and tranche 3 in the amount of €7.0 million (EIB Loan). Under the EIB Loan Agreement, the EIB Loan tranche balances are due six years from their respective disbursement dates. In connection with disbursement of each tranche, EIB is entitled to receive certain warrants (EIB Warrants).

In November 2020, we initiated the process to receive the funds from the disbursement of tranche 1 of the EIB Loan in the aggregate amount of €7.0 million but due to the timing of the IPO we did not finalize a disbursement offer. In connection therewith, EIB received 351,036 EIB Warrants, which vested immediately, pursuant to the terms of a separate warrant agreement, or the EIB Warrant Agreement. As of December 31, 2021, we initiated the drawdown of the first tranche of the EIB Loan Agreement amounting to €7.0 million. We received the first tranche of €7.0 million on February 17, 2022. The remaining two tranches have become void as of December 31, 2023.

In July 2025, we reached an agreement with EIB, where EIB converted €3.5 million of its €7 million loan to Evaxion into equity via a purchase of ordinary Evaxion warrants. The agreement immediately increased our equity and reduced our EIB Loan by \$4.1 million (€3.5 million).

Under Article 18, Paragraph 2 of the Statute of the European Investment Bank (EIB Statute), establishing EIB, a direct equity investment by EIB requires a separate authorization from the EIB Board of Governors pursuant to which the EIB Board of Directors, acting by qualified majority, has to establish the terms and conditions of such direct equity investment. Under the EIB Statute, in the absence of a separate authorization from the EIB Board of Governors, commercial shareholdings financed from EIB's own resources are not allowed. Since the EIB Loan is being made from EIB's own resources, the EIB Statute does not allow EIB to acquire any of our ordinary shares, therefore, we fully expect that if and when EIB exercises the EIB Warrants, it will do so on either a net cash settlement basis at a price equal to the market price on the date of exercise thereof, or by means of exercising its right to cause us to purchase the EIB Warrants at a purchase price equal to the volume weighted average price per ordinary share, or VWAP, for a period of six months following the exercise of such Put Right. Since we fully expect the EIB Warrants to be cash settled, we do not expect them to affect our share capital at any time. However, since the amount of cash that we will need in order to meet our obligations to pay the amounts due and payable to EIB upon the exercise of the EIB Warrants is based on valuations to be determined in the future and, therefore, cannot be determined as of the date of this Form 20-F, we may not have sufficient funds on hand to pay such amounts in which case we may be required to use a portion of our investments for such payments. For a more detailed discussion of the terms of the EIB Warrants see the section herein entitled "Description of Share Capital - Our EIB Warrants."

Because we do not currently pay cash dividends, investors must rely on capital appreciation for any return on their investment.

Currently, we do not have any plans to declare or pay cash dividends on our ordinary shares. Our intention is to retain all future earnings, if any, to finance the growth and development of the business. Additionally, the terms of any future debt agreements may preclude dividend payments. As a result, capital appreciation, if any, on the ADSs will be the sole source of gain for the foreseeable future.

ADSs holders may face limitations or delays in surrendering ADSs and withdrawing underlying shares.

Temporary delays in the cancellation of the ADSs and withdrawal of the underlying shares may arise because the depository has closed its books or we have closed our transfer books, the transfer of shares is blocked to permit voting at a shareholders' meeting, or we are paying a dividend on our shares. In addition, you may not be able to cancel the ADSs and withdraw the underlying shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities. See "Description of American Depositary Shares."

We could be subject to securities class action litigation, which could result in significant costs and divert management's attention.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement or relating to our ordinary shares or the ADSs, which could result in less favorable outcomes to the plaintiffs in an action of that kind.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depository arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under United States federal securities laws.

If we or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that holders of ADSs consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other ADS holders bring a claim against us or the depository in connection with matters arising under the deposit agreement or relating to the ADSs, including claims under federal securities laws, you may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depository. If a lawsuit is brought against us or the depository under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in that action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial.

No condition, stipulation or provision of the deposit agreement or the ADSs serves as a waiver by any ADS holder or by us or the depository of compliance with any substantive provision of the United States federal securities laws and the rules and regulations promulgated thereunder.

We face risks and uncertainties related to litigation, regulatory actions and government investigations and inquiries.

We are subject to, and may become a party to, litigation, claims, suits, regulatory actions and government investigations and inquiries.

The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Negative perceptions of our business may result in additional regulation, enforcement actions by the government and increased litigation, or harm to our ability to attract or retain customers or strategic partners, any of which may affect our business. Any damage to our reputation, including from publicity from legal proceedings against us or companies that work within our industry, governmental proceedings, unfavorable media coverage or class action could adversely affect our business, financial condition and results of operations.

An unfavorable outcome or settlement or any other legal, administrative and regulatory proceeding may result in a material adverse impact on our business, results of operations, financial position and overall trends. In addition, regardless of the outcome, litigation can be costly, time-consuming, and disruptive to our operations. Any claims or litigation, even if fully indemnified or insured, could damage our reputation and make it more difficult to compete effectively or to obtain adequate insurance in the future.

Unfavorable market or economic conditions could limit our access to capital and could adversely affect our business, financial condition or results of operations.

Global economic uncertainty, including recession, inflation, or reduced growth rates, could adversely affect our business and financial condition. Our operations require substantial cash, and we expect to continue significant spending to advance our product candidates. In unstable markets, we may be unable to raise additional capital on acceptable terms or at all, and we have no committed source of funding. Failure to obtain financing could force us to delay, scale back, or discontinue development programs.

Adverse economic conditions could also affect our manufacturers, suppliers, distributors, and other partners, impairing their ability to provide materials or services, and could increase our risk of uncollectible receivables.

Item 4. Information on the Company

4.A. History and Development of the Company

We were organized under the laws of the Kingdom of Denmark in August 2008 as a private limited liability company (Anpartsselskab, or ApS) and then transformed into a public limited liability company (Aktieselskab, or A/S), effective April 9, 2019. Prior to the transformation, on April 1, 2014, our legal name changed from Novvac ApS to Evaxion Biotech ApS. April 20, 2025, our legal name changed from Evaxion Biotech A/S to Evaxion A/S. We commenced operations in August 2008.

Our corporate website address is www.evaxion.ai. The information on, or that can be accessed through, our website is not part of and should not be incorporated by reference into this annual report or any other report we file or furnish to the U.S. Securities and Exchange Commission ("SEC"). We have included our website address as an inactive textual reference only. Our shares (ADSS) are traded on The Nasdaq Capital Market under the symbol "EVAX".

The SEC maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

For additional information relating to the development of our company, see "Item 4.B. Information on the Company - Business Overview." For additional information relating to the Company's capital expenditures, see "Item 5.A. Operating and Financial Review and Prospects - Operating Results."

4.B. Business Overview

General

Evaxion is a pioneering TechBio company based upon our proprietary AI platform, AI-Immunology™, which has been continuously developed and refined over the past 18 years. This validated and scalable platform harnesses the power of artificial intelligence to decode the human immune system and develop novel vaccines for cancer and infectious diseases. We are planning to expand into autoimmune diseases as well.

Based upon AI-Immunology™, Evaxion has developed a pipeline of preclinical and clinical R&D-programs, including therapeutic cancer vaccines (both personal and off-the-shelf) and prophylactic vaccines against bacterial and viral diseases with high unmet medical needs. We are committed to transforming patients' lives by providing innovative and targeted treatment options. Our pipeline contains vaccines against pathogens for which no vaccines exist today; *S. aureus*, Group A *streptococcus*, *N. gonorrhoeae* and cytomegalovirus.

Our purpose is simple: Saving and improving lives with AI-Immunology™ powered vaccines. We invest to fulfil this purpose and to create long-term value for our owners, patients and other stakeholders. As a business, we create and derive value both from our AI-Immunology™ platform and our pipeline of vaccine candidates under development. This sets us apart from traditional biotech companies basing their value only on development candidates and from tech companies with just a platform.

Platform and Technology

AI-Immunology™ can find targets and suggest vaccine designs that could not be identified with conventional methods. Further, it is faster, cheaper and more accurate and can be scaled for application towards more than 100 different diseases and used with different vaccine modalities. As such, the platform completely revolutionizes vaccine development compared to traditional approaches like reverse vaccinology. And it improves as iterative learning loops causes the platform to keep building on its aggregated learnings and improvements.

The predictive power of AI-Immunology™ stems from its ability to process and interpret vast amounts of complex biological data. These data are transformed into advanced algorithms that we believe can accurately predict cellular interactions and identify the right target to stimulate a relevant, potentially lifesaving protective immune response. We have established a direct link between the predictive power of the AI-Immunology™ platform and preclinical and clinical outcome.

We have developed our core technology to deeply understand the biological processes relevant for engaging the immune system. It enables broad applicability across diseases with immunological components. With deep insights into the biological processes of the immune system, we bridge technology, engineering expertise and drug development know-how to bring novel vaccines to patients.

AI-Immunology™ contains a number of AI prediction models. It features a unique modular building block architecture where the specific building blocks are used across the different prediction models. This means that improvements in individual building blocks will lead to improvements in all the AI prediction models where those building blocks are used. This, we believe, serves to further enhance the predictive capabilities of AI-Immunology™ and to ensure we will retain a differentiated position going forward.

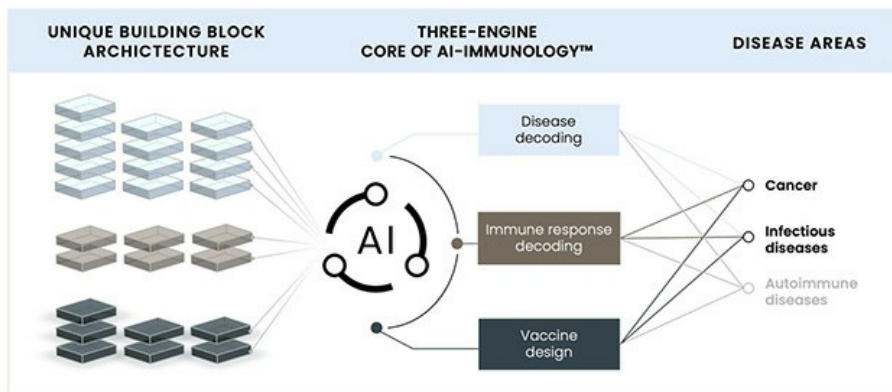


Figure 1: The unique architecture of AI-Immunology™

Cancer Vaccines

AI-Immunology™ allows for development of different types of novel cancer vaccines targeting the disease with multiple approaches. vaccine EVX-01 is our most advanced cancer vaccine, currently being evaluated as a treatment for advanced melanoma (skin cancer).

EVX-01 targets so-called neoantigens most likely to generate a strong T-cell response and anti-tumor effect. Combining these neoantigens in vaccines activates the immune system to specifically target and kill tumor cells with potential high efficacy and no or very limited adverse effects on healthy non-cancer cells.

With AI-Immunology™, relevant neoantigens can be identified rapidly and with very high accuracy. As an example, 81% of the vaccine neoantigen targets in EVX-01 triggers a tumor-specific immune response, a substantially higher frequency than what has been reported for other similar vaccine candidates.

AI-Immunology™ also enables us to design precision cancer vaccines relevant also for patients not responding to conventional immunotherapies. We have developed new vaccine concepts targeting ERV (endogenous retrovirus) tumor antigens as our cancer vaccine candidates EVX-03 and EVX-04 both utilize ERVs.

ERVs are traces of ancient viruses embedded in our genome – viruses that infected our ancestors and incorporated themselves into our genome. This happened long ago (100K to millions of years). In normal cells, these traces of viruses lay dormant in the genome. Cancer cells, on the other hand, may express these old virus proteins, making them a perfect target for immunotherapy. AI-Immunology™ enables us to potentially utilize this to bring forward novel superior treatments.

AI-Immunology™ can identify and select vaccine targets from ERVs expressed in cancer cells, enabling the design of precision cancer vaccines for multiple specific cancer types. This concept leverages our unique data insights and expertise in identifying vaccine targets compatible with the diversity of the immune system. By selecting ERV fragments that match a broad spectrum of immune system profiles, these vaccines have the potential to be effective across a wide range of patients.

Infectious Disease Vaccines

AI-Immunology™ enables a highly innovative approach to development of vaccines to combat bacterial and viral diseases. This allows us to potentially design and develop vaccines for diseases for which no vaccines exist today, even despite decades of research. One example is gonorrhoea for which no vaccine is available, yet we have achieved preclinical Proof of Concept for our candidate EVX-B2, which is demonstrating strong efficacy against 50 clinically relevant bacteria strains.

Where traditional methods for vaccine development like reverse vaccinology relies heavily on previously tested antigens, AI-Immunology™ is trained to identify underlying protective feature patterns that enable the discovery of novel and unbiased targets. It can rapidly identify a broad range of vaccine antigens against almost any virus and bacteria, including drug-resistant bacteria.

Further, AI-Immunology™ has learned to filter out irrelevant proteins, narrowing the field of candidates from thousands to a few dozen proteins and reducing the burden on preclinical development.

A common problem when trying to combat bacterial diseases is the evolution of the bacterial genome that can occur in some bacterial pathogens. This makes it difficult to capture all pathogen strains with a single vaccine and therefore make an effective vaccine. AI-Immunology™ can solve this problem by leveraging genomic sequencing data to find important targets or domains that are present in the majority of clinical strains. By combining the correct antigens, the technology can provide broad protection and cover most, if not all, relevant strains.

For viral diseases, AI-Immunology™ predicts both cross-protective B-cell antigens and protective T-cell epitopes. This allows for a robust and durable antibody and cellular response – implying broader, more reliable and more future variant-agnostic vaccines.

The B- and T-cell antigens can be administered as individual components, but we can – uniquely - also further analyze the B-cell antigen sequence to identify sites where T-cell epitopes can be grafted into the protein. This produces a T-cell response while preserving B-cell antibody generation, which results in increased breadth, avidity, magnitude, and duration of the immune response. These identified antigens can be administered by any established vaccine delivery technology.

Strategy and Milestones

We specialize in target discovery and the early stages of development with a business model based on partnerships around both our platform and pipeline. Existing partnerships include a license agreement with Merck & Co., Inc., Rahway, NJ, USA (MSD), the world leader in vaccine development and commercialization, on EVX-B3, a vaccine candidate against an undisclosed bacterial pathogen. MSD, through their venture arm, is also a major shareholder in Evaxion.

In parallel with the AI-Immunology™ platform development, we have built a strong multidisciplinary capability set spanning the full value chain from target discovery to early clinical development. Our state-of-the-art wet-lab and animal facility gives us a unique opportunity for rapidly validating our AI predictions in preclinical models thereby, generating proprietary data as well as new pipeline assets.

The AI-Immunology™ platform together with our multidisciplinary capability set drives a clear differentiation for our AI driven approach to development of novel vaccine candidates and provides a strong value proposition towards potential partners

We have the internal capabilities and facilities to complete the entire process from early target discovery to clinical testing. As such, we are a one stop-shop for partner companies and capable of replenishing and advancing our own pipeline of potential new vaccines.

We have a strong track record of strategy execution and achieving our milestones. In 2026 we are pursuing the below milestones.

	Milestone	Target
EVX-01	Additional biomarker and immunogenicity data	H1
AI-Immunology™	New application for autoimmune diseases	H2
EVX-01	Three-year phase 2 clinical efficacy data	H2
EVX-04	Regulatory filing for phase 1 trial	H2
EVX-B4	Design and preclinical validation of antigens	H2

Figure 2: 2026 milestones

Markets

Evaxion operates in significant markets characterized by high-growth projections. Globally, the market for AI-based drug discovery is projected to grow to more than \$40 billion by 2040, equaling a 25% average annual growth rate. Growth is reinforced by demand for AI solutions able to deliver advanced therapeutics, rising chronic disease prevalence, and increased R&D investment by pharmaceutical companies. We operate in this market by offering pharma companies our unified end-to-end AI-Immunology™ platform for target discovery, drug design, and validation.

The unmet medical needs we address are huge. Globally, ten million people die from cancer annually and close to eight million die from infectious diseases. The rise of antimicrobial resistance further increases the threat of the latter. Addressing such massive medical challenges in turn offers significant commercial opportunities. The global cancer immunotherapy market is projected to grow to \$229 billion by 2030, the market for infectious disease vaccines to \$68 billion by 2031.

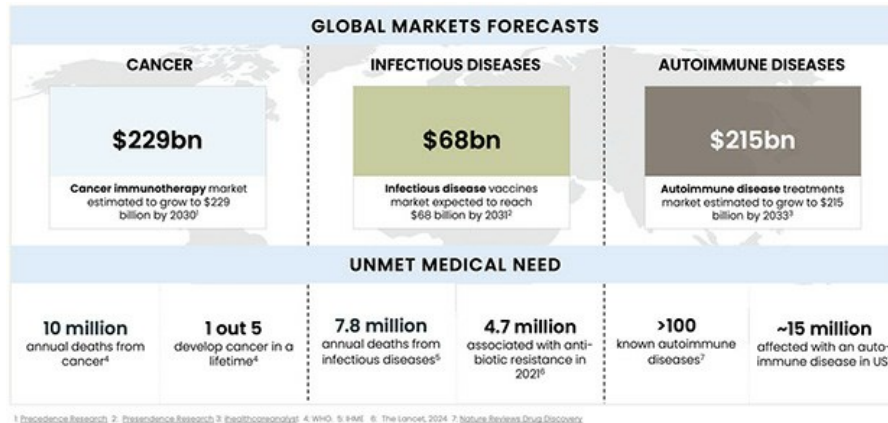


Figure 3: Global market forecast - targeting significant unmet needs and large markets

R&D Pipeline

Our pipeline of novel vaccine candidates is summarized below. Currently, it consists of three programs for cancer and six within infectious diseases, including the EVX-B3 program licensed to MSD. The AI-identified targets included in our different drug candidates can be delivered using any delivery modality, such as peptides, recombinant proteins, mRNA and our proprietary DNA-targeting technology, and we are building a diverse vaccine pipeline utilizing such different delivery modalities.

CANDIDATE	INDICATION/ PATHOGEN	STAGE OF DEVELOPMENT			
		TARGET DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2
CANCER					
EVX-01* (Episomal/peptide)	Advanced melanoma	[Progress bar spanning all stages]			
EVX-03 (Targeted DNA)	TBD	[Progress bar spanning Target Discovery to Phase 1]			
EVX-04 (DNA)	AML	[Progress bar spanning Target Discovery to Phase 1]			
Multiple candidates	Undisclosed	[Progress bar in Target Discovery]			
INFECTIOUS DISEASES					
EVX-B1 (Protein)	S. aureus	[Progress bar spanning Target Discovery to Phase 1]			
EVX-B2 (Protein)	N. gonorrhoeae	[Progress bar spanning Target Discovery to Phase 1]			
EVX-B2** (mRNA)	N. gonorrhoeae	[Progress bar spanning Target Discovery to Phase 1]			
EVX-B3	Bacterial pathogen	[Progress bar spanning Target Discovery to Phase 1]			
EVX-B4	Group A Streptococcus	[Progress bar spanning Target Discovery to Phase 1]			
EVX-V1	Cytomegalovirus	[Progress bar spanning Target Discovery to Phase 1]			
Multiple candidates	Undisclosed	[Progress bar in Target Discovery]			

* Pembrolizumab supply agreement with MSD (Epidemiology of Merck & Co, Inc., Rahway, NJ, USA)
** Collaboration with Afrigen for low- and middle-income countries

Figure 4: The Evaxion pipeline.

EVX-01

EVX-01 is a peptide-based personalized vaccine currently being evaluated as a first-line treatment of advanced melanoma (skin cancer) and is administered in combination with MSD’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). The concept behind EVX-01 is believed to be applicable to several different types of cancer and has been granted Fast Track-designation by the US Food and Drug Administration (FDA).

EVX-01’s vaccine targets are neoantigens identified by AI-Immunology™ based on individual tumor profiles meaning that each and every patient get their own specific vaccine. The data generated to date are highly encouraging with two-year clinical efficacy data presented at the European Society for Medical Oncology (ESMO) Congress 2025. The data showed a 75% Objective Response Rate, a 25% Complete Response Rate and immune activation observed in all patients with 81% of EVX-01’s vaccine targets triggering a specific response. Moreover, a durable clinical benefit was observed as 92% of patients were still responding at 24 months follow-up and no relapses were observed. Further, 54% of patients had a deepened response during treatment, improving from stable disease or partial response to partial or complete response. Tumor reduction (target lesions) was observed in 15 out of the 16 patients enrolled in the trial. Data also confirmed EVX-01 to be a well-tolerated treatment.

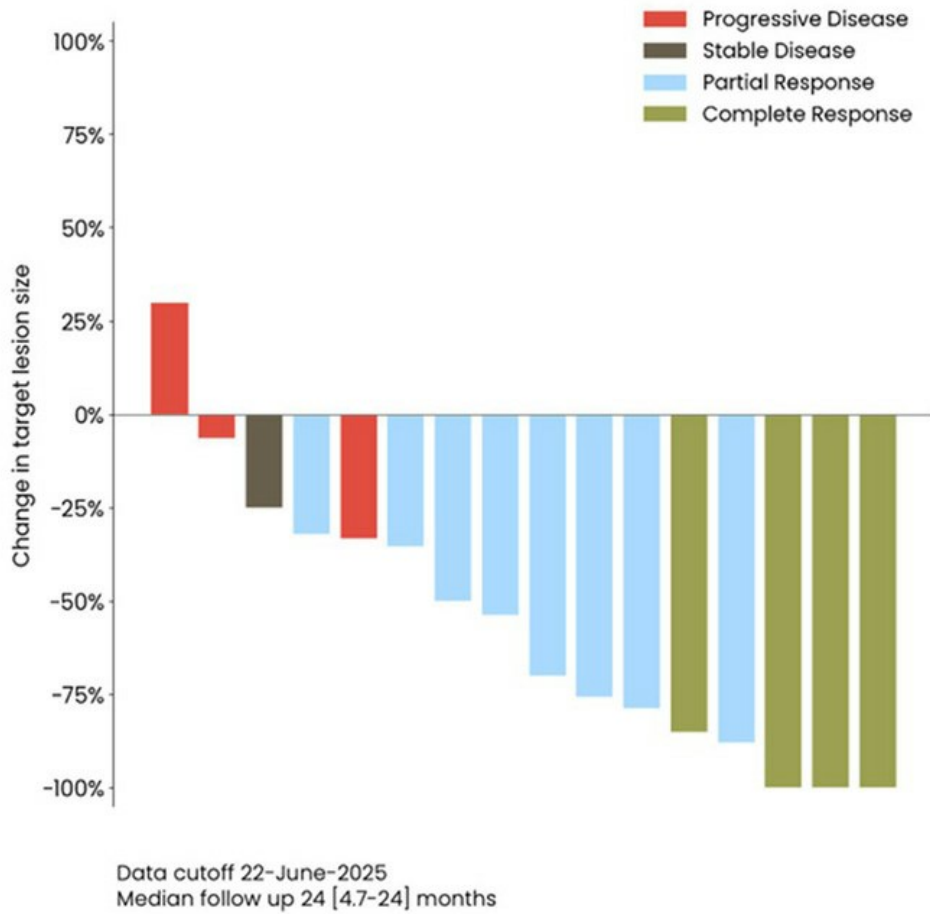


Figure 5: Two-year clinical data form the EVX-01 phase 2 study

A one-year extension to the phase 2 trial, in which EVX-01 will be administered as monotherapy, is expected to read out in the second half of 2026, providing three-year clinical efficacy data. This may provide further insights into potential enhanced treatment effects and durability of induced immune response and as such further strengthen EVX-01's already strong clinical data package. This will also be supplemented by additional biomarker and immunogenicity data expected to be presented at a scientific conference in the first half of 2026.

EVX-03

EVX-03 is a targeted DNA personalized cancer vaccine candidate for treatment of solid tumors, e.g. several different types of cancer. It is the first ever vaccine candidate combining personalized neoantigens and endogenous retrovirus (ERV) antigens and contains a proprietary targeting unit that directs the antigens to the relevant immune cells. EVX-03 has induced antitumor immunity with complete responses in mouse tumor models. The antitumor effect has been obtained in both prophylactic and therapeutic models. EVX-03 induces strong and durable neoantigen- and ERV-specific T-cell responses with an additive effect of combining with anti-PD1 agents in mice.

EVX-04

EVX-04 is an off-the-shelf therapeutic cancer vaccine candidate for Acute Myeloid Leukemia (AML). It targets tumor-specific antigens derived from ERVs and is planned to be investigated in a first-in-human study in AML patients unfit for allogeneic stem cell transplantation in combination with azacitidine and venetoclax. The novel targets and therapeutic modality may allow for increased durability of clinical response. We plan to carry out preparation for a phase 1 trial with EVX-04 and expect to submit regulatory filing for this trial before the end of the year.

Using sequencing data from AML patients, the AI-Immunology™ platform first identified ERV tumor antigens and then mined these to determine smaller fragments with the potential for immune recognition when designing EVX-04. From the five million ERV antigens fragments discovered, AI-Immunology™ combined and selected 16 optimal sets of ERV fragments based on their cross-patient relevance and immunogenic potential. All 16 ERV fragments included in EVX-04 elicit a specific immune response (figure 6) and EVX-04 prevents tumor growth in preclinical tumor models. No EVX-04 related toxicity or off target effects have been observed in mice.

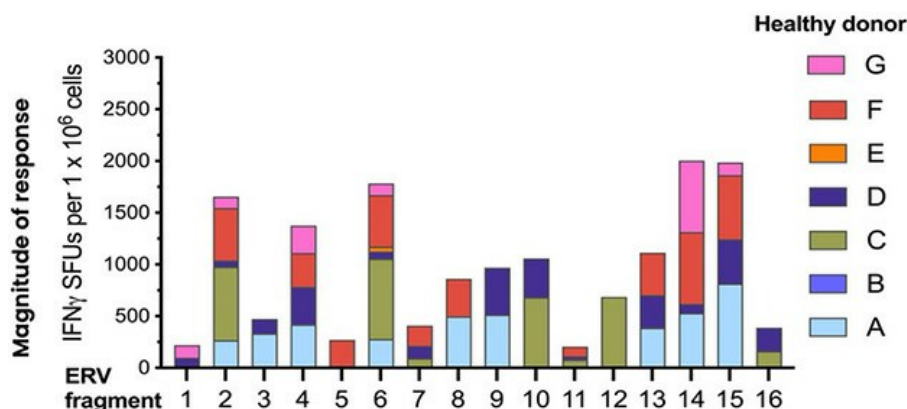


Figure 6: all 16 EVX-04 ERV antigen fragments induce a specific immune response in healthy donors.

The data-driven target selection ensures that EVX-04 provides broad tumor coverage regardless of immune and tumor ERV antigen differences across patients. Thus, EVX-04 is developed as an off-the-shelf vaccine preproduced and ready for immediate administration after diagnosis. The same concept is broadly applicable across cancers where immunotherapies remain inadequate and conserved immunogenic antigens can be identified.

EVX-B1

EVX-B1 is a multi-component prophylactic vaccine targeting Skin and Soft Tissue Infections (SSTI) with *S. aureus* (SA) bacteria. It is designed to act against SA across multiple parameters, ensuring potential high efficacy, high immunogenicity and targeting of functionality.

EVX-B1 targets essential toxins and major virulence factors widely present and conserved in relevant clinical strains. It has the potential to be applied both as a prophylactic and therapeutic vaccine. No prophylactic SA vaccine is available today.

Preclinical data gathered to date documents that EVX-B1 protects against surgical site infections in minipigs and protects against lethal sepsis (Figure 6) and skin infections in mice. Immunized mice clear the infection from internal organs and EVX-B1 induces a long-lasting immune response in mice.

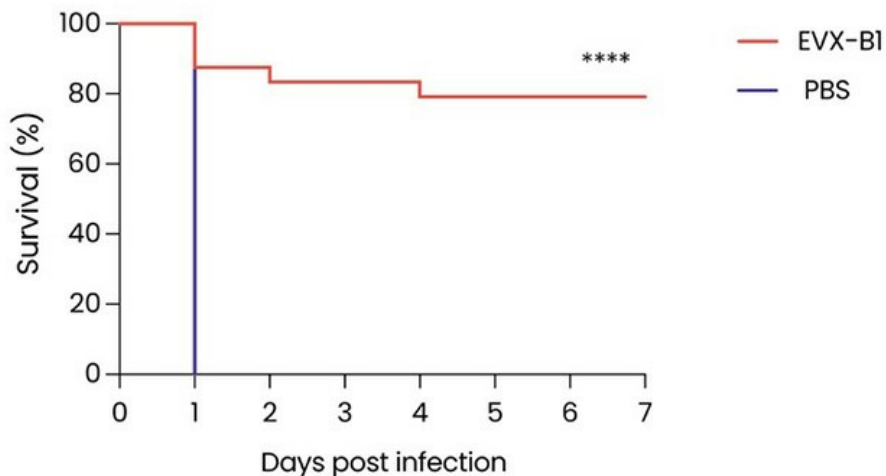


Figure 7: EVX-B1 induces protection in a mouse sepsis model.

EVX-B2

EVX-B2 is a multi-component prophylactic vaccine against gonorrhea bacteria. We are developing it with two different modalities; protein and mRNA. The mRNA-version is developed for low-and middle-income countries in collaboration with Afrigen Biologics. Also, for gonorrhea, no prophylactic vaccine exists today.

EVX-B2 contains antigens that are present in all 1,200 published *N. gonorrhoeae* (Ng) genomes analyzed. This implies potential efficacy against bacteria strains globally. It has a unique Mode of Action as it kills off bacteria by targeting its cell division processes.

In mouse infection models, EVX-B2 induces strong protective efficacy (Figure 8) and bactericidal analyses demonstrate that EVX-B2 induces killing against 50 clinically relevant Ng strains.

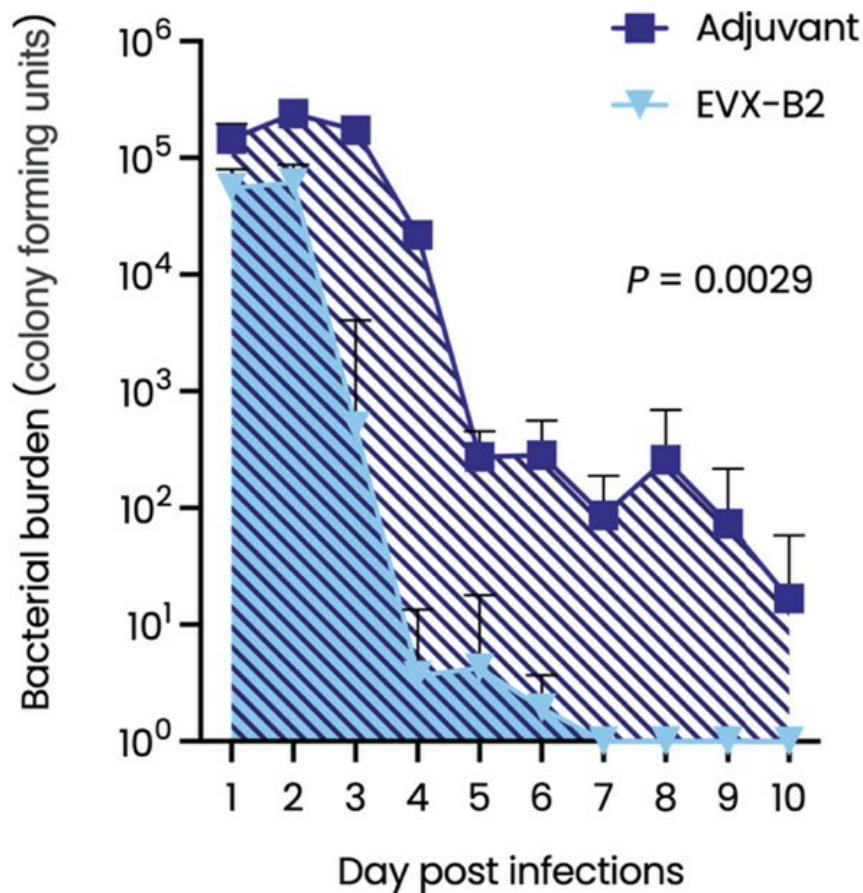


Figure 8: EVX-B2 induce significant protection against challenge in a *N. gonorrhoeae* colonization mouse model.

EVX-B3

EVX-B3 addresses a serious global medical issue by targeting a bacterial pathogen associated with repeated infections. It was initially discovered in a collaboration with MSD entered in September 2023.

In September 2025, MSD exercised its option to license EVX-B3, marking the first time ever an AI-designed vaccine candidate was licensed by a pharmaceutical company.

As per the license agreement, Evaxion is eligible for future development, regulatory and sales milestone payments of up to \$592 million, as well as royalties on net sales. MSD has assumed full responsibility and will carry all costs for the further development EVX-B3.

EVX-B4

EVX-B4 is a prophylactic vaccine against Group A *Streptococcus* (GAS). It was added to our R&D pipeline in June 2025 after initial computational analysis demonstrated that AI-Immunology™ can identify novel vaccine targets to combat GAS. We currently focus on identification and testing of novel antigens for immunogenicity, functionality and protection in mouse models and in vitro assays. Design and preclinical validation of antigens for the vaccine candidate is expected to be concluded in the second half of 2026.

This is another great example of how AI-Immunology™ has the potential to identify novel approaches to combatting diseases for which no treatments exist despite decades of research: Development and testing of potential GAS vaccines can be traced back to 1923, yet no vaccine exists today.

EVX-V1

EVX-V1 is a next-generation, multi-component prophylactic vaccine candidate against cytomegalovirus (CMV). It combines novel AI-Immunology™ discovered antigens with AI-optimized versions of established CMV vaccine antigens. EVX-V1 is being developed to combat CMV infection in connection with e.g. solid organ transplants.

The newly discovered and thus previously unexplored CMV-antigens induce specific immune responses, inhibit viral infection and reduce cell-to-cell spread in cellular and animal viral infection models. These are significant discoveries since very few protective CMV-antigens have been identified despite decades of intensive research.

As an example of the improved versions of well-established CMV vaccine components to combine with our novel antigens, we have developed an AI-optimized proprietary prefusion glycoprotein B (gB) antigen. Our optimized version demonstrates superior performance compared to the traditional gB antigen, including enhanced CMV neutralization.

Through the combination of different antigens, EVX-V1 attacks the virus from multiple, complementary angles. This broader multi-targeted strategy is expected to strengthen the protective potential of the future vaccine.

Our Management Team

We have a seasoned and broadly skilled management team with decades of combined experience from the global biotech and pharmaceutical industry.

Chief Executive Officer Dr Helen Tayton-Martin joined Evaxion on November 24, 2025. Holding a Ph.D. in molecular immunology, and an MBA from London Business School, Helen Tayton-Martin was a co-founder of cancer-focused biotech company Adaptimmune, where she served as Chief Operating Officer and later Chief Business & Strategy Officer during her 17 years with the company. Through this time, she oversaw transatlantic growth, multiple clinical, academic and commercial collaborations and private and public financing through to its Nasdaq IPO. Dr. Tayton-Martin was responsible for all Adaptimmune's strategic partnerships including those with Astellas, Genentech, a member of the Roche Group, GlaxoSmithKline and Galapagos NV.

Prior to Adaptimmune, Dr. Tayton Martin spent 15 years working within the pharma, biotech and consulting environments for various companies. She also previously served as a non-executive director of Trillium Therapeutics Inc. from October 2017 through to the sale of the company in November 2021 to Pfizer Inc.

Chief Science Officer (CSO) Birgitte Rønø joined in 2017 and was appointed CSO in 2021. Dr. Rønø has more than 25 years' experience in biopharmaceutical drug discovery from academia and industry and received her PhD in experimental oncology and immunology from National Institutes of Health, Bethesda, USA, and Copenhagen University Hospital, Denmark. Prior to joining Evaxion, Birgitte Rønø served as a specialist, team leader and project manager at Novo Nordisk A/S, where she was leading early drug discovery projects, evaluating in-licensing opportunities, and supporting drug development projects with preclinical and biomarker expertise.

Chief Financial Officer Thomas Schmidt was permanently appointed in November 2025, having joined Evaxion on an interim basis on November 1, 2024. Mr. Schmidt has more than 30 years of financial management experience from across different industries with more than 25 years of these being based in the life science industry including roles as country Managing Director and country Chief Financial Officer in Roche and Group CFO in Ambu.

Founder Andreas Holm Mattsson serves as Chief AI Officer at Evaxion, where he's been at the forefront *in silico*-based vaccine target discovery. He has played a key role in developing AI-Immunology™ platform. Andreas has a strong educational background in bioinformatics from the Technical University of Denmark and has previously worked at Novo Nordisk. Since founding Evaxion in 2008, he has been an essential part of the company's growth, serving in various executive roles.

Manufacturing

Evaxion does not maintain our own manufacturing capacity. Instead, we utilize one or more contract manufacturers to manufacture relevant investigational drugs. We source from suppliers we believe have sufficient capacity to meet our demands. However, there is a risk that if such supply was interrupted, it would materially harm our business.

We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture drug substances. We rely on third-party manufacturers to produce the drug substances required for our preclinical and clinical trials and expect to continue to rely on third parties to manufacture and test trial drug supplies for the foreseeable future.

Our contract suppliers manufacture drug substance for our development candidates for trial use in effort to comply with current good manufacturing practice (“cGMP”), applicable local regulations and similar foreign requirements. cGMP and similar foreign requirements include requirements relating to organization of personnel; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling controls; holding and distribution; laboratory controls; records and reports; and returned or salvaged products.

The manufacturing facilities for our drug candidates must be in compliance with cGMP requirements and similar foreign requirements. Our third-party manufacturers may also be subject to periodic inspections of facilities by the FDA, the EU member states competent authorities, and other authorities, including reviews of procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

We also contract with additional third parties for the filling, labeling, packaging, testing, storage and distribution of our drug candidates. We employ personnel with the scientific, technical, production, quality and project management experience required to oversee our third-party suppliers and to manage manufacturing, quality data and information for regulatory compliance purposes.

Third-Party Collaboration

Evaxion’s strategy is based on extensive third-party collaboration across all areas of our business from research to business development and partnering. Thus, we are engaged in a number of collaborations with both scientific and business partners.

We are collaborating with MSD (tradename of Merck & Co., Inc., Rahway, NJ, USA) through their licensing of EVX-B3. MSD carries all cost and risk related to the development and subsequent potential approval and commercialization of EVX-B3 with Evaxion eligible for milestone payments up to \$592 million as well as royalties on net sales. MSD has also been supplying its anti-PD-1 therapy KEYTRUDA® for the phase 2 trial with EVX-01. We will continue to collaborate with MSD as the data matures.

In the EVX-B2 program we are collaborating with Afrigen Biologics to develop an mRNA-based gonorrhea vaccine for low and middle income countries (LMICs). Following the validation phase, the partners will negotiate a subsequent agreement for clinical development and commercialization, with the opportunity to bring in additional partners. Afrigen Biologics will be responsible for the development and commercialization of the resulting mRNA vaccine in LMICs and African territories.

In 2025, we initiated a collaboration with the Gates Foundation based on applying our AI-Immunology™ platform to identify and combine various antigens to combat polio virus and develop design options for a potential new vaccine construct. We remain in dialogue with the foundation about this project and could potentially expand to collaboration to include other new projects as well.

We retain the commercial rights to EVX-01 and our other clinical stage programs. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and the FDCA's implementing regulations and regulates biologics under both the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations.

The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or following approval may subject a sponsor to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the institutional review board, or IRB, or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with good clinical practice, or GCP, regulations;
- preparation and submission to the FDA of a NDA for a drug product, or a biologics license application, or BLA, for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, efficacy, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical trial sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA;
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our investigational medicines and any future investigational medicines will be granted on a timely basis, or at all.

Preclinical Studies and IND Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials being conducted under the IND may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of an NDA or a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation. Clinical trials are conducted under trial protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of an IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the trial data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on access to certain data from the trial.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.

- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Compliance with cGMP Requirements

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable deterioration over its shelf life. In particular, the PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Sponsors of BLAs and NDAs must report changes in CMC including manufacturing sites to FDA. Such changes may result in delays in approval of pending BLAs and NDAs or delays in manufacturing approved products.

Manufacturers and others involved in the manufacture and distribution of approved drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA charges drug and biologic product manufacturers user fees, which are adjusted on an annual basis in accordance with the Prescription Drug User Fee Act, or PDUFA. The fee for the submission of an NDA or BLA for which clinical data is substantial (for example, for the fiscal year 2025 this application fee exceeds \$4.1 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than \$400,000 per program. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement to a BLA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or the FDASIA, enacted in 2012, made permanent PREA to require a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA will issue a complete response letter, or CRL, which describes the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. If a CRL is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a CRL who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the CRL have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast-track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast-track product at any time during the clinical development of the product. For fast-track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast-track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast-track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway and Regenerative Medicine Advanced Therapy Designation

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early actions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients or subjects, and the severity, rarity or prevalence of the condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our US patents may be eligible for limited patent term extension. These patent term extensions permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, or the USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA, subject to certain limited exceptions, cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Post-Approval Regulation

If regulatory approval for marketing of a new drug or biologic product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period, starting in 2013 and is expected to culminate soon. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. A federal district court ruling in Texas struck down the Affordable Care Act in its entirety based on constitutionality, and in December 2019 the Fifth Circuit Court of Appeals upheld lower court's finding that the individual mandate in the law is unconstitutional. On June 17, 2021, the Supreme Court reversed the District Court decision on the basis that the Plaintiffs lacked standing.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or
- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union and Australia, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states.

Clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific trial site after the independent ethics committee has issued a favorable opinion.

The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide 'no fault' compensation to any trial subject injured in the clinical trial.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted, and implemented in January 2023. The Clinical Trials Regulation is directly applicable in all the European Union Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union initiated before January 2023 will continue to be bound by the Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation became applicable (January 2023) the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned European Union Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the EMA and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU member states (decentralized procedure, national procedure or mutual recognition procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical trial reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical trial reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. A similar requirement is contained in the new Clinical Trials Regulation. A marketing authorization may be granted only to a sponsor established in the European Union.

Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, inter alia, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long-term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;

- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a “normal” marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization.

Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product’s immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

Conditional Approval

In specific circumstances, European Union legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

European Union Regulatory Exclusivity

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union, are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

PRIME Designation

The EMA grants access to the Priority Medicines, or PRIME, program to investigational medicines for which it determines there to be pre-liminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner.

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Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details are governed by regulations in each member state and can differ from one country to another.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

Australian Regulatory Requirements

We are currently conducting a Phase 2 clinical trial of our EVX-01 product candidate in Australia, which has laws and regulations related to the conduct of clinical trials with which we and the entities and persons conducting the clinical investigations must comply. A failure to do so, may affect our ability to use the data from such trial when seeking marketing authorization and/or may result in regulatory action by the TGA, including, but not limited to, civil and criminal penalties.

The Therapeutic Goods Act 1989, or the 1989 Act, sets out the legal requirements for the import, export, manufacture and supply of pharmaceutical products in Australia. The 1989 Act requires that all pharmaceutical products to be imported into, supplied in, manufactured in or exported from Australia be included in the Australian Register of Therapeutic Goods, or the ARTG, unless specifically exempted under the Act.

Medicines with a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy and are registered on the ARTG. Medicines with a lower risk (many over the counter medicines including vitamins) are assessed only for quality and safety. Medicines included in the ARTG can be identified by the AUST R number (for registered medicines) or an AUST L number (for listed medicines) which appears on the packaging of the medicine.

In order to ensure that a product can be included in the ARTG, a sponsoring company must make an application to the TGA. The application usually consists of a form accompanied by data (based on the EU requirements) to support the quality, safety and efficacy of the product for its intended use and payment of a fee.

The first phase of evaluation, known as the Application Entry Process, is usually a short period during which an application is assessed at an administrative level to ensure that it complies with the basic guidelines. The TGA may request further details from the applicant and may agree with sponsors that additional data (which while not actually required by the application, could enhance the assessment outcome) may be submitted later at an agreed time. The TGA must decide within at least 40 working days whether it will accept the application for evaluation.

Once an application is accepted for evaluation, aspects of the data provided are allocated to evaluators within the different relevant sections, who prepare clinical evaluation reports. Following evaluation, the chemistry, quality control bioavailability and pharmacokinetics aspects of a product may be referred to a Pharmaceutical Sub-Committee, or the PSC, which is a sub-committee of the TGA prescription medicine expert advisory committee, the Advisory Committee on Prescriptive Medicines, or the ACPM, to review the relevant clinical evaluation reports.

The clinical evaluation reports (along with any resolutions of the ACPM sub-committee) are sent to the sponsoring company who then has the opportunity to comment on the views expressed within the evaluation report, provide corrections and to submit supplementary data to address any issues raised in the evaluation reports.

Once the evaluations are complete, the TGA prepares a summary document on the key issues on which advice will be sought from either the ACPM (for new medicines) or from the Peer Review Committee, or the PRC, for extensions to products which are already registered. This summary is sent to the sponsoring company, which is able to submit a response to the ACPM or PRC dealing with issues raised in the summary and those not previously addressed in the evaluation report. The ACPM/PRC provide independent advice on the quality, risk/benefit, effectiveness and access of the product and conduct medical and scientific evaluations of the application. The ACPM meets every two months to examine the applications referred by the TGA and its resolutions are provided to the sponsoring company within five working days after the ACPM meeting.

The TGA takes into account the advice of the ACPM or PRC in reaching a decision to approve or reject a product. Any approval for registration on the ARTG may have conditions associated with it.

From the time that the TGA accepts the initial application for evaluation, the TGA must complete the evaluation and make a decision on the registration of the product within at least 255 working days. If not completed within 255 working days, the TGA forfeits 25% of the evaluation fee otherwise payable by the sponsor, but any time spent waiting for a response from the sponsor is not included in the 255 working days. The TGA also has a system of priority evaluation for products that meet certain criteria, including where the product is a new chemical entity that it is not otherwise available on the market as an approved product, and is for the treatment of a serious, life-threatening illness for which other therapies are either ineffective or not available.

Rest of the World Regulation

For other countries outside of the European Union, Australia and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (e.g., patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (e.g., to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules.

Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

Australian Privacy Laws

Australia, where we are currently conducting clinical trials for EVX-01, regulates data privacy and protection through a mix of federal, state and territory laws. The federal Privacy Act 1988 (*Cth*) (Privacy Act) or the Privacy Act, and the Australian Privacy Principles, or the APPs, contained in the Privacy Act apply to private sector entities (including body corporates, partnerships, trusts and unincorporated associations) with an annual turnover of at least AU\$3 million, and all Commonwealth Government and Australian Capital Territory Government agencies.

The Privacy Act regulates the handling of personal information by relevant entities and under the Privacy Act, the Privacy Commissioner has authority to conduct investigations, including own motion investigations, to enforce the Privacy Act and seek civil penalties for serious and egregious breaches or for repeated breaches of the APPs where an entity has failed to implement remedial efforts.

In December 2022, the Australian Government increased fines for violations of the Privacy Act. The maximum fine for a serious invasion or repeated invasions of privacy (i.e. breaches of the privacy law) was increased to up to the greater of AUD \$50 million, three times the benefit of a contravention, or (where the benefit can't be determined) 30% of domestic turnover.

In addition, most States and Territories in Australia (except Western Australia and South Australia) have their own data protection legislation applicable to relevant State or Territory government agencies, and private businesses that interact with State and Territory government agencies. These Acts include:

- *Information Privacy Act 2014* (Australian Capital Territory)
- *Information Act 2002* (Northern Territory)
- *Privacy and Personal Information Protection Act 1998* (New South Wales)
- *Information Privacy Act 2009* (Queensland)
- *Personal Information Protection Act 2004* (Tasmania), and
- *Privacy and Data Protection Act 2014* (Victoria)

Additionally, there are other parts of Australian State, Territory and federal legislation that relate to data protection. For example, the following all impact privacy and data protection for specific types of data or activities: the *Telecommunications Act 1997 (Cth)*, the *Criminal Code Act 1995 (Cth)*, the *National Health Act 1953 (Cth)*, the *Health Records and Information Privacy Act 2002 (NSW)*, the *Health Records Act 2001 (Vic)* and the *Workplace Surveillance Act 2005 (NSW)*.

Specific regulators have also expressed an expectation that regulated entities should have specified data protection practices in place. For example, the Australian Prudential and Regulatory Authority, or the APRA, which regulates financial services institutions requires regulated entities to comply with Prudential Standards, including Prudential Standard CPS 234 Information Security (CPS 234), and the Australian Securities and Investment Commission regulates corporations more generally.

Coverage, Pricing and Reimbursement

Sales of pharmaceutical products approved by the FDA will depend in significant part on the availability of third-party coverage and reimbursement for the products. Third-party payors include government healthcare programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other United States Healthcare Laws and Regulations

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the United States federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union Member States;
- the U.K. Bribery Act 2010; and
- analogous state and foreign laws and regulations, such as state anti-kickback, false claims laws, and sunshine acts, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Current and Future Healthcare Reform Legislation

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, a primary trend in the United States health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the United States Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. As noted above, a 2018 federal district court ruling struck down the Affordable Care Act in its entirety although the Fifth Circuit Court of Appeals recently limited it to the individual mandate and remanded the case to the district court to determine if other reforms not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act. On June 17, 2021, the Supreme Court reversed the district court decision on the basis that the plaintiffs lacked standing.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act that affect health care expenditures. There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on “commercially reasonable, market-based terms.” Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects’ firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other United States Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Intellectual Property

Introduction

We actively seek to protect the intellectual property (IP) and proprietary technology that we believe is important to our business. Further, we seek to protect our proprietary position by, amongst other methods, filing patent applications in Europe, the United States and potentially other relevant jurisdictions relating to our inventions, improvements and product candidates. We also pursue IP protection for assets that may be used in future development programs and/or that may be of interest to our collaborators, or otherwise may prove valuable in the field. We pursue a patent strategy which seeks to protect marketed products and methods of their production, as well as therapy methods enabled by our proprietary AI-Immunology™ platform without disclosure to the public the core elements in our technology. Furthermore, we have filed patent protection of aspects of our PIONEER™, EDEN™, AI-DeeP™ and RAVEN™ models, however, we do not believe that the value of obtaining patent protection for all component of our platform technologies outweighs the risks of disclosing such information. We rely on trade secrets and know-how relating to our proprietary technologies to develop, maintain and strengthen our proprietary position in AI-based drug discovery and development.

Patent applications that relate to the PIONEER™ technology cannot meaningfully be directed to single antigens and their various uses; neoantigens identified by PIONEER™ are by nature unique for each patient, therefore, the precise nature of each neoantigen has no relevance as an object for intellectual property rights. We are therefore establishing patent portfolio around the PIONEER™ model which protects generally applicable aspects of the model, enabling personalized cancer vaccine, i.e. protection of additional features and elements which characterize the PIONEER-enabled therapy compositions, and which could be applied to other anti-cancer therapies that are based on immunization against neoantigens. The focus on the patent protection in the PIONEER™ setting is therefore aiming at securing patent protection for 1) specific essential elements/ features needed to identify neoantigens not specific to the PIONEER™ system, 2) specific features characterizing the composition of the designed therapy, and 3) specific features related to patient safety of the administered composition.

For the AI-Immunology™ model; EDEN™, we file patents to protect vaccine antigens identified, vaccine compositions, antibodies, and antibody compositions as well as methods for prophylactic treatment of infectious diseases where the vaccine antigens and antibodies constitute the active ingredient. We file applications relating to several vaccine targets for each infectious agent causing the diseases and prosecute those antigens that have shown greatest promise as protective antigens in animal models. Our patent strategy for the EDEN™ technology also entails identification of optimal combinations of vaccine antigens as well as identification of specific vaccine formulations and modes of immunization that can be made the subject of second- and later generation patent applications that protect the final marketed product. Furthermore, we have one patent family pending covering the EDEN™ method itself.

For the AI-Immunology™ model; RAVEN™, we have filed patent applications related to some aspects of the method for viral vaccine design as well as product claims related to viral vaccines designed by RAVEN™ thus harboring unique features of the RAVEN™ design. However, the core functionality of RAVEN™ is protected by trade-secret and not patents as we have assessed that disclosure of methods do not outweigh the benefit of obtaining patent protection.

Most of our IP assets were developed and are owned solely by us. In the few cases where our IP assets are jointly owned or in-licensed from third parties, we retain full rights to the commercial exploitation of such assets. We expect that we will continue to make additional patent application filings and will continue to pursue opportunities to acquire and license additional IP assets.

Regardless, given the early stage of prosecution for some of our patent application, we cannot be certain that any of the patent filings or other IP rights that we have pursued or obtained will provide protection for any product candidates that may ultimately be commercialized. Our most advanced product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions, and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and proprietary rights of third parties. For more information, please see "Risk Factors — Risk Related to Our Intellectual Property".

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their accorded filing date (which is the earliest filing date to which the patent claims lineage, excluding filing dates claimed as priorities under the Paris Convention Priorities and/or priorities claimed from provisional patent applications). We believe that due to the patient- specific nature of our PIONEER™ based cancer vaccines, in which our PIONEER™ model is an inherent part of the product, and the platform predicted neoantigens cannot, we believe, be copied, such therapies will not be subject to competition from generic products even when the patent protection expires.

Patent Portfolio

As of December 31, 2025, we owned a total of 28 patent families, of which 5 are currently in their priority year or international phase and we own several granted patents in the United States (15), Germany (4), France (4), Spain (2), Great Britain (6) and 2 European unitary patent (in force 17 EU-member states) and have 83 pending national/regional applications.

So far, none of our granted patents has been subject to opposition, administrative reexamination, inter partes review, invalidity actions, or similar actions aiming at revoking or restricting the scope of a granted patent.

The patent portfolio related to our most advanced product candidates and technologies as of December 31, 2025, are summarized below.

EVX-01

EVX-01 is protected by trade secrets, patent applications related to, and the proprietary nature of the AI-Immunology™ model; PIONEER™. In addition to IP protection of the PIONEER™ model, our patent portfolio related to EVX-01 currently includes one patent family directed to a method of treating cancer in a patient using neopeptides (EVX-01). The patent application has entered national phase in CA, CN, US, EP, JP and is granted in AU. We expect the patent family to lapse in January 2040.

EVX-02

EVX-02 is protected by trade secrets, patent applications related to, and the proprietary nature of the PIONEER™ models. In addition to IP protection of the PIONEER™ model, our patent portfolio related to EVX-02 currently includes two patent families. The first patent family is claiming a method directed at inducing an anti-cancer immune response in patients by administering the EVX-02 vaccine concept comprising DNA plasmid and poloxamer 188, a novel adjuvant. The second patent family is directed at a method of inducing an anti-cancer immune response in patients by administering the EVX-02 plasmid alone. Both patent families are in national phase in EP, CA, CN, US, JP and AU. One patent is granted in JP. The first patent family is expected to lapse in March 2040 and the second in December 2040.

EVX-03

EVX-03 is protected by trade secrets, patent applications related to, and the proprietary nature of the PIONEER™ model. Furthermore, due to the similarities between our two DNA-based cancer vaccines, EVX-03 and EVX-02, our patent families covering EVX-02 also applies to EVX-03. In addition, one patent family has been filed that specifically relates to the targeting unit, unique to EVX-03. The patent family is a composition of matter application directed to the EVX-03 product concept. The patent family has national applications pending in the following Jurisdictions: AU, CA, CN, EP, JP and US. We expect that the patent rights will lapse in April 2041.

EVX-04

EVX-04 is protected by is protected by one patent family. The family is directed at a vaccine composition comprising HERV derived protein sequences useful for vaccination against AML. The patent family is in international phase (PCT) and is expected to lapse in 2045.

EVX-B1

Our patent portfolio related to EVX-B1, includes five patent families. The patent families are composition of matter patents, or methods for inducing anti *S. aureus* immunity, directed against compositions comprising one or more *S. aureus* antigens. The first patent family comprise five issued patents in the US, one in DE, one in FR and one in GB as well as one pending application in EP. The patent family is expected to expire in April 2032. The second patent family comprises one US patent, one European unitary patent (in force 17 EU-member states), one ES patent, one GB patent and one US and one EP pending applications. We expect the patent family to lapse in December 2034. The third patent family comprises one US, one GB, one DE and one FR registered patents. We expect the family to lapse in February 2037. Our fourth EVX-B1 related patent family comprises two issued US patents as well as pending applications in EP. We expect this patent family to lapse in July 2037. The fifth family claims a composition used for vaccination against *S. aureus* comprising our EVX-B1 vaccine. The application has entered national phase in AU, CA, CN, EP, JP and US. We expect this patent family to lapse in 2042.

EVX-B2

Our Patent portfolio related to EVX-B2 comprise two patent families. Both families are directed against antigens useful in vaccines against *N. gonorrhoeae*. The first patent family is at national stage and contains pending applications in EP and the US. Subject to grant, we expect these patents to expire in 2041. The second family has entered national phase in AU, CA, CN, EP, JP, ZA and US. We expect that pending applications, if granted, will be in force until 2042.

EVX-V1

The EVX-V1 product is protected by two patent families disclosing antigens and variants useful in a CMV vaccine. The first patent family is in international phase (PCT) and is, upon entry into national phase, expected to lapse in September 2044. The second family is still in priority year and will, if filed as a patent application and eventually granted (e.g. PCT application), be expected to be in force until 2046.

PIONEER™

The AI-Immunology™ model: PIONEER™ is mainly protected as a trade secret as computational methods are complicated to patent and protect from infringement. However, our current patent portfolio comprises one patent family related to PIONEER™ covering some aspects that are important for neoantigen selection and detectable for infringement and one patent family directed at a method for T-cell epitope identification. The first patent family is directed against a method for selecting and de-selection of neoantigens for treatment of cancer comprising the SLICE model used in PIONEER for epitope prioritization. The patent family have pending applications in AU, CA, CN, EP, JP and US. We expect the family to lapse in July 2041. The second family is directed against as method for identifying antigens (including neoantigens) using the AI-framework used in PIONEER™ for MHC ligand identification. The patent family is currently in priority year.

ObsERV™

The AI-Immunology™ model: ObsERV™ is, like the PIONEER™ model, protected by trade-secrets and one patent family. The family supplements the identification of neoantigens with a system for identifying highly immunogenic epitopes from human endogenous retroviral sequences, or hERVs, and other normally non-expressed tumor specific epitopes found in the human genome and use these to treat cancer. The patent discloses a method for deselecting potentially harmful and non-immunogenic hERV epitopes. This patent application is currently in national phase in AU, CA, CN, EP, JP and US.

RAVEN™

Our AI-Immunology™ model; RAVEN™, is in addition to trade secrets and the proprietary nature of the model, protected by two patent families. The first patent family is a composition of matter family directed to the vaccine delivery concept that can be utilized together with the RAVEN™ model. The family comprise one AU, one CA, one CN, one EP, one JP and one US patent application. We expect the patent family to lapse in July 2041. The second patent family also a matter of composition patent aimed at a vaccine product designed from analyzing genomes of pathogens by the RAVEN™ model. The patent family comprise one EP and one US patent application. We expect the patent family to lapse in 2042.

EDEN™

Our AI-Immunology™ model EDEN™, has provided input for multiple patent applications within our bacterial vaccine portfolio. The model itself is been kept as trade-secret.

In-Licensing

We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. On November 30, 2020, we entered into a CAF®09b Supply, Patent Know How Trademark License Agreement with Statens Serum Institut, or SSI, which will grant us an exclusive, royalty-bearing sub-licensable license to a product comprising SSI's adjuvant technology CAF®09b and PIONEER™ identified neopeptides. Pursuant to the terms of the agreement, we or our affiliates may import, have imported, export, have exported, formulate or have formulated, commercialize, market, use, offer for sale, sell, have sold, supply, or have supplied PIONEER™ derived cancer vaccines administered together or in combination with licensed adjuvant, but not, on a stand-alone basis, the licensed adjuvant. The license specifically excludes any manufacturing rights to the licensed adjuvant, unless the license is extended and the license further excludes any research and development in relation to the licensed adjuvant other than where such research and development is in connection with and for the purpose of research and development in respect of PIONEER™ derived cancer vaccines administered together or in combination with licensed adjuvant.

Pursuant to the SSI agreement, we have rights to three issued United States patents and other patents and patent applications in jurisdictions outside the United States.

The SSI license requires us to pay to SSI an upfront licensing fee equal to €50,000. In addition, in the event we commercialize any PIONEER™ derived cancer vaccines administered together or in combination with licensed adjuvant on our own, we are required to pay SSI a royalty on net sales in the low teens. The royalty term extends for a fixed period of 10 years commencing on the first calendar day of the calendar month following the first commercial sale of a PIONEER™ derived cancer vaccine administered together or in combination with the licensed adjuvant. Upon expiration thereof, the SSI license shall be deemed to be fully paid up, royalty-free, irrevocable and perpetual with respect to such vaccine. However, if any PIONEER™ derived cancer vaccine administered together or in combination with licensed adjuvant are commercialized by one of our partners, if any, we are required to pay SSI a percentage of any out-licensing revenue (milestones and royalties) earned by us and our affiliates. The size of the income share due to SSI shall be determined and reflect the extent to which we have invested in carrying out the Phase 2 and Phase 3 clinical trials in respect of the PIONEER™ derived cancer vaccines administered together or in combination with licensed adjuvant prior to entering into a sub-license agreement. If we enter into a sublicense agreement with a partner on our EVX-01 product candidate subsequent to the initiation of a Phase 2 clinical trial, we are required to pay to SSI a percentage of any sublicensing income in an amount in the lower double-digit range.

If we enter into a sublicense agreement with a partner on our EVX-01 product candidate subsequent to the initiation of a Phase 3 trial, we are required to pay to SSI a percentage of any sublicensing income in the mid-teens range. The agreements states that if we enter into a sublicense agreement with a partner on our EVX-01 product candidate without initiating Phase 2 trial, we are required to pay to SSI a percentage of any sublicensing income in the mid double-digit range. We have initiated a Phase 2 trial, hence this term is no longer relevant. Prior to any out-licensing commercialization of EVX-01, we are not required to make any additional payments to SSI outside of the €50,000 upfront fee mentioned above.

The SSI license will terminate on the earlier of (i) a fixed period of 10 years commencing on the first calendar day of the calendar month following the first commercial sale of a PIONEER™ derived cancer vaccine administered together or in combination with licensed adjuvant and (ii) the effective date of termination. In this connection, we or SSI may terminate the license upon prior written notice in the event of (a) a material breach which is not capable of remedy, or if capable of being remedied, such remedy does not occur within a specified time after notification or (b) an order is made or a resolution passed for the winding up of either SSI or us. In addition, we may terminate the SSI License upon prior written notice if we are not able to reach a supply agreement with SSI's designated commercial supplier of the licensed adjuvant. Apart from such causes, SSI may not terminate the license agreement and we may only terminate the SSI license on (c) the grounds of lack of efficacy of a PIONEER™ derived cancer vaccine administered together or in combination with licensed adjuvant, as a result of which we determine not to progress with the development and commercialization of such product or (d) due to safety concerns, market and/or competitive situation that would prevent commercialization of a PIONEER™ derived cancer vaccine administered together or in combination with licensed adjuvant.

On April 28, 2022, we received formal notice that on April 21, 2022, SSI, had initiated a legal proceeding against us in The Danish Maritime and Commercial High Court (S. og Handelsretten), claiming sole ownership of a patent application (PCT/EP2020/050058 and subsequently national filings, EP3906045), we had filed related to a method for treating malignant neoplasm by administering a composition comprising a high dose of neopeptides, a solvent and an liposomal adjuvant, e.g. CAF.09b, for which we have a license agreement.

On June 27, 2024, the Company entered into a Patent Co-Ownership Agreement with SSI, pursuant to which it has been agreed that the Company and SSI shall have co-ownership of certain patents related to the legal proceeding before The Danish Maritime and Commercial High Court, with the Company having all commercial rights related to such patents. This resolves the claim before the Danish Maritime and Commercial High Court and SSI has withdrawn its case.

Further on June 27, 2024, the Company entered into an updated CAF®09b Patent, Know How & Trademark License Agreement with SSI (the “License Agreement”), which replaces the original agreement entered into November 30, 2020. The License Agreement grants the Company an exclusive, royalty bearing sub-licensable license to a product comprising SSI’s adjuvant technology CAF®09b and PIONEER™ identified neopeptides. The License Agreement has been updated among other things to reflect for better commercial terms for the Company.

On June 29, 2020, we entered into a license agreement with PharmaJet or the PharmaJet License Agreement, which grants us non-exclusive, sub-licensable license to certain intellectual property of PharmaJet from one or more of our product candidates in the field of prophylaxis, diagnosis prediction, and/or treatment of cancer in humans and/or animals. Subject to meeting certain development milestones, additional consideration of up to \$320,000 is to be transferred to the seller. Further, \$250,000 is to be transferred to the seller upon each regulatory approval of an Evaxion product utilizing the in-licensed technology. Also, we will owe PharmaJet customary royalties in the low single digits based on net commercial sales of any products derived from our product candidates for so long as we continue to use in our product candidates the intellectual property and products licensed from PharmaJet pursuant to the PharmaJet License Agreement. The PharmaJet License Agreement will remain in effect for an initial period until successful completion of the first Phase 1/2a clinical study of our product candidate in combination with the PharmaJet product with the option to extend the term for additional 10 years, after which the term will automatically extend for successive periods of 24 months if not terminated prior to the beginning of each such subsequent extension. Either party may terminate the agreement upon six months prior notice with effect immediately prior to a subsequent extension term. Either party may terminate the agreement with immediate effect upon written notice to the other party due to a material breach by the other party. Moreover, we may terminate the agreement in the event of i) change of control or divestment, ii) regulatory action taken by the FDA or EMA, iii) termination of development of our product in combination with PharmaJet product or iv) if PharmaJet undergoes a change of control to a third party who does not agree to continue to supply us PharmaJet product.

Trade Secret Protection

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or AI-based prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including but not limited to algorithms and software, from becoming public knowledge. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, invention assignment agreements with our employees and internal processes for handling trade-secrets. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See “Risk Factors — Risks Related to our Intellectual Property” for a more comprehensive description of risks related to our intellectual property.

Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face potential substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

More specifically, we could face competition both on our AI-Immunology™ platform and our individual development candidates. Such competition could, in theory, come from a broad range of players active in AI-based target discovery for novel immunotherapies.

We face competition from several companies developing AI platforms and software. However, because most of these companies are not necessarily focused on developing therapeutic drug candidates centered around neoantigens, ERV antigens or bacteria or viral antigens, we do not consider the majority of them to be our direct competitors.

In principle, each of our R&D programs could face direct competition from other large and specialty pharmaceutical and biotechnology companies with drug candidates in development or on the market targeting the same indications and patient populations.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects or may obtain regulatory approvals more quickly than we are able to, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost, speed and convenience. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

4.C. Organizational Structure

Certain of our operations are conducted through our wholly owned subsidiaries, Evaxion Biotech Australia Pty Ltd (Australia) and Evaxion Biotech, Inc., in Australia and the United States, respectively, both of which are listed in Exhibit 8.1 to this annual report.

4.D. Property and Equipment

Our material tangible fixed assets relate to leased facilities, which are recognized and measured as right-of-use assets in the consolidated financial statements. We do not own any of our facilities.

Our corporate headquarters is located in Hørsholm, Denmark.

In October 2020, the Company entered a lease for approximately 1,356 square meters, which is allocated on 839 square meters of office space, and 518 square meters of laboratory space in Hørsholm, Denmark. The commencement date for the lease of 839 square meters of office space was February 1, 2021, and the lease continues for a term of 10 years from that date. The commencement date for the lease of the laboratory space is August 13, 2021, and the lease continues for a term of 10 years. Both leases have a subsequent 12-month cancellation notice period. The lease agreement contains an early termination provision which would trigger a termination fee of \$2.7 million. Throughout the term, the lease is subject to annual increases ranging from two to four percent on the annual lease payment amount.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

5.A. Operating Results

You should read the following discussion of our financial condition and results of operations in conjunction with our audited financial statements and the related notes thereto included elsewhere in this annual report as well as the discussion in the Business section of this annual report.

Our financial information is presented in our presentation currency, United States Dollar (USD). Our functional currency is the Danish Krone (DKK). Some DKK amounts in this discussion and analysis have been translated solely for convenience into USD at an assumed exchange rate of DKK 6.3527 per \$1.00, which was the official exchange rate of such currencies as of December 31, 2025, rounded to four decimal places.

In addition to historical information, the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are not historical facts, but rather reflect our plans, estimates, assumptions and projections about our industry, business and future financial results.

Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of various factors, including those set forth in the “Item 3.D. Key Information - Risk Factors” and “Special Note Regarding Forward-Looking Statements” sections and elsewhere in this annual report.

The financial statements as of December 31, 2025, and 2024 and for the years ended December 31, 2025, and 2024 were prepared in accordance with IFRS, as issued by the IASB.

The discussion included in the following sections covers our operating results in 2025 compared with 2024. For the discussion of our operating results in 2024 compared with 2023, reference is made to “Item 5. Operating and Financial Review and Prospects” included in our 2024 Annual Report on Form 20-F, filed with the SEC on April 1, 2025.

Overview

For a description of business highlights in 2025, please refer to “Item 4B. Information on the Company—Business Overview.”

Selected Financial Data

The selected historical consolidated financial information for the years ended December 31, 2025, and 2024 and the selected statements of financial position data as of December 31, 2025, and 2024 have been derived from, and should be read in conjunction with, the audited consolidated financial statements and notes thereto appearing elsewhere in this annual report.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this annual report and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion included below.

Consolidated Statements of Comprehensive Loss Data

	Years Ended December 31,	
	2025	2024
	(USD in thousands, except per share data)	
Consolidated Statement of Comprehensive Loss Data:		
Revenue	\$ 7,528	\$ 3,344
Research and development expenses	(9,975)	(10,457)
General and administrative expenses	(6,787)	(7,619)
Operating loss	(9,234)	(14,732)
Finance income	6,355	6,500
Finance expenses	(5,736)	(3,123)
Net loss before tax	(8,615)	(11,355)
Income taxes	908	788
Net loss for the period	\$ (7,707)	\$ (10,567)
Net loss attributable to equity holders of Evaxion A/S	\$ (7,707)	\$ (10,567)
Loss per share – basic and diluted	\$ (0.02)	\$ (0.20)
Number of shares used for calculation (basic and diluted)	320,406,391	53,644,483

Consolidated Statements of Financial Position Data

	December 31,	
	2025	2024
	(USD in thousands)	
Consolidated Statements of Financial Position Data:		
Cash and cash equivalents	\$ 23,234	\$ 5,952
Total assets	28,408	12,485
Total liabilities	11,369	14,137
Share capital	15,791	10,516
Other reserves	127,492	106,369
Accumulated deficit	(126,244)	(118,537)
Total equity (deficit)	17,039	(1,652)
Total liabilities and equity (deficit)	\$ 28,408	\$ 12,485

Key Components of Our Results of Operations

Revenue

Revenue primarily consists of licenses and services revenue earned as part of an option and license agreement and collaborative research agreement with MSD (tradename of Merck Sharp & Dohme LLC). Licenses revenues are recognized from non-refundable, up-front fees allocated to the license of intellectual property. Services revenues are recognized as we provide research and development services to the customer for achievement of development milestones under the option and license agreement. In addition to revenue earned from the agreement with MSD, the Company recognized grant revenue received from the Gates Foundation.

Research and Development

Research and development expenses are primarily internal and external costs incurred in the development of our product candidates, including personnel costs, share-based compensation, external research and development expenses, maintenance of our patents, overhead allocation and enhancements and maintenance of our technology platforms.

We may receive government grants or tax credits in the future that may result in a reduction of our research and development expenses.

The research activities are comprised of activities performed before filing an Investigational New Drug, or IND, or equivalent and necessary preclinical activities for such product candidates. All research expenses are recognized in the period in which they are incurred and payments made prior to the receipt of goods or services to be used in research and development are deferred until the goods or services are received. We record accruals for estimated research and development costs, including payments for work performed by third-party contractors and others. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid expenses or accrued expenses.

For the year ended December 31, 2025, substantially all of our third-party expenses were related to the development of product candidates in conjunction with our AI platforms. We deploy our personnel and facilities across all of our research and development activities. Costs incurred directly for individual programs consist primarily of trial and product production-related costs. Other costs such as share-based compensation, personnel and facilities expenses, which are not directly attributable to individual programs, are allocated between research and development and other functions and recorded as incurred.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf by third-party service providers and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Payments for these services are based on the terms of individual agreements and payment timing may differ significantly from the period in which the services were performed. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. In accruing service fees, we estimate the period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical and non-clinical studies, and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development.

General and Administrative

General and administrative expenses consist primarily of fees paid to external consultants and personnel costs, including share-based compensation for our executive, finance, corporate and business development functions. In addition, general and administrative expenses also include depreciation and lease expenses for corporate headquarters as well as other allocated overhead.

Finance Income

Finance income consists primarily of foreign currency gains, and gains from changes in fair value of liability-classified warrants.

Finance Expenses

Finance expenses consist primarily of foreign currency losses, losses from changes in fair value of the derivative liability, interest expense and related loan costs on the EIB Loan Agreement (as defined herein), and interest expense on leasing liabilities.

Income Taxes

We are subject to corporate taxation in Denmark and Australia and may be subject to taxation in other jurisdictions where we maintain subsidiaries or otherwise engage in business. Due to the nature of our business, we have generated losses since inception and have therefore not paid Danish taxes to date. Tax payable in Australia has been offset against tax receivable and receivable tax credits classified as government grants receivable. Tax on the profit or loss for the year comprises current tax. Tax is recognized in the statement of comprehensive loss, except to the extent that it relates to items recognized directly in equity, in which case it is recognized in equity. Current tax is the expected tax payable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the balance sheet date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. The amount of deferred tax is based on the expected manner of realization or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the balance sheet date. A deferred tax asset is recognized only to the extent that it is probable that future taxable profits will be available against which the asset can be utilized. No deferred tax assets are recognized for our losses carried forward because there is currently no indication that we will make sufficient profits to utilize these tax losses.

Research and development tax credits are available to the Group under the tax laws of Denmark and Australia respectively, based on qualifying research and development expenses as defined under those tax laws. Tax credits not exceeding the corporate tax rate are recognized as a reduction of income tax expense. Tax credits in excess of the corporate tax rate are classified as government grants. Tax credits are accrued for the year based on calculations that conform to Danish research and development programs. The current tax credits amount to 108% (2025).

Results of Operations

Comparison of the years ended December 31, 2025 and 2024:

	Years Ended December 31,		Change
	2025	2024	2025 vs 2024
	(USD in thousands)		
Revenue	\$ 7,528	\$ 3,344	\$ 4,184
Research and development expenses	(9,975)	(10,457)	482
General and administrative expenses	(6,787)	(7,619)	832
Operating loss	(9,234)	(14,732)	5,498
Finance income	4,616	6,500	(1,884)
Finance expenses	(3,997)	(3,123)	(87)
Net loss before tax	(8,615)	(11,355)	2,740
Income taxes	908	788	120
Net loss for the year	\$ (7,707)	\$ (10,567)	\$ 2,860

Revenue

Revenues were \$7.5 million for the year ended December 31, 2025, compared to \$3.3 million for the year ended December 31, 2024. The increase in revenue was primarily due to revenue recognized upon exercise under the option and license agreement with Merck & Co., Inc., as well as an additional \$0.1 million in revenue recognized from a grant from the Gates Foundation.

Research and Development

Research and development expenses were \$10.0 million for the year ended December 31, 2025, compared to \$10.5 million for the year ended December 31, 2024. The decrease in research and development expenses was primarily due to a decrease in external spending of \$1.4 million, offset by increased employee-related expenses of \$0.9 million.

General and Administrative

General and administrative expenses were \$6.8 million for the year ended December 31, 2025, as compared to \$7.6 million for the year ended December 31, 2024. The decrease was primarily due to external costs related to legal fees, professional fees, and costs related to capital raises.

Finance Income

Finance income for the year ended December 31, 2025, consists primarily of recognized gains of \$1.1 million from remeasurement of derivative liability related to the 2025 and 2024 Investor Warrants, \$2.6 million from the gain on conversion of the EIB loan, foreign currency gains of \$0.7 million, and interest income of \$0.2 million.

Finance income for the year ended December 31, 2024, consists primarily of recognized gains of \$5.5 million from remeasurement of derivative liability related to the 2024 Investor Warrants and 2023 SPA Warrants and foreign currency gains of \$0.5 million, a gain from changes in fair value of liability-classified warrants of \$0.2 million, and interest income of \$0.3 million.

Finance Expenses

Finance expenses for the year ended December 31, 2025, were \$4.0 million, compared to \$3.1 million for the year ended December 31, 2024. The increase in finance expenses was primarily driven by an increase in unrealized losses of \$0.7 million due to the remeasurement of derivative liability of the 2025 and 2024 Investor Warrants, as well as an increase of \$0.3 million in foreign currency exchange losses, partially offset by a decrease in interest expense of \$0.1 million.

Income Taxes

The income tax benefits were \$0.9 million for the year ended December 31, 2025, compared to \$0.8 million for the year ended December 31, 2024. Our effective tax rates for the year ended December 31, 2025, and 2024 were different from the Danish effective statutory tax rate of 22% as only expected tax receivables from R&D tax schemes in Denmark and Australia are recognized.

5.B. Liquidity and Capital Resources

For the discussion of Liquidity and Capital Resources for the year ended December 31, 2024, reference is made to “Item 5. Operating and Financial Review and Prospects” included in our 2024 Annual Report on Form 20-F, filed with the SEC on April 1, 2025.

Liquidity and Capital Resources

Overview

As a pioneering TechBio company using artificial intelligence to decode the human immune system and develop novel vaccines for cancer, bacterial diseases, and viral infections we are exposed to a variety of financial risks including liquidity risks. We have incurred significant losses and negative cash flows from operations since our inception. We generated revenues of \$7.5 million, and \$3.3 million, for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$126.2 million and expect to continue to incur significant losses for the foreseeable future.

As of December 31, 2025, and December 31, 2024, our available liquidity, comprised of cash and cash equivalents, was \$23.2 million and \$6.0 million, respectively and our total equity was \$17.0 million and \$(1.7) million, respectively. We have in the period ended December 31, 2025, generated revenues \$7.5 million primarily from our license agreement with Merck Sharpe Dome (MSD).

We monitor our funding situation closely to ensure that we have access to sufficient liquidity to meet our forecasted cash requirements. Analyses are run to reflect different scenarios including, but not limited to, cash runway, human capital resources and pipeline priorities to identify liquidity risk. This enables Management and the Board of Directors to prepare for new financing transactions and/or adjust the cost base accordingly.

With our current cash position, planned cash outflows from operating, investing and financing activities, we believe we will have sufficient funds into second half of 2027. If we are successful in delivering business development deals or partnership agreements during 2026, we will further extend our cash runway. Additionally, funding could also come through grants, equity offerings or use of other financing transactions or through investor warrants being exercised.

In August 2020, we executed a loan agreement, or the EIB Loan Agreement, with the European Investment Bank, or EIB, for a principal amount of €20.0 million, divided into three tranches of €7.0 million, €6.0 million and €7.0 million on the EIB Loan. Under the EIB Loan Agreement, the EIB Loan tranche balances are due six years from their respective disbursement dates. For all tranches, EIB is entitled to an aggregate of 1,003,032 cash settled warrants with an exercise price of 1 DKK per warrant. The 351,036 warrants attributable to the first tranche of €7.0 million were incorporated in the articles of association on December 17, 2020. As of December 31, 2021, we initiated the draw down of the first tranche of the EIB Loan Agreement amounting to €7.0 million. The Company received the first tranche of €7.0 million on February 17, 2022. The two remaining tranches have become void as of December 31, 2023.

In July 2025, we reached an agreement with EIB, where EIB converted €3.5 million of its €7 million loan to Evaxion into equity via a purchase of ordinary Evaxion warrants at a price of \$4.87, corresponding to a premium of 89% to the share price by market close the day before the announcement. The agreement immediately increased our equity by \$4.1 million (€3.5 million), bolstering our capital structure. Further, it substantially reduced our overall liabilities, simplified our balance sheet and improved our financial flexibility as well as future cash flow.

In October 2020, we entered into a lease for office and laboratory space in Hørsholm, Denmark. The commencement date office space was February 1, 2021, and a term of 10 years. In October 2020, we entered a lease agreement for additional laboratory space, in Hørsholm, Denmark. The commencement date for the lease was August 13, 2021, for a term of 10 years.

In addition to the ordinary lease payments, we obtained financing from DTU Science Park A/S (“DTU”) in 2021 for rebuilding the laboratory facility and engineering building to match our needs. We will repay the \$1.3 million financing at a fixed interest rate of 6% over 8 years. If the lease is terminated due to default by us before the outstanding balance, including interest accrued, has been repaid, the remaining balance is due immediately.

On June 7, 2022, we entered into a purchase agreement (the Purchase Agreement), with Lincoln Park Capital Fund, LLC (“Lincoln Park”), pursuant to which we have the right, but not the obligation, to sell to Lincoln Park up to \$40.0 million of our ordinary shares, DKK 1 nominal value, represented by ADSs, subject to certain limitations, from time to time over the 36-month period commencing on the date that a registration statement covering the resale of the ADSs is declared effective by the SEC. In connection with the execution and delivery of the Purchase Agreement, we issued 428,572 ordinary shares represented by ADSs to Lincoln Park as consideration for a commitment fee of \$1.2 million for Lincoln Park’s commitment to purchase ordinary shares represented by ADSs under the Purchase Agreement (Commitment Shares). In the Purchase Agreement, Lincoln Park represented to the Company, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, or the Securities Act). The securities were sold by the Company under the Purchase Agreement in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) of the Securities Act. The LPC Purchase Agreement has expired as of July 1, 2025.

On July 31, 2023, we entered into a financing agreement with Global Growth Holding Limited (“GGH”), for the issuance of convertible notes into the Company’s ordinary shares represented by ADSs, DKK 1 nominal value. Pursuant to the agreement, we may elect to sell to GGH up to \$20.0 million in such notes on any business day over the 36 month term of the agreement. We have the right, but not the obligation to direct GGH to purchase tranches of up to \$0.7 million, subject to certain limitations and conditions set forth in the agreement. In connection with the agreement, we are obligated to pay GGH a commitment fee totaling \$1.1 million. At any time, GGH may, in its sole discretion, convert the notes into ordinary shares at specified conversion prices upon submission of a request for conversion by GGH to us. As of December 31, 2025, the facility has not been used as the registration statement has not been filed with the SEC.

On January 24, 2025, the Company sold 696,400 ADSs at an average price of USD \$7.1776 per ADS. The ADSs were sold in an at-the-market (ATM) offering pursuant to the terms and subject to the conditions contained in that certain Capital Demand Sales Agreement between the Company and Jones Trading Institutional Services LLC dated October 3, 2022. After deducting fees and expenses, total proceeds to the Company from the sales of the ADSs were approximately \$4.85 million.

On January 31, 2025, the Company closed its public offering of an aggregate of 3,997,361 of its ADSs and warrants to purchase up to 50% of the ADSs offered at a combined public offering price of \$2.71 per ADS with one accompanying warrant for each two ADSs, with gross proceeds of \$10.8 million. The Company registered aggregate share capital increases of nominal DKK 49,967,012.50 with the Danish Business Authority, with effective date of January 31, 2025, corresponding to an aggregate increase in the Company’s share capital to nominal DKK 78,332,151.50. This reflected issuances of 199,868,050 shares in connection with the public offering.

On September 25, 2025, the Company sold 1,018,000 ADSs, representing the Company’s ordinary shares, DKK 0.25 nominal value with each ADS representing fifty (50) ordinary shares, at an average price of USD \$4.3931 per ADS. The ADSs were sold in an at-the-market (ATM) offering pursuant to the terms and subject to the conditions contained in that certain Capital Demand™ Sales Agreement between the Company and Jones Trading Institutional Services LLC dated October 3, 2022. After deducting fees and expenses, total proceeds to the Company from the sales of the ADSs were approximately \$4.3 million.

As of December 31, 2025, due to the issue of shares and warrant exercise, our outstanding share capital was nominal DKK 104,252,689.

Financing Requirements

Our funding strategy is to balance the funding of cash needs through equity offerings, or other capital sources in case this is not covered by income from potential collaborations or licenses.

We monitor our funding situation closely to ensure that we have access to sufficient liquidity to meet our forecasted cash requirements. Analyses are run to reflect different scenarios including, but not limited to, cash runway, human capital resources and pipeline priorities to identify liquidity risk. This enables Management and the Board of Directors to prepare for new financing transactions and/ or adjust the cost base accordingly.

Management and the Board of Directors has assessed the Company's ability to continue as a going concern and believes the Company has adequate resources to meet its obligations in the foreseeable future. Based on the Company's current financial position, available funding, and projected cash flows, Management and Board is confident that the Company will continue its operations for at least the next 12 months.

Accordingly, the annual report has been prepared on a going concern basis in accordance with applicable accounting standards.

We have considered potential risks and uncertainties, including market conditions, economic factors, and liquidity needs. After reviewing the Company's financial forecast and access to capital, the Board does not anticipate material uncertainties that would cast significant doubt on the Company's ability to continue as a going concern.

Our future financing requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our AI platforms and related models;
- the timing of, and the costs involved in providing support to our future partners, if any, in connection with their efforts in seeking regulatory approvals in the United States and elsewhere for any future products derived from our product candidates if clinical trials are successful;
- the cost of providing support to our future partners, if any, in connection with their commercialization activities for products derived from our product candidates, if approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any future product candidates for clinical trials and scaling up manufacturing in preparation for late stage clinical trials;
- the number and characteristics of additional product candidates that we pursue;
- our ability to establish and maintain collaborations, partnerships, licensing or other arrangements with third parties, including the timing of receipt of any potential milestone payments, licensing fees or royalty payments under these agreements;
- the impact of climate change on our business operations;
- the effects of the continuing conflict between Ukraine and Russia and other global conflicts, along with the retaliatory measures by the global community have created global security concerns,
- including the possibility of expanded regional or global conflict, which have had, are likely to continue to have, short-term and likely longer-term adverse impacts on Ukraine and Europe and around the globe;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense, and enforcement of any patents or other intellectual property rights;

- the timing, receipt, and amount of sales of, or royalties on, any products developed by our future partners, if any, derived from our product candidates;
- our need and ability to retain and hire additional management, scientific, technical and business personnel; and the extent to which we acquire or invest in businesses, products, or technologies (although we currently have no commitments or agreements relating to any of these types of transactions).

We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of current shareholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the current shareholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable and/or may reduce the value of our ordinary shares. Failure to raise capital or enter into such other arrangements when needed could have a negative impact on financial conditions and our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate our product candidate development or grant rights to develop and market our product candidates.

If we are unable to obtain additional financing on a timely basis we may be required to file for reorganization or liquidation under applicable reorganization or bankruptcy laws.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Years Ended December 31,	
	2025	2024
(USD in thousands)		
Cash Flow Data:		
Net cash used in operating activities	\$ (6,625)	\$ (12,940)
Net cash used in investing activities	(14)	(3)
Net cash provided by financing activities	22,410	13,129
Net (decrease)/increase in cash and cash equivalents	<u>\$ 15,771</u>	<u>\$ 186</u>

Operating Activities

Net cash used in operating activities was \$6.6 million for the year ended December 31, 2025. The largest components of our cash used in operating activities during this period was a net loss for the year of \$7.7 million, non-cash adjustments of \$0.6 million, and net cash change in our working capital of \$0.1 million, offset by net interest received of \$0.3 million. The non-cash charges primarily consisted of a gain on conversion of the EIB loan of \$2.6 million, income tax benefit of \$0.9 million, and interest income of \$0.3 million, offset partially by a loss on remeasurement of derivative liability of \$1.3 million, interest expense of \$0.9 million, depreciation expense of \$0.6 million, and exchange rate adjustment of \$0.1 million.

Net cash used in operating activities was \$12.9 million for the year ended December 31, 2024. The largest components of our cash used in operating activities during this period was a net loss for the year of \$10.6 million and non-cash adjustments of \$3.1 million, offset by net interest received of \$0.2 million and net cash change in our working capital during the period of \$0.5 million. The non-cash charges primarily consisted of a gain from changes in fair value of liability-classified warrants of \$3.7 million, income tax benefit of \$0.8 million, and interest income of \$0.3 million. These non-cash charges were offset by a depreciation of \$0.6 million, a gain from changes in fair value of liability-classified warrants of \$0.2 million, and interest expenses of \$0.9 million. The positive net cash attributable to changes in our current operating assets (excluding cash) and our current operating liabilities during the period was due to the timing and payment of invoices received from various minor items.

Investing Activities

Net cash used in investing activities was nil for the year ended December 31, 2025.

Net cash used in investing activities was nil for the year ended December 31, 2024.

Financing Activities

Net cash provided by financing activities was \$22.4 million for the year ended December 31, 2025, which was primarily due to net proceeds from the issuance of shares of \$25.1 million, partially offset by \$0.4 million related to repayment of lease liabilities and \$1.9 million related to transaction costs related to issuances of shares, as well as repayment of borrowings of \$0.4 million.

Net cash provided by financing activities was \$13.1 million for the year ended December 31, 2024, which was primarily due to net proceeds from the issuance of shares of \$16.6 million, partially offset by \$0.4 million related to repayment of lease liabilities and \$2.3 million related to transaction costs related to issuances of shares, as well as repayment of borrowings of \$0.8 million.

Off-Balance Sheet Arrangements

As of December 31, 2025, we did not have any material off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources. We did not have any other off-balance sheet arrangements, as defined in the rules and regulations of the SEC, as of or during the periods presented.

The following summarizes our contractual obligations, which include research and development and other service contract commitments, as of December 31, 2025.

Tabular Disclosure of Contractual Obligations

	Payments Due by Period				Total
	Within 1 Year	1–2 Years	2–5 Years	Over 5 Years	
			(USD in thousands)		
Leases ⁽¹⁾	\$ 374	\$ 381	\$ 1,190	\$ 550	\$ 2,495
Loan from lessor ⁽⁵⁾	190	202	345	—	737
EIB Loan ⁽⁶⁾	191	148	5,489	—	5,828
Purchase obligations ⁽²⁾	79	68	111	—	258
Total ⁽³⁾⁽⁴⁾	\$ 834	\$ 799	\$ 7,315	\$ 550	\$ 9,318

(1) In September 2020, we entered into a 10-year lease for office and laboratory space. The office space commenced in February 2021 and the laboratory space commenced in August 2021. The initial monthly payment was \$28,800 and the lease is subject to two to four percent increases in annual lease payment throughout the term.

- (2) The loan amount as of December 31, 2025, is still subject to possible minor adjustment. Further information is provided in Note 6 to our financial statements appearing at the end of this annual report.
- (3) Further information is provided in Note 6 to our financial statements appearing at the end of this annual report.
- (4) We enter into contracts in the normal course of business with Clinical Research Organizations, or CROs, and other third parties for clinical trials and preclinical research studies and testing. Purchase obligations in the preceding table include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions, and the approximate timing of the transaction. For obligations with cancellation provisions, the amounts included in the preceding table are limited to the non-cancelable portion of the agreement terms or the minimum cancellation fee.
- (5) In June 2020, we entered into a license agreement for the rights to certain intellectual properties which triggered a milestone payment of \$35,000 upon execution. Throughout the term, the agreement may require additional future milestone payments between \$70,000 to \$250,000.
- (6) In November 2020, we entered into a license agreement with SSI for the rights to three issued United States patents and other patents which triggered an upfront payment of \$60,000. In addition, in the event we commercialize any PIONEER derived vaccines administered together or in combination with licensed adjuvant on our own, we are required to pay SSI a royalty on net sales in the low teens. However, if any PIONEER derived vaccines administered together or in combination with licensed adjuvant are commercialized by one of our partners, if any, we are required to pay SSI a percentage of any out-licensing revenue (milestones and royalties) earned by us and our affiliates. The size of the income share depends on the stage of the development of any such immunotherapy when the out-licensing arrangement is entered into and ranges from the lower to mid double digits. For more information on the terms of the SSI license agreement see the section herein entitled “Business Overview — In-Licensing.”

Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to changes in market prices. The type of market risk that primarily impacts us is foreign currency risk.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The primary exposure derives from our expenditures in foreign currencies, mainly USD, AUD and GBP. This exposure is known as transaction exposure. We are exposed to foreign currency risk as a result of operating transactions and the translation of foreign currency bank accounts and short-term deposits. For the years ended December 31, 2025, and 2024, our net foreign exchange impact was a \$0.1 million loss, and \$0.3 million gain, respectively. We believe a 10% change in foreign exchange rate would not have a material impact on our operating results.

Interest Rate Risk

We manage interest rate risk by monitoring short- and medium-term interest rates and placing cash on deposit for periods that optimize the amount of interest earned while maintaining access to sufficient funds to meet day-to-day cash requirements. We do not currently have any loans or holdings that have variable interest rate. Accordingly, we are not exposed to material interest rate risk.

Recently adopted accounting pronouncements and accounting pronouncements not yet adopted

A description of recently adopted accounting pronouncements and accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is disclosed in Note 3 to our financial statements appearing at the end of this annual report.

5.C. Research and Development, Patents and Licenses, etc.

For a description of the Company’s research and development policies for the last three years see “Item 5. Operating and Financial Review and Prospects – A. Operating Results – Results of Operations – Research and Development.” For a description of Evaxion’s intellectual property, see “Item 4. Information On the Company – B. Business Overview – Intellectual Property Introduction.”

5.D. Trend Information

We are currently in the development stage, and we expect to remain in that stage for the upcoming year, and therefore trends relating to production, sales, inventory, backlog and selling prices are not applicable. See “Item 5. Operating and Financial Review and Prospects – A. Operating Results.”

5.E. Critical Accounting Estimates

The discussion in “Item 5.A. Operating and Financial Review and Prospects – Operating Results” is based on our financial statements, which have been prepared in accordance with IFRS, issued by the IASB. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in greater detail in Note 3 to our consolidated financial statements included in this annual report, the following discussion describes the judgments and estimates used in the preparation of our financial statements.

Share-Based Compensation

Accounting for share-based compensation requires us to make a number of judgments, estimates and assumptions. If any of our estimates prove to be inaccurate, our net loss and operating results could be adversely affected. Since our warrants issued before December 2021 are exercisable for nominal consideration, we estimate the fair value of warrant grants by using the fair value of the underlying ordinary share on the grant date. Prior to our initial public offering, we were required to estimate the fair value of our ordinary shares, as discussed in “Ordinary Share Valuation” below.

Prior to IPO, the fair value of each warrant grant is estimated on the date of grant using the interpolated ordinary share value. Warrants granted since 2021 were valued using Black-Scholes option pricing model, using the below-mentioned assumptions.

The table below summarizes the fair value by grant through December 31, 2025:

	Per warrant grant date fair value (DKK)	Per warrant grant date fair value (USD)
Outstanding program		
Grant (December 2016)	20.91	3.13
Grant (April 2017)	24.05	3.60
Grant (September 2017)	28.71	4.30
Grant (December 2017)	28.71	4.30
Granted (during 2018)	37.05	5.55
Granted (January 2019)	37.05	5.55
Granted (February 2019)	42.57	6.38
Granted (September 2019)	56.35	8.44
Granted (October 2019)	56.97	8.53
Granted (December 2019)	57.48	8.60
Granted (December 2020)	56.75	9.35
Granted (June 2021)	40.86	6.56
Granted (December 2021)	19.22	2.93
Granted (March 2022)	13.46	1.93
Granted (June 2022)	8.85	1.27
Granted (June 2022)	8.85	1.27
Granted (June 2022)	8.85	1.27
Granted (September 2022)	10.46	1.50
Granted (December 2022)	10.95	1.57
Granted (December 2022)	10.95	1.57
Granted (January 2023)	9.17	1.32
Granted (September 2023)	4.27	0.61
Granted (September 2023)	2.57	0.37
Granted (December 2023)	3.61	0.52
Granted (May 2024)	2.23	0.32
Granted (February 2025)	0.29	0.04
Granted (November 2025)	0.50	0.08

Ordinary Share Valuation

Prior to our initial public offering the fair value of our ordinary shares underlying our warrants has historically been determined by our board of directors with input from management, as there has been no public market for the ordinary shares. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our ordinary shares. Given the absence of a public trading market of our ordinary shares, our board of directors exercised reasonable judgement and considered numerous objective and subjective factors to determine the best estimate of the fair value of our ordinary shares at each grant date. These factors include important developments in our operations and development, financing transactions with unrelated parties, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price, and the lack of liquidity of our ordinary shares. Following our IPO, the fair value of each ordinary share is determined based on the ADSs closing sale price reported on the Nasdaq Capital Market.

Refer to Note 3 and Note 9 to our consolidated financial statements included in this annual report for additional detail on our accounting policy, judgements and assumptions used in accounting for share-based compensation.

EIB Loan and Warrant Liability

In February 2022, the first tranche related to the Company's loan agreement with EIB was drawn down. As part of the loan arrangement warrants were issued to EIB.

The liability is initially recognized at fair value, net of transaction costs incurred (this includes the amount attributable to the warrants. The loan is subsequently measured at amortized cost using the effective interest method. The effective interest rate is determined based on the outstanding amount and the fixed interest payments during the period outstanding and the accumulated payment-in-kind interest payment to be paid upon repayment.

In July 2025, we reached an agreement with EIB, where EIB converted €3.5 million of its €7 million loan to Evaxion into equity via a purchase of ordinary Evaxion warrants at a price of \$4.87, corresponding to a premium of 89% to the share price by market close the day before the announcement. The agreement immediately increased our equity by \$4.1 million (€3.5 million), and reduced our loan with EIB.

The warrants are considered to be part of the overall return to EIB on the financing arrangement and are thus accounted for in accordance with the financial instruments standards. The liability is measured initially at its fair value. The cost upon initial recognition is accounted for as transaction costs as it is directly linked to the drawdown on each individual tranche of the EIB Loan. The warrant liability is subsequently remeasured at the redemption amount. Significant judgment is made in respect of valuation of the warrants.

2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants

In December 2023 and February 2024, the Company entered into Securities Purchase Agreements with the 2023 SPA Investors and 2024 Public Offering Investors, for the issuance and sale in a private placement of the Company's ordinary shares, DKK 1 nominal value represented by ADSs and accompanying 2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants to purchase ordinary shares represented by ADSs. The Company determined that the 2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants are derivative financial instruments because while they contain no contractual obligation to deliver cash or other financial instruments to the holders other than the Company's own ordinary shares, the exercise price of the 2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants are in USD and not the Company's functional currency. The 2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants are accounted for in accordance with IFRS 9, Financial Instruments and were determined to be liability classified.

The warrant liability was measured at fair value at initial recognition and subsequently remeasured at fair value each reporting date until either exercised or expired. Significant judgment was made in respect of valuation of the warrants. The fair value of the warrants were determined using a Black-Scholes valuation model, considering relevant inputs, including the expected share price volatility, remaining contractual term, risk-free interest rate and expected dividend.

As announced on May 23, 2024, and on June 21, 2024, the Company entered into an amendment to each of its 2023 SPA Warrants and 2024 Investor Warrants. The amendments convert the exercise price per ADS for the 2023 SPA Warrants from \$7.07 to DKK 47.99 and for the 2024 Investor Warrants from \$4.00 to DKK 27.52, subject to adjustment (not taking into account the ADS Ratio Change in 2025). As the awards are no longer settled in foreign currency, the warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the derivative liability was reclassified to other reserves at the time of the amendment.

Refer to Note 6 for detailed information on the fair value measurement of the 2023 SPA Investor Warrants and 2024 Public Offering Investor Warrants, including the significant inputs, and the effect of changes in those inputs.

2025 Investor Warrants

As part of the January 2025 Public Offering, the Company issued warrants to all participating investors with an exercise price based on the traded price prevailing as of the issue date. As set out in IAS 32, the warrants were classified as derivative financial instruments due to the exercise price being denominated in a currency other than the Company's functional currency, and therefore the fixed for fixed criteria was not met. As such, the warrants were deemed derivative liabilities at issuance, and the liability were measured and remeasured at their fair value. The fair value of the 2025 Investor Warrants was determined using a Black-Scholes valuation model, considering relevant inputs, including the expected share price volatility, remaining contractual term, risk-free interest rate and expected dividend.

As announced on May 27, 2025, the Company entered an amendment to its 2025 Investor Warrants, with approximately 50% of the participating investors. The amendments convert the exercise price per ADS for the 2025 Investor Warrants from \$2.71 to DKK 19.15 on average. As the converted awards are no longer settled in foreign currency, the converted warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the converted portion of the derivative liability was reclassified to other reserves at the time of the amendment.

Refer to Note 6 for detailed information on the fair value measurement of the 2025 Investor Warrants, including the significant inputs, and the effect of changes in those inputs.

Leasehold Improvements and Loan from Lessor

Our lease contract comprises funding for the customization of the premises to our specific needs. The payment is determined based on the actual costs incurred for the customization, a repayment period of 8 years and an interest rate of 6% per annum. We have assessed whether this is a lease component, or a leasehold improvement funded by the lessor. We have considered the following factors:

1. Which party designed the customization
2. Which party had the right to direct changes to the work
3. Who is taking on the economic risk of the cost price of the work

A third party has designed the project according to our instructions, and we had the right to direct changes to the work during the construction period. Further, we have the full economic risk of the work due to 1:1 linkage between construction costs and payments to the lessor. Consequently, we have assessed that the customization is a leasehold improvement funded by the lessor and accordingly presented a leasehold improvement and a corresponding liability for the loan from the lessor.

Refer to Note 4 to our consolidated financial statements included in this annual report for additional detail on our accounting policy, judgements and assumptions used in accounting for the loan from the lessor.

Item 6. Directors, Senior Management and Employees

6.A. Directors and Senior Management

We have a two-tier governance structure consisting of a board of directors and an executive management team. The two bodies are separate. Below is a summary of relevant information concerning our board of directors, executive board and senior management.

Board of Directors

The following table sets forth certain information relating to our board of directors as of the date of this annual report. All members of our board of directors are elected for one year and eligible for re-election at each annual general meeting.

Name	Position	Age	Independent	Year of first appointment	Expiration of current term
Marianne Søgaard ⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾	Chairman	57	Independent	2020	2026
Roberto Prego ⁽¹⁾⁽²⁾⁽³⁾	Member	55	Independent	2018	2026
Lars Holtug ⁽²⁾⁽³⁾	Member	67	Independent	2021	2026
Lars Aage Staal Wegner ⁽¹⁾⁽⁴⁾	Member	52		2024	2026
Helen Tayton-Martin ^{(1) (4) (5)}	Member	59	Independent	2025	2026 ⁽⁵⁾

(1) Member of Nomination Committee

(2) Member of Audit Committee

(3) Member of Compensation Committee

(4) Member of Business Development Committee

(5) Appointed CEO of Evaxion as of November 24, 2025, and stepped down from the Board of Directors same date.

The following is a brief summary of the business experience of the members of our Board of Directors:

Marianne Søgaard joined us in 2018 as an executive and legal advisor and in November 2020 she was elected and became the Chairman of our board of directors. In 1996, Ms. Søgaard joined Kammeradvokaten/Law Firm Poul Schmith where she worked for more than 20 years as a lawyer, primarily working with technology and processes to acquire technology solutions. For more than 17 years, Ms. Søgaard was a partner at Kammeradvokaten/Law Firm Poul Schmith and from January 2014 to March 2017 she served on the board of directors of the law firm. Ms. Søgaard serves as a member of the board of directors at various privately held companies, including as the chairperson of the board at Garbanzo ApS, a small startup food company, Homemate ApS, a ready to cook food company, and Altapay A/S, a payment solution company. Ms. Søgaard received her Master of Law degree from Aarhus Universitet in 1993.

Roberto Prego joined us in 2018. Mr. Prego has over 20 years of pharmaceutical experience and was one of our first outside investors. Mr. Prego was with Teva Venezuela as its General Manager from 1998 to 2012 and with Teva Latin American Region as its Head of Region from 2011 to 2015. Since 2015, he has served as the General Manager of Viax Dental Technologies, a research and development venture firm in the dental field. Mr. Prego has a B.S. in Economics from Universidad Católica Andrés Bello in Caracas, Venezuela and an M.B.A. from Fuqua School of Business at Duke University.

Lars Holtug joined us in 2021. Mr. Holtug was a partner at PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, or PwC from 1993 to 2015. Mr. Holtug also currently serves as a board member of Ascendis Pharma and a chairman of Erhvervsinvest Management A/S, a private equity investment firm, Gaming Investment A/S, a gaming solutions provider, and its seven subsidiaries, and of Caretag ApS, a healthcare technology company. Previously, he was Chairman of PwC in Denmark from 2005 to 2009. From 2004 to 2015, Mr. Holtug was a member of the Danish Commercial Appeals Board (Erhvervsankenaevnet) and a board member of the Danish Company law association (Dansk Forening for Selskabsret). He was also a member of the Accounting Standards Board of the Federation of State Authorized Accountants in Denmark (Foreningen af Statsautoriserede Revisorer) from 1998 to 2002, and a member of the Auditing Standards Board from 1993 to 1998. Mr. Holtug holds an M.Sc. from Copenhagen Business School and is educated as a state authorized public accountant in Denmark.

Lars Aage Staal Wegner, M.D. joined us in 2013. Mr. Wegner was Chairman of the Board from 2013-2014, member of the board from 2015 to 2016 and was elected as CEO in July 2017, which he stepped down from in September 2022 and was then elected as a member of the board of directors in April 2024. Mr. Wegner works as VP of Business Development at Hengrui Pharmaceuticals, leading global pharmaceutical company committed to promoting a healthier life for humankind through advancements in science. He brings in deep experience in artificial intelligence and biotechnology finance, business development, and research. He has helped build numerous biotech, diagnostics, and IT companies, sitting on multiple boards. Earlier in his career, he held different roles of increasing responsibility at Bavarian Nordic A/S, including as Vice President of Commercial Affairs, during which time he contributed to developing the company's Ebola vaccine and different previous roles in Pfizer.

Executive Management

The following table sets forth certain information relating to our executive management as of the date of this annual report.

Name	Age	Position(s)
Helen Tayton-Martin, Ph.D.(1)	58	Chief Executive Officer
Thomas Frederik Schmidt, MSc	54	Chief Financial Officer
Birgitte Rønø, Ph.D.	49	Chief Scientific Officer
Andreas Holm Mattsson, MSc	50	Chief AI Officer

(1) Dr. Tayon-Martin was appointed CEO effective November 24, 2025.

The following is a brief summary of the business experience of our executive management:

Helen Tayton-Martin has served as our Chief Executive Officer since November 24, 2025, replacing Christian Kanstrup who stepped down as CEO on June 30, 2025. Holding a Ph.D. in molecular immunology, and an MBA from London Business School, Helen Tayton-Martin was a co-founder of cancer-focused biotech company Adaptimmune, where she served as Chief Operating Officer and later Chief Business & Strategy Officer during her 17 years with the company. Through this time, she oversaw transatlantic growth, multiple clinical, academic and commercial collaborations and private and public financing through to its Nasdaq IPO. Dr. Tayton-Martin was responsible for all Adaptimmune's strategic partnerships including those with Astellas, Genentech, a member of the Roche Group, GlaxoSmithKline and Galapagos NV.

Thomas Frederik Schmidt has served as our Chief Financial Officer since November 1, 2024. Mr. Schmidt brings more than 30 years of financial management experience from across different industries with more than 26 years of these being based in the life science industry including roles as country Managing Director and country Chief Financial Officer in Roche and Group CFO in Ambu, a MedTech company listed on the Nasdaq Copenhagen Stock Exchange. Mr. Schmidt holds a Master of Science in Business Economics and Auditing from Copenhagen Business School and has undergone training and preparation for State Authorized Public Accountant (CPA) exam.

Birgitte Rønø has served as our Chief Science Officer since 2021, having joined Evaxion in 2017. Dr. Rønø has more than 25 years of experience in biopharmaceutical drug discovery from academia and industry and received her PhD in experimental oncology and immunology from National Institutes of Health, Bethesda, USA, and Copenhagen University Hospital, Denmark. Prior to joining Evaxion, Birgitte Rønø served as a specialist, team leader and project manager at Novo Nordisk A/S, where she was leading early drug discovery projects, evaluating in-licensing opportunities, and supporting drug development projects with preclinical and biomarker expertise.

Andreas Holm Mattsson is founder of Evaxion and has served as Chief AI Officer. Mr. Mattsson has been at the forefront in silico-based vaccine target discovery. He has played a key role in developing Evaxion's innovative AI-Immunology™ platform, a proprietary AI technology for identifying novel vaccine targets for cancer and infectious diseases. Andreas brings a strong educational background in bioinformatics from the Technical University of Denmark and has previously worked at Novo Nordisk. Since founding Evaxion in 2008, he has been an essential part of the company's growth, serving in various executive roles.

Family Relationships

There are no family relationships among any of our directors and/or executive management.

6.B. Compensation

Compensation of Executive Management and Directors

The primary objective of our board of directors and senior management (executive board and non-executive senior management) compensation program is to attract, motivate, reward and retain the managerial talent needed to achieve our business objectives. In addition, the compensation program is intended to compensate all employees at competitive market rates, while recognizing extraordinary accomplishments.

The following table lists compensation to our board of directors for the years ended December 31, 2025, and 2024:

	Years Ended December 31,	
	2025	2024
	(USD in thousands)	
Marianne Sogaard (Chairman of the Board of Directors)		
Board and committee fees	\$ 155	\$ 143
Other Fee	—	33
Share-based compensation	41	32
Total	196	208
Roberto Prego		
Board and committee fees	58	61
Other Fee	—	—
Share-based compensation	6	8
Total	64	69
Lars Holtug		
Board and committee fees	64	59
Other Fee	—	—
Share-based compensation	6	8
Total	70	67
Lars Staal Wegner(3)		
Board and committee fees	49	31
Other Fee	—	—
Share-based compensation	5	1
Total	54	32
Helen Tayton-Martin(1)		
Board and committee fees	30	—
Other Fee	—	—
Share-based compensation	2	—
Total	32	—
Niels Iversen Møller(2)		
Board and committee fees	—	24
Other Fee	—	33
Share-based compensation	1	9
Total	1	66
Total		
Board and committee fees	356	318
Other Fee	—	66
Share-based compensation	61	58
Total	\$ 417	\$ 442

(1) Dr. Tayton-Martin was elected as member of the Board at the 2025 Annual General Meeting. Dr. Tayton-Martin stepped down from the Board as of November 24, 2025, as she was appointed CEO of Evaxion.

(2) Dr. Møller stepped down June 30, 2024.

(3) Dr. Wegner was appointed as a member of the Board in April 2024.

No member of the board of directors is entitled to any kind of compensation upon retirement from his or her position as a member of the board of directors. We have not allocated funds for any pension benefits, severance schemes or similar measures, or undertaken any other obligations to do so on behalf of the board of directors, and we have no obligation to do so.

The members of our executive management are eligible to receive an annual performance-based cash bonus subject to certain predefined corporate and individual goals as determined by our board of directors on an annual basis. The members of our executive management are also eligible to receive an extraordinary bonus at the discretion of our board of directors.

The following table presents compensation received by our executive management, for the years ended December 31, 2025, and 2024.

	Years Ended December 31,	
	2025	2024
	(USD in thousands)	
Helen Tayton-Martin (CEO)(1)		
Salary	\$ 37	\$ —
Bonus	7	—
Other employee benefits	31	—
Total	75	—
Thomas Frederik Schmidt (CFO)(2)		
Salary	350	77
Bonus	23	—
Other employee benefits	3	—
Total	376	77
Birgitte Røne, Ph.D. (CSO)(3)		
Salary	317	261
Bonus	60	52
Other employee benefits	25	30
Total	402	343
Andreas Holm Mattsson (CAIO)		
Salary	288	255
Bonus	54	51
Other employee benefits	22	20
Total	364	326
Christian Kanstrup (former CEO)(4)		
Salary	381	360
Bonus	—	72
Other employee benefits	27	50
Total	408	482
Jesper Nygaard Nissen (former COO & CFO)(5)		
Salary	—	233
Bonus	—	23
Other employee benefits	—	(2)
Total	—	254
Bo Karmark (former CFO)(6)		
Salary	—	46
Bonus	—	—
Other employee benefits	—	(23)
Total	—	23
Per Norlén (former CEO)(7)s		
Salary	—	95
Bonus	—	—
Other employee benefits	—	—
Total	—	95
Erik Deichmann Heegaard, Ph.D., DMSc (former CMO)(8)		
Salary	—	70
Bonus	—	—
Other employee benefits	—	(37)
Total	—	33
Total		
Salary	1,373	1,397
Bonus	144	198
Other employee benefits	108	38
Total	\$ 1,625	\$ 1,633

(1) Dr. Tayton-Martin joined us on November 24, 2025, as the Chief Executive Officer.

- (2) Mr. Schmidt joined us on November 01, 2024, as the Chief Financial Officer.
- (3) Dr. Rønø was appointed interim Chief Executive Officer from July 1, 2025, to November 24, 2025, in addition to her role as Chief Scientific Officer.
- (4) Mr. Kanstrup stepped down as Chief Executive Officer July 1, 2025, and with employment ending March 31, 2026.
- (5) Mr. Nissen resigned as COO & CFO effective as of October 30, 2024.
- (6) Bo Karmark stepped down as CFO in July 2023 and employment ended without further notice February 29, 2024.
- (7) Dr. Norlén resigned as the Chief Executive Officer of the Company effective August 31, 2023.
- (8) Dr. Heegaard contract terminated March 2023.

Executive Management Agreements

Helen Tayton-Martin, Ph.D.

In November 2025, we entered into an executive service contract with Dr. Tayton-Martin, who started in November 2025. Dr. Tayton-Martin's executive service contract also confirms her title, base salary, her eligibility for an annual bonus, and her eligibility for benefits and provides for certain benefits upon termination of her employment under specified conditions. Dr. Tayton-Martin's employment under the executive service contract continues until terminated by us or Dr. Tayton-Martin. We may terminate Dr. Tayton-Martin's employment for any reason with 6 months' notice and Dr. Tayton-Martin may terminate her employment with 6 months' notice.

Thomas Frederik Schmidt, M.Sc.

In November 2024, Thomas Frederik Schmidt joined Evaxion as interim Chief Financial Officer, and in July 2025 we entered into an executive service contract with Mr. Schmidt starting August 1, 2025. Mr. Schmidt's executive service contract also confirms his title, base salary, his eligibility for an annual bonus, and his eligibility for benefits and provides for certain benefits upon termination of his employment under specified conditions. Mr. Schmidt's employment under the executive service contract continues until terminated by us or Mr. Schmidt. We may terminate Mr. Schmidt's employment for any reason with 9 months' notice and Mr. Schmidt may terminate his employment with 3 months' notice.

Birgitte Rønø, Ph.D.

In September 2021, we entered into an executive service contract with Dr. Rønø. The contract confirms Dr. Rønø's employment by the Company since September 2017. Dr. Rønø's executive service contract also confirms her title, base salary, her eligibility for an annual bonus, and her eligibility for benefits and provides for certain benefits upon termination of her employment under specified conditions. Dr. Rønø's employment under the executive service contract continues until terminated by us or Dr. Rønø. We may terminate Dr. Rønø's employment for any reason with 12 months' notice and Dr. Rønø may terminate her employment with three months' notice.

Andreas Holm Mattsson

In September 2020, we entered into an executive service contract with Mr. Mattsson. The executive service contract confirms Mr. Mattsson's title, his base salary, his eligibility for an annual bonus, and his eligibility for benefits and also provides for certain benefits upon termination of his employment under specified conditions. Mr. Mattsson's employment under the executive service contract continues until terminated by us or Mr. Mattsson. We may terminate Mr. Mattsson's employment for any reason with 12 months' notice and Mr. Mattsson may terminate his employment with three months' notice.

Warrant Incentive Plan

Our directors, executive management, employees, consultants, and advisors are eligible to participate in our warrant incentive program. Warrants have been issued by the board of directors pursuant to valid authorizations in our articles of association or by the shareholders acting in general meetings.

The terms and conditions of the warrants have, in accordance with applicable Danish laws and regulations, been incorporated into our articles of association as appendices 1-3 and 5.

Warrants Granted during 2025

During 2025, the Company granted 6,544,725 warrants, of which 1,496,750 were granted to members of the Company's executive management team as follows; 61,850 were granted to the Chief Executive Officer; 247,400 were granted to the Chief Financial Officer; 593,750 were granted to the Chief Scientific Officer and 593,750 were granted to the Chief AI Officer. All granted employee and management warrants vest monthly over 36 months. Board warrants vest monthly over twelve months. The weighted average exercise price of the warrants granted during 2025 was USD 0.087 per warrant.

Warrants Granted during 2024

During 2024, the Company granted 538,460 warrants, of which 141,668 were granted to members of the Company's executive management team as follows; 16,668 were granted to its Chief Executive Officer ("CEO"), 25,000 were granted to its Chief AI Officer, 50,000 were granted to its Chief Scientific Officer and 50,000 were granted to its Chief Financial Officer. All granted employee and management warrants vest monthly over 36 months. Board warrants vest monthly over twelve months. The weighted average exercise price of the warrants granted during 2024 was USD 0.4 per warrant.

General Matters Related to Warrants

As of March 5, 2026, our board of directors is authorized to issue remaining nominal DKK 7,482,257 warrants during the period ending April 15, 2029, to members of the Company's Board, Executive Management as well as key-employees, advisors and consultants.

The grant of warrants to any participant is at the discretion of our board of directors and based on the recommendation of our Compensation Committee. The board of directors may determine the terms and conditions of the warrants issued, including exercise periods, subscription price and adjustments caused by changes to our company's share capital.

The table below provides an overview of the warrants granted to our board of directors and executive management as of December 31, 2025.

Name	Grant Date	Number of Ordinary Shares Underlying Warrants
Marianne Søgaard (Chairman)	2018-2025	353,487
Lars Aage Staal Wegner	2016-2025	625,896
Lars Holtug (Director)	2021-2025	59,583
Roberto Prego (Director)	2017-2018, 2021-2025	93,747
Helen Tayton-Martin (CEO)	2025	2,500,000
Andreas Holm Mattsson (CAIO)	2022-2025	191,250
Birgitte Røno (CSO)	2017-2019, 2021-2025	286,876

Warrants Granted to Investors and Consultants

No warrants have been granted to investors and consultants during 2025. The warrants granted during 2024 have expired during 2025.

Warrants Granted during 2024

In February the company granted 37,500,000 ordinary warrants and 29,925,000 pre-funded warrants to investors. Such warrants vested immediately, and the ordinary warrants may be exercised until February 5, 2029, whereas the pre-funded warrants do not expire.

In May the company granted 50,000 warrants to a consultant. The warrants vested immediately and expire in May 2025.

In August the company granted 1,400,000 and 50,000 warrants to two consultants. The warrants vested immediately and expire in February 2025 and August 2025 respectively.

Insurance and Indemnification

Under Danish law, members of the board of directors or senior management may be held liable for damages in the event where loss is caused due to their negligence. They may be held jointly and severally liable for damages to the company and to third-parties for acting in violation of the articles of association and Danish law.

The general meeting is permitted to discharge our directors and members of our executive management from liability for any particular financial year based on a resolution relating to the period covered by the financial statements for the previous financial year. This discharge means that the general meeting will relieve such directors and members of our executive management from liability to us. However, the general meeting cannot discharge any claims by individual shareholders or other third parties. In addition, the discharge can be set aside in case the general meeting prior to its decision to discharge was not presented with all reasonable information necessary for the general meeting to assess the matter at hand.

Additionally, we have agreed to indemnify our directors and members of our executive management and employees in relation to certain claims. We will not, however, indemnify our directors, executive management and employees, in respect of: (i) claims against a person pursuant to Danish law raised before the Danish Courts, except claims arising from the offer, sale and listing of our securities in the United States and/or our subsequent status as a listed company in the United States, including in respect of our reports filed with or furnished to the SEC; (ii) claims against a person for damages and legal costs related to criminal and/or grossly negligent or willful acts or omissions committed by the indemnified person; (iii) claims against an indemnified person, which is attributable to the gaining or purported gaining of any profit or advantage to which the indemnified person or any related natural or legal person was not legally entitled; (iv) claims covered by insurance; (v) claims brought against the indemnified person by the Company or any subsidiary of the Company; and (vi) any sum payable to a regulatory authority by way of a penalty in respect of the indemnified person's personal non-compliance with any requirement of a regulatory nature howsoever arising. The indemnification will be limited to a maximum amount per claim per person equivalent to the gross proceeds obtained by us in connection with the offering of ADSs in the United States. The indemnification shall remain in force for a period of five years after the resignation of the indemnified person from the company or its subsidiaries, if the claims made within such period are related to such person's services to us.

There is a risk that such indemnification will be deemed void under Danish law, either because the indemnification is deemed contrary to the rules on discharge of liability in the Danish Companies Act (*Selskabsloven*) as set forth above, because the indemnification is deemed contrary to sections 19 and 23 of the Danish Liability for Damages Act (*Erstatningsvarsloven*), which contain mandatory provisions on recourse claims between an employee (including members of our executive management) and the company, or because the indemnification is deemed contrary to the general provisions of the Danish Contracts Act (*Aftaleloven*).

In addition, we provide our directors and executive management with directors' and officers' liability insurance.

6.C. Board practices

Members of Our Board of Directors

Director Compensation Policy

Our board of directors and shareholders have approved and adopted a policy with respect to the compensation payable to our directors, which became effective as of January 1, 2024. Under this policy, each director will be eligible to receive compensation for his or her service on the board of directors and for service on each committee on which the director is a member, which will consist of annual cash retainers. Our directors have received the following annual cash payments for their service in 2025:

Board member	Position	Committees	Retainer
Marianne Sogaard	Chairman	Audit Committee Nominating Committee Compensation Committee Business Development Committee	\$ 155,000
Roberto Prego	Director	Audit Committee Nominating Committee Compensation Committee	\$ 58,000
Lars Holtug	Director	Audit Committee Compensation Committee	\$ 64,000
Lars Staal Wegner	Director	Nomination Committee Business Development Committee	\$ 49,000
Helen Tayton-Martin	Director	Nomination Committee Business Development Committee	\$ 30,000

Directors may also receive equity awards. Directors will be reimbursed for travel, food, lodging and other expenses directly related to their service as directors. Directors are also entitled to the protection provided by their indemnification agreements and the indemnification provisions in our current certificate of incorporation and bylaws, as well as our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon completion.

Committees of our Board of Directors

Our board of directors has four standing committees: Audit Committee, Compensation Committee, Capital Markets and Business Development Committee, and Nomination and Corporate Governance Committee.

Audit Committee

The audit committee consists of Lars Holtug, Marianne Sogaard and Roberto Prego, and assists the board of directors in overseeing our accounting and financial reporting processes. Mr. Holtug serves as chairperson of the audit committee. The audit committee consists exclusively of members of our board of directors who are financially literate, and Mr. Holtug is considered an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that all of the members of the audit committee satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act and the Nasdaq rules as of December 31, 2023, and prior to that date we relied on home country rules of Denmark that did not prohibit non-independent audit committee members and Nasdaq Rule 5615(a)(3), which provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and in particular Nasdaq Rule 5605(c)(2). The audit committee has been in compliance with Nasdaq Rule 5605(c)(3). The audit committee is governed by a charter that complies with Nasdaq rules.

The audit committee’s responsibilities include, among other things:

- recommending and supervising our external auditors;
- pre-approve all non-audit services to be provided by any external auditors exceeding a cap determined by our board of directors;
- providing our board of directors with advice regarding the proposed external auditors from time to time as well as evaluate the quality of work being performed by the external auditors;
- ensuring that appropriate policies with regard to hiring employees from our external auditors are in place;

- reviewing and monitoring the independence and quality of work being performed by our external auditors, especially the appropriateness of the provision of non-audit services;
- evaluating the information contained in our external financial reporting;
- reviewing our annual and quarterly financial statements prior to publication and/or filing (or submission, as the case may be) with the SEC;
- informing our board of directors of the result of the statutory audit, including the financial reporting process;
- monitoring the financial reporting process and submit recommendations or proposals to ensure its integrity and monitoring of remediation of the material weakness in internal controls over financial reporting;
- evaluating the “going-concern” principle, including any special assumptions, qualifications and/or uncertainties related thereto;
- evaluating the main accounting policies and principles applied including to make recommendations to our board of directors regarding whether these should be amended;
- evaluating significant accounting estimates and judgments made and changes hereto;
- reviewing and evaluating transactions with related parties;
- evaluating relevant risks and uncertainties for the relevant year, e.g. in relation to the outlook in the financial reporting;
- evaluating the overall presentation of our financial reporting in order to ensure that it provides a true and fair view of the financial position as well as our development and performance;
- evaluating our compliance with relevant audit and accounting related laws and regulations;
- supervising our internal audit program;
- such other matters that are specifically delegated to our audit committee by our board of directors from time to time; and
- meeting separately, periodically, with management, internal auditors and the independent auditor.

Compensation Committee

The compensation committee consists of Roberto Prego, Lars Holtug and Marianne Sogaard. Mr. Prego serves as chairperson of the compensation committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard director fees. Our board of directors has determined that all the members of the compensation committee satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act and the Nasdaq rules. Until December 2023, Ms. Sogaard was not deemed to be independent under Nasdaq Rule 5605(a)(2)(A), since as noted herein, she was an executive and legal adviser of our company during the past three (3) years, but we relied on home country rules of Denmark that did not require a compensation committee, and Nasdaq Rule 5615(a)(3), which provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and in particular Rule 5605(d)(2).

The compensation committee’s responsibilities include, among other things:

- At least annually, review the compensation philosophy of the Company;
- Obtain information on market trends in executive compensation and shall review the competitiveness of the Company’s executive compensation programs to ensure (i) the attraction and retention of officers;

- At least annually, review and recommend to the Board for approval the corporate goals and objectives relevant to CEO and other officer compensation, evaluate CEO and officer performance in light of those goals and objectives, and review and recommend to the Board all compensation of the Company's officers based on such evaluation;
- Periodically and as and when appropriate, review and recommend to the Board the following as they affect the Company's officers: (i) any employment agreements and severance arrangements, including any amendments, supplements or changes thereto; (ii) any change-in-control agreements and change-in-control provisions affecting any elements of compensation and benefits and (iii) any special or supplemental compensation and benefits for the officers and individuals who formerly served as officers, including supplemental retirement benefits and the perquisites provided to them during and after employment;
- Oversee the Company's compliance with the requirement under Nasdaq rules that, with limited exceptions, shareholders approve equity compensation plans. Subject to such shareholder approval, or otherwise required by the Exchange Act, the Code or other applicable law, the Committee shall have the power to periodically review and make recommendations to the Board regarding annual bonus, long-term incentive compensation, equity awards, employee pension and welfare benefit plans including 401(k) plans, employee share purchase plans, long-term incentive plans, management incentive plans and others and with respect to each plan shall have responsibility for making recommendations to the Board;
- Be responsible for recommending that the Board certify that any and all performance targets used for any performance-based compensation plans have been met before payment of any officer bonus or compensation or exercise of any officer award granted under any such plan(s);
- Periodically review and make recommendations to the Board regarding policies concerning perquisite benefits;
- Determine the Company's policy with respect to change of control or "parachute" payments;
- Monitor the Company's compliance with applicable legal requirements of the Sarbanes Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act and other applicable local laws and regulations relating to employee compensation and benefits;
- Review and make recommendations regarding the compensation policies applicable to all employees of the Company, including periodic reviews of the adequacy of the Company's compensation structure, performance review procedures, employee turn-over and retention, succession plans and other human resource issues;
- Review and discuss with the Executive Management of the Company the compensation disclosures to be included in the Company's filings and submissions with the SEC;
- Periodically review and make recommendations to the Board with respect to the compensation of the Board's non-management board members;
- Annually and with input from the Nominating and Corporate Governance Committee of the Board if deemed appropriate, perform an evaluation of the performance of the Committee and its members; and
- Annually and with input from the Nominating and Corporate Governance Committee if deemed appropriate, review and reassess this Charter and submit any recommended changes to the Board for its consideration.

Capital Markets and Business Development Committee

The Capital Markets and Business Development Committee consists of Marianne Søgaard, Helen Tayton-Martin (stepped down November 24, 2025, as she took role of CEO of Evaxion), and Lars Staal Wegner. Ms. Søgaard serves as chairperson of the committee.

The Committee will review and comment on the Company's business development, capital market strategy and/or plan and whether the Company is being properly valued and positioned with shareholders whose investment objectives are consistent with the Company's strategy of creating and attaining long-term shareholder value.

The Business Development Committee's responsibilities include, among other things:

- Review and assess the overall capital markets activities, business development and communication strategy and/or plan periodically to determine its status and progress.

- Periodically review issues that affect capital markets activities, business development and communication including trends in corporate governance, shareholder activism, and regulatory actions.
- Monitor the results of the capital market activities, business development and communication strategy and/or plan and offer suggestions for improvement.
- Ensure that Executive Management has allocated adequate resources to support the implementation and achievement of the objectives of the capital market activities, business development and communication strategy and/or plan.
- Based on information provided by the Executive Management, make recommendations - as necessary - to the Board on possible actions with regard to shareholder engagement and value.
- Receive and review information from various sources as necessary.
- Participate to the extent necessary or desirable in meetings with investors or potential investors.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee consists of Roberto Prego, Lars Staal Wegner and Marianne Sogaard. Mr. Prego serves as chairperson of the nomination and corporate governance committee. All Committee members, Mr. Prego, Mr. Wegner and Ms. Sogaard (as of December 2023) meet Nasdaq's independence requirements for membership on the Nomination and Corporate Governance Committee. Prior to December 2023, we relied on home country rules of Denmark that did not require a nomination and corporate governance committee and Nasdaq Rule 5615(a)(3), which provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and in particular Nasdaq Rule 5605(e)(1).

The Nomination and Corporate Governance Committee's responsibilities include, among other things:

- Prior to each annual meeting of stockholders at which board members are to be elected or reelected, the Committee shall recommend to the Board for nomination by the Board such candidates as the Committee, in the exercise of its judgment, has found to be well qualified and willing and available to serve.
- After a vacancy arises on the Board or a member of the Board advises the Board of his or her intention to resign, the Committee shall recommend to the Board for appointment by the Board to fill such vacancy, such prospective member of the Board as the Committee, in the exercise of its judgment, has found to be well qualified and willing and available to serve.
- Annually, review the performance of each current board member and shall consider the results of such evaluation when determining whether or not to recommend the nomination of such board member for an additional term.
- In appropriate circumstances, the Committee, in its discretion, shall consider and may recommend the removal of a board member for cause, in accordance with the applicable provisions of the Rules of Procedure and applicable law.
- Oversee the Board in the Board's review of its performance (including its composition and organization), which will occur once per fiscal year, and will make appropriate recommendations to improve performance.
- Make recommendations to the Board regarding governance matters, including, but not limited to, the Rules of Procedure, this Charter and the charters of the Board's other committees.
- Review and assess the composition of the various committees of the Board and recommend, for approval by the Board, the assignment and rotation of Board members to such committees.
- Develop, review, and recommend to the Board the Rules of Procedure and, on a regular basis, review and recommend revisions to the Rules of Procedure.
- Develop and recommend to the Board a policy regarding the consideration of candidates to the Board recommended by the Company's security holders and procedures for submission by security holders of nominee recommendations to the Board.
- Consider, develop, and recommend to the Board such policies and procedures with respect to the nomination of members to the Board or other corporate governance matters as may be required or required to be disclosed pursuant to any rules promulgated by the Securities and Exchange Commission, Nasdaq, or otherwise considered to be desirable and appropriate in the discretion of the Committee.
- Review the leadership structure of the Board and provide the Board with any recommendations for changes in such leadership structure.

- Recommend to the Board the employment and appointment of future executive officers, as well as promotion and changes in position of incumbent executive officers upon review of their performance.
- Periodically report to the Board on its findings and actions.
- At least annually, perform an evaluation of the performance of the Committee and its members, including a review of the Committee's compliance with this Charter, and provide any written material with respect to such evaluation to the Board, as appropriate, including any recommendations for changes in procedures or policies governing the Committee. The Committee shall conduct such evaluation and review in such manner as it deems appropriate.
- Review and reassess this Charter at least annually and submit any recommended changes to the Board for its consideration.

6.D. Employees

As of December 31, 2025, and 2024, Evaxion had 46 and 46 full-time equivalent, respectively. All our employees are engaged in either research and development or general and administrative functions. None of our employees are represented by a labor union, and are not covered under a collective bargaining agreement. We consider our employee relations to be good.

6.E. Share Ownership

See "Item 7.A. Major Shareholders and Related Party Transactions – Major Shareholders." Our employees are eligible to own shares of the company through a warrant incentive plan. For information on the plan, see "Item 6.B. Compensation—Warrant Incentive Plan."

Item 7. Major Shareholders and Related Party Transactions

7.A. Major Shareholders

The following table presents information, as of December 31, 2025, regarding the beneficial ownership of our ordinary shares by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and members of our executive management individually; and
- each of our directors and members of our executive management as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our board of directors or members of our executive management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of December 31, 2025, through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

The percentage of beneficially owned is computed on the basis of 417,010,756 ordinary shares outstanding as of December 31, 2025. Ordinary shares that a person has the right to acquire within 60 days of December 31, 2025, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. Unless otherwise indicated, the business address for each beneficial owner is Dr. Neergaards Vej 5F, DK-2970 Hørsholm, Denmark.

Name of beneficial owner	Shares beneficially owned	
	Number	Percent
<i>5% or Greater Shareholders</i>		
Merck Global Innovation Fund LLC(1)	63,004,138	15.03
<i>Executive Management</i>		
Helen Tayton-Martin(2)	277,778	*
Thomas Frederik Schmidt(3)	968,600	*
Birgitte Rønø(4)	262,871	*
Andreas Holm Mattsson(5)	6,330,118	1.52
<i>Directors</i>		
Marianne Søgaard(6)	6,473,997	1.54
Lars Holtug(7)	483,391	*
Roberto Prego(8)	1,402,789	*
Lars Staal Wegner(9)	837,900	*
All current directors and executive management, as a group (8 persons)	17,037,444	4.07

* Represents beneficial ownership of less than 1%

- (1) Includes 2,297,794 shares subject to warrants that are exercisable within 60 days of December 31, 2025. The address of Merck Global Innovation Fund LLC is c/o Merck & Co., Inc., Rahway, NJ, USA.
- (2) Includes 277,778 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (3) Includes 322,850 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (4) Includes 226,106 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (5) Includes 805,152 shares subject to warrants that are exercisable within 60 days of December 31, 2025, as well as 4,142,521 ordinary shares held by Mattsson Holding af 2008 ApS, which is a personal investment company wholly owned by Mr. Mattsson.
- (6) Includes 2,610,882 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (7) Includes 225,362 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (8) Includes 231,759 shares subject to warrants that are exercisable within 60 days of December 31, 2025.
- (9) Includes 708,761 shares subject to warrants that are exercisable within 60 days of December 31, 2025.

Holdings by United States Shareholders

As of December 31, 2025, approximately 44% of our issued and outstanding ordinary shares were held by more than 2,800 United States record holders. The number of individual holders is based exclusively upon the Non-Objecting Beneficial Owners (NOBO) List, combined with our share register, relative to our total number of outstanding shares.

Significant Changes in Percentage Ownership

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. To Evaxion's knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with Evaxion's initial public offering in the United States, the two follow on public offerings and the private placement there has been no significant change in the percentage ownership held by the major shareholders listed above in the last three years, except as discussed in "Item 7.B. Related Party Transactions."

7.B. Related Party Transactions

There are no grants, agreements, and transactions in which the amount involved exceeded or will exceed \$120,000, and in which any of our then directors, executive management or holders of more than 10% of any class of our voting securities at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest.

Share-based Awards for Directors and Executive Management

We have granted share-based awards to certain of our directors and executive management. For more information regarding the warrants granted to our executive management and directors see the section herein entitled "Warrant Incentive Plan".

Employment Agreements and Indemnification Agreements

We have entered employment agreements with each member of our executive management and intend to enter into indemnification agreements with each member of our executive management and each of our directors. For more information see the sections herein entitled “Compensation of Executive Officers and Directors” and “Insurance and indemnification.”

Policies and Procedures for Related Person Transactions

Prior to our IPO, we have not had a formal policy regarding approval of transactions with related parties. We have adopted a related person transaction policy setting forth the policies and procedures for the identification, review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and a related person were or will be participants and the amount involved exceeds \$120,000, including purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness and guarantees of indebtedness. In reviewing and approving any such transactions, our audit committee will consider all relevant facts and circumstances as appropriate, such as the purpose of the transaction, the availability of other sources of comparable products or services, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction, management’s recommendation with respect to the proposed related person transaction, and the extent of the related person’s interest in the transaction.

7.C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

8.A. Consolidated Statements and Other Financial Information

See “Item 18. Financial Statements.”

Legal Proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Evaxion is aware) that may have or have had in the recent past (covering the 12 months immediately preceding the date of this annual report), significant effects on Evaxion’s financial position or profitability.

Dividend Policy

Evaxion does not expect to pay dividends in the foreseeable future. If we pay any dividends on our ordinary shares, we will pay those dividends, which shall be payable in respect of the ordinary shares underlying the ADS to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to the ADS holders in proportion to the ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. Cash dividends on our ordinary shares, if any, will be paid in USD.

Legal and Regulatory Requirements

In accordance with the Danish Companies Act, dividends, if any, are declared with respect to a financial year at the annual general meeting of shareholders in the following year, where the statutory annual report (which includes the audited financial statements) for that financial year is approved. Any resolution to distribute interim dividends within six months of the date of the statement of financial position as set out in our latest adopted annual report must be accompanied by the statement of financial position from our latest annual report or an interim statement of financial position which must be reviewed by our auditor. If the decision to distribute interim dividends is passed more than six months after the date of the statement of financial position as set out in our latest adopted annual report, an interim statement of financial position must be prepared and reviewed by our auditor. The statement of financial position or the interim statement of financial position, as applicable, must show that sufficient funds are available for distribution. Dividends may not exceed the amount recommended by the board of directors for approval by the general meeting of shareholders. Moreover, dividends and interim dividends may only be made out of distributable reserves and may not exceed what is considered sound and adequate with regard to our financial condition or be to the detriment of our creditors and such other factors as the board of directors may deem relevant.

In accordance with the Danish Companies Act, share buybacks, if any, may only be carried out by the board of directors using funds that could have been distributed as dividends at the latest annual general meeting of shareholders. Any share buyback must be conducted in accordance with an authorization obtained at a general meeting of our shareholders. Authorization must be granted for a defined period of time not exceeding five years. In addition, the authorization must specify the maximum permitted value of treasury shares as well as the minimum and maximum amount that we may pay as consideration for such shares. A decision by our board of directors to engage in share buybacks, if any, will be made in accordance with the factors applicable to dividend payments set forth above.

See “Item 10.E. Taxation – Danish Tax Considerations” for a description of Danish withholding taxes and certain other Danish considerations relevant to the purchase or holding of ordinary shares and ADSs and “Item 10.E. Taxation – Certain Material United States Federal Income Tax Considerations” for a description of United States federal income tax considerations relevant to the purchase or holding of shares and ADSs.

8.B. Significant changes

See Note 24 “Events After the Reporting Period” to the audited consolidated financial statements included elsewhere in this Form 20-F.

Item 9. The Offer and Listing

9.A. Offer and Listing Details

ADSs/Ordinary Shares

Our ADSs, each representing fifty ordinary shares, with a DKK 0.25 nominal value per share, have been listed on The Nasdaq Capital Market since February 5, 2021. Our ADSs trade under the symbol “EVAX.” Prior to that date, there was no public trading market for our ADSs.

On January 17, 2025, an extraordinary general meeting of Evaxion was held, where it was approved to reduce our share capital by nominal DKK 58,980,417 from nominal DKK 78,640,556 to nominal DKK 19,660,139 to cover loss. Furthermore, it was approved to reduce the nominal value of the shares from nominal DKK 1 per share to nominal DKK 0.25 per share, and our Article of Association were amended accordingly.

ADS Ratio Change

On January 14, 2025, we made effective a change to our ratio of ADSs to ordinary shares, DKK 1 nominal value (the “ADS Ratio”). The ratio has changed from one ADS representing ten (10) ordinary shares to a new ADS Ratio of one ADS representing fifty (50) ordinary shares of the Company. Unless specified otherwise, all references in this annual report to ADS share and ADS per share data have been adjusted, including historical data which has been retroactively adjusted, to give effect to the ADS Ratio change.

9.B. Plan of Distribution

Not applicable.

9.C. Markets

For a description of our publicly-traded ADSs, see “Item 9.A. Offer and Listing Details—ADSs/Ordinary Shares.”

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

10.A. Share Capital

Development of the Share Capital

As of December 31, 2025, our registered, issued and outstanding share capital was nominal DKK 104,252,689 divided into 417,010,756 ordinary shares of DKK 0.25. Following the reduction of the nominal share capital to DKK 0.25 per share approved at extra ordinary general meeting the share capital was reduced from DKK 78,640,556 to DKK 19,660,139. Since December 31, 2024 s set forth in the table below. Since December 31, 2024, the below share capital transactions have been made based on the registrations with the Danish Business Authority:

Date	Transaction	Share Capital After Transaction	Price Per Share (DKK)
December 31, 2024		70,130,556	
January 2025	Prefunded Warrant Exercise	78,640,556	1.00
January 2025	Reduction of share capital from DKK1 to DKK 0.25 per share	19,660,139	
January 2025	JonesTrading Sales Agreement (696,400 ADSs / 34,820,000 new share issue)	28,365,139	1.02
January 2025	Public offering (3,997,361 ADSs /199,868,050 new share issue)	78,332,152	0.39
February 2025	Warrant Exercise	78,957,152	0.39
September 2025	JonesTrading Sales Agreement (1,018,000 ADSs / 50,900,000 new share issue)	91,682,152	0.56
October 2025	Warrant Exercise	103,783,939	0.35
November 2025	Warrant Exercise	104,252,689	0.35

10.B. Memorandum and Articles of Association

The following describes our issued share capital, summarizes the material provisions of our articles of association and highlights certain differences in corporate law in the Kingdom of Denmark and Delaware corporate law, the law under which many publicly listed companies in the United States are incorporated. Please note that this summary is not intended to be exhaustive. For further information, please refer to the full version of our articles of association, which are included as an exhibit to this annual report.

Introduction

Set forth below is a summary of certain information concerning our share capital as well as a description of certain provisions of our articles of association and relevant provisions of the Danish Companies Act. The summary includes certain references to and descriptions of material provisions of our articles of association to be effective in connection with the consummation of the offering and Danish law in force as of the date of this annual report. The summary below contains only material information concerning our share capital and corporate status and does not purport to be complete and is qualified in its entirety by reference to our articles of association. Further, please note that as an ADS holder you will not be treated as one of our shareholders and will not have any shareholder rights.

General

We were incorporated under the laws of the Kingdom of Denmark on August 11, 2008, as a private limited liability company (in Danish: *Anpartsselskab*, or *ApS*) under Danish law and are registered with the Danish Business Authority (in Danish: *Erhvervsstyrelsen*) in Copenhagen, Denmark under registration number 31762863. On March 29, 2019, our company was converted into a public limited liability company (in Danish: *Aktieselskab*, or *A/S*). Our principal executive offices are located at Dr. Neergaards Vej 5f, DK-2970 Hoersholm, Denmark. Our website address is www.evaxion.ai. The information on, or that can be accessed through, our website is not part of and is not incorporated by reference into this annual report. We have included our website address as an inactive textual reference only.

Authorizations to the Board of Directors

As of December 31, 2025, our board of directors is authorized to increase the share capital as follows:

- The board of directors is until January 3, 2026, authorized at one or more times to increase the company's share capital by the issuance of new shares with up to nominal DKK 11,000,000 with pre-emptive subscription rights for the company's shareholders. Capital increases according to this authorization shall be carried out by the board of directors by way of cash contributions. The shares may be issued at market price or at a discount price as determined by the board of directors.
- The board of directors is until January 3, 2026, authorized at one or more times to obtain loans against issuance of convertible loan notes which give the right to subscribe for shares for a total of up to nominal value of DKK 14,700,000 without pre-emptive subscription rights for the company's shareholders. The conversion shall be carried out at a price that corresponds in aggregate to at least the market price at the time of the decision of the board of directors. Shares shall be considered issued at market price if the shares are issued at +/-10 of the listed price for the company's shares on a relevant stock exchange in Europe or the USA.
- The board of directors is until April 15, 2029, authorized at one or more times to issue warrants to members of our board of directors and executive management, as well as to key employees, and to increase our share capital by up to nominal DKK 9,118,438.25 without preemptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof.
- The board of directors is until 15 April, 2029, authorized at one or more times to issue warrants to investors, lenders, consultants and/or advisors in the company or its subsidiaries entitling the holder to subscribe for shares for a total of up to nominal value of DKK 90,387,500 without pre-emptive subscription rights for the company's shareholders. The exercise price for the warrants issued shall at the time of issuance be determined by the board of directors at market price or at a discount price. The board of directors shall determine the terms for the warrants issued and the distribution hereof.
- The board of directors is until May 1, 2027, authorized at one or more times to increase the company's share capital by up to nominal DKK 87,275,000 without pre-emptive subscription rights for the company's shareholders. Capital increases according to this authorization must be carried out by the board of directors by way of cash contributions. The shares may be issued at market price or at a discount to the listed price of the ADSs as determined by the board of directors. The board of directors is authorized to make the required amendments to the articles of association if the authorization to increase the share capital is used and to cause such shares to be deposited with a depository bank and the simultaneous issuance of ADSs representing such shares.

Our ADSs are listed on The Nasdaq Capital Market under the symbol "EVAX."

Our ADSs issued are settled through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning ADSs held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the ADSs.

Our Warrants

We have established warrant programs for members of our board of directors, our executive management, other employees, consultants and advisors. Under the terms of our warrant plans, warrants are issued to our directors, executive management and employees, on a discretionary basis following consultation with and recommendation from our Compensation Committee. All warrants have been issued by the general meeting or by our board of directors pursuant to valid authorizations in our articles of association and the terms and conditions have, in accordance with the Danish Companies Act, been incorporated in our articles of association.

The description below merely contains a summary of the applicable terms and conditions and does not purport to be complete. As of March 11, 2025, we have issued and outstanding 4,417,201 warrants (excluding (1) the 373,127 warrants issued to the European Investment Bank, or EIB, as described below and in the section herein entitled “EIB Warrants” and (2) 50,000 warrants issued to an consultant related to the Company on September 19, 2023, (3) 9,726,898 warrants to investors as part of a direct offering in December 2023 described below in the section entitled “Investor warrants, December 21, 2023”, and (4) 39,375,000 ordinary warrants to investors and placement agent as part of a public offering in February 2024 described below in the section entitled “Public Offering Investor warrants, February, 2024”, (5) 50,000 warrants issued to an consultant related to the Company on May 7, 2024, (6) 1,500,000 warrants issued to consultants related to the Company on August 20, 2024 of which 1,400,000 warrants have expired, and (7) 99,933,850 ordinary warrants to investors as part of a public offering in January 2025 described below in the section entitled “Public Offering Investor warrants, January, 2025”. 2,500,000 of the warrants have been exercised). All prefunded warrants have been exercised. Each such warrant confers upon the holder thereof the right to subscribe to nominal DKK 0.25 share. Our warrants have previously been granted, on the dates, and with exercise prices as set forth below:

Grant Date	Vesting Period	Expiration Date	Exercise Price	Number of Warrants
December 19, 2016	Upon IPO Event	December 31, 2036	DKK 1.0	758,448
December 10, 2017	Upon IPO Event	December 31, 2036	DKK 1.0	632,700
December 19, 2017	Upon IPO Event	December 31, 2036	DKK 1.0	141,804
December 17, 2020	See vesting principles below	December 31, 2031	DKK 1.0	757,620
June 2021	See vesting principles below	December 31, 2031	DKK 1.0	62,147
December 7, 2021	See vesting principles below	December 31, 2031	USD 5.38	523,599
March 11, 2022	See vesting principles below	December 31, 2031	USD 2.96	35,000
June 14, 2022	See vesting principles below	December 31, 2031	USD 1.83	65,000
September 2022	See vesting principles below	December 31, 2031	USD 2.42	11,000
December 2022	See vesting principles below	December 31, 2031	USD 2.23	380,612
March 2023	See vesting principles below	December 31, 2031	USD 1.90	10,000
September 2023	See vesting principles below	December 31, 2031	USD 1.02	100,000
December 2023	See vesting principles below	December 31, 2031	USD 0.75	216,074
December 2023	See vesting principles below	December 31, 2031	USD 0.75	90,000
May 2024	See vesting principles below	December 31, 2031	USD 0.40	438,460
May 2024	See vesting principles below	December 31, 2031	USD 0.40	100,000
February 2025	See vesting principles below	December 31, 2031	USD 0.07	1,372,407
Exercised				(811,196)
Lapsed or annulled without exercise				(466,474)
Total issued and outstanding as of March 11, 2025				4,417,201

On December 17, 2020, our board of directors issued 757,620 warrants related to 2018 – 2020.

Vesting Principles Generally

Warrants granted for the years 2016 – 2018 vested upon the closing of our initial public offering. Warrants granted for the years 2019 and 2020 generally vest at a rate of 1/36th per month. Vested warrants may be exercised in four annual exercise windows of two weeks each that commence two trading days following publication of our annual report, the six-month report and the interim quarterly reports. However, our board of directors determined that the first such exercise window began November 2021.

For the 331,632 warrants granted in 2019 (issued in 2020), 117,612 warrants were fully vested on the date of grant and 214,020 warrants vest with 1/36 per month from date of grant. For the 236,196 warrants granted and issued in 2020, 120,888 warrants were fully vested on the date of issuance, 6,084 vest with 1/36 per month starting on January 1, 2020, 19,008 warrants vest three years from the date of joining us, 90,216 warrants vest with 1/36 per month starting on January 1, 2021.

62,147 warrants granted on June 17, 2021, and on October 21, 2021, formally issued shall vest with 1/36th per month and vesting shall be calculated from April 1, 2021. For warrants granted on December 7, 2021, 500,683 warrants vest with 1/36th per month from January 1, 2022, and 22,916 warrants shall be deemed fully vested at the time of issuance.

28,750 warrants granted to the Board of Directors granted from 2022 vest with 1/12th per month. 35,000 warrants were granted on March 11, 2022, vest with 1/36th per month from April 1, 2022. 65,000 warrants were granted on June 14, 2022. 10,000 warrants vest with 1/36th per month from February 1, 2022, 10,000 warrants vest with 1/36th per month from April 1, 2022, and 45,000 warrants vest with 1/36th per month from June 1, 2022.

11,000 warrants were granted on September 15, 2022. 5,000 warrants vest with 1/36 per month from August 1, 2022, and 6,000 warrants vest with 1/36 per month from August 8, 2022.

For 380,612 warrants granted on December 12, 2022, 2,500 warrants were fully vested per December 7, 2022, 50,000 warrants vest with 1/36 per month from December 7, 2022, 299,362 warrants vest with 1/36 per month from January 1, 2023, and 28,750 warrants vest with 1/12 per month from January 1, 2023.

10,000 warrants were granted on March 15, 2023. The warrants vest with 1/36th per month from January 1, 2023. 100,000 warrants were granted on September 1, 2023. The warrants vest with 1/36th per month from September 1, 2023. 150,000 warrants were granted in August 2023 to a consultant. 37,500 of which vested on November 20, 2023, 37,500 warrants vest on February 20, 2024, 37,500 warrants vest on May 20, 2024, and 37,500 vest on August 20, 2024. The warrants granted and vested may be exercised until and including September 19, 2026. 90,000 warrants granted on December 11, 2023. The warrants vest with 1/12th per month from January 1, 2024. 219,115 warrants granted on December 11, 2023. The warrants vest with 1/36th per month from January 1, 2024.

438,460 warrants granted on May 1, 2024. The warrants vest with 1/36th per month from May 1, 2024. 100,000 warrants granted on May 1, 2024. The warrants vest with 1/12th per month from May 1, 2024.

1,167,199 warrants granted on February 6, 2025. The warrants vest with 1/36th per month from January 1, 2025. 205,208 warrants granted on February 6, 2025. The warrants vest with 1/12th per month from January 1, 2025.

There are certain restrictions on exercise if warrant holders terminate their employment or are dismissed for prior to exercise.

Adjustments

Warrant holders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain changes to our share capital at a price other than the market price. Events giving rise to an adjustment include, among other things, increases or decreases to our share capital at a price below or above market value, respectively, and issuance of bonus shares. For the purpose of implementing the capital increases necessary in connection with the exercise of warrants, our board of directors has been authorized to increase our share capital by one or more issuances of shares with a total nominal value corresponding to the number of warrants issued upon cash payment of the exercise price without any preemptive subscription rights to existing shareholders.

Public Offering Investor Warrants January 2025

In January 2025, we completed a public offering through which we offered 3,997,361 ADSs representing an aggregated 199,868,050 ordinary shares, DKK 0.25 nominal value per share, together with warrants to purchase up to 1,998,675 ADSs representing 99,933,750 ordinary shares. The ADSs and Warrants were sold in a fixed combination, with each 2 ADSs accompanied by one Warrant to purchase one ADS. The public offering price for each ADS and accompanying warrant was \$2.71. The warrants have an exercise price per ADS of \$2.71 and are immediately exercisable for a term of five years from the date of issuance.

Public Offering Investor Warrants February 2024

In February 2024, we completed a public offering through which we offered 151,500 ADSs representing an aggregated 7,575,000 ordinary shares, DKK 0.25 nominal value per share, together with warrants to purchase up to 151,500 ADSs representing 7,575,000 ordinary shares. The public offering price for each ADS and accompanying warrant was \$20.00. The warrants have an exercise price per ADS of \$20.00 (amended to 137.60 DKK as of May 23, 2024) and are immediately exercisable for a term of five years from the date of issuance. Additionally, as part of the public offering, the Company offered prefunded warrants to purchase up to 598,500 ADSs representing 29,925,000 ordinary shares, together with ordinary warrants to purchase up to 598,500 ADSs representing 29,925,000 ordinary shares. The public offering price for each ADS and accompanying prefunded warrant was \$20.00. The prefunded warrants have an exercise price per ADS of \$1.4537 (not considering the ADS Ratio Change of 2025) and have all been exercised. Ordinary warrants have an exercise price of \$20.00 and are immediately exercisable for a term of five years from the date of issuance. Additionally, the Company issued placement agent warrants for consultants to purchase up to 37,500 ADSs representing 1,875,000 ordinary shares. The placement agent warrants have an exercise price per ADS of \$27 and are immediately exercisable for a term of five years from the date of issuance.

The above numbers have been adjusted to reflect the 2025 ADS Ratio Change and the share split resolved at the extraordinary general meeting on 17 January 2025.

2023 SPA Investor Warrants

On December 18, 2023, we entered into a Securities Purchase Agreement with a group of certain investors including all members of the Company's Management and Board of Directors, and MSD GHI, a corporate venture capital arm of Merck & Co., Inc., Rahway, NJ, USA, for the issuance and sale in private placement of 9,726,898 of ordinary shares, DKK 1 nominal value represented by ADSs, and accompanying warrants to purchase up to 9,726,898 ordinary shares represented by ADSs at a purchase price of \$0.54 per ordinary share. The 2023 SPA Investor Warrants are exercisable immediately upon issuance and expire three years after the closing date of the private placement and have an exercise price equal to \$0.71 per ordinary share. The gross proceeds to us from the private placement were \$5.3 million, with up to an additional \$6.8 million of gross proceeds in the event of cash exercise of the 2023 SPA Investor Warrants, before deducting offering expenses payable by us.

Our EIB Warrants

In connection with the EIB Loan Agreement, we agreed to issue the EIB Warrants to EIB in the event we draw on the EIB Loan. Under the terms of the EIB Warrant Agreement, we are obligated to issue up to an aggregate of 1,047,744 EIB Warrants in three separate tranches with each tranche of EIB Warrants to be issued upon a drawdown of a tranche of the EIB Loan in accordance with the following schedule: (i) 351,036 EIB Warrants upon a drawdown of the first tranche of the EIB Loan in the amount of €7.0 million; (ii) 345,672 EIB Warrants upon a drawdown of the second tranche of the EIB Loan in the amount of €6.0 million, upon shareholders' approval and (iii) 351,036 EIB Warrants upon a drawdown of the third and final tranche of the EIB Loan in the amount of €7.0 million, upon shareholders' approval. In November 2020, we initiated the process of making a draw down on the first tranche of the EIB Loan in the amount of €7.0 million and, in connection therewith, on December 17, 2020, and through the date of the annual report, our board of directors approved the issuance of 351,036 EIB Warrants to EIB.

Under the terms of the EIB Warrant Agreement, each EIB Warrant entitles EIB to subscribe for one ordinary share, nominal DKK 1, at an exercise price of DKK 1 per ordinary share. In addition, EIB has the right to cause us to net settle the exercise of the EIB Warrants in cash based on the value of our ordinary shares on the date of exercise thereof. Finally, upon the occurrence of certain events, including the completion of our initial public offering, the prepayment of the EIB Loan, the sale of all or substantially all of our issued share capital or assets, a change in control transaction, or Messrs. Mattsson and Moller cease to own and control directly or indirectly 25% or more of the voting rights or economic interest of our company, EIB has the right, but not the obligation, to cause us to purchase any EIB Warrant, or the Put Right. If EIB exercises its Put Right, we are required to pay EIB an amount equal to the volume weighted average price per ordinary share, or VWAP, for a period of six months following the exercise of such Put Right. In the first six months following the completion of our initial public offering, the VWAP price to be paid by us is calculated for the entire period from the completion of our initial public offering until the exercise of the Put Right.

Under Article 18, Paragraph 2 of the Statute of the European Investment Bank, or the EIB Statute, establishing EIB, a direct equity investment by EIB requires a separate authorization from the EIB Board of Governors pursuant to which the EIB Board of Directors, acting by qualified majority, has to establish the terms and conditions of such direct equity investment. As of the date of this annual report, the EIB Board of Governors has not granted any such special authorization to the EIB Board of Directors. Under the EIB Statute, in the absence of a separate authorization from the EIB Board of Governors, commercial shareholdings financed from EIB's own resources are not allowed. Since the EIB Loan is being made from EIB's own resources, the EIB Statute does not allow EIB to acquire any of our ordinary shares, therefore, we fully expect that if and when EIB exercises the EIB Warrants it will do so on either a net cash settlement basis or by means of exercising its Put Right. In either case, we may not have sufficient funds on hand to pay such amounts, in which case we may be required to use proceeds from a public offering in order to meet our obligations to pay the amounts due and payable to EIB upon the exercise of the EIB Warrants.

Under the terms of the EIB Warrant Agreement, EIB may not exercise the EIB Warrants and cause us to settle the exercise of the EIB Warrants on a net cash basis or pursuant to its Put Right, for a period of 180 days from the date of the completion of our initial public offering, provided that such lock-up arrangement shall cease to be effective in the event there is a material adverse event relating to our company as determined in accordance with ordinary principles of Danish law.

The number of our ordinary shares that may be subject to either net cash settlement or EIB's Put Right upon the exercise of the EIB Warrants are subject to adjustment in the event of changes to our capital structure which are not carried out at the then current market price, provided that there shall be no such adjustment as a result of the issuance of additional shares or warrants to employees as well as for any future exercise of such warrants. In addition, the EIB Warrants are not subject to any adjustment in the event of any capital increases in directed issuances or our ordinary shares following the completion of our initial public offering with customary discounts of up to 10% of the market price.

Pursuant to a board resolution dated October 3, 2024, the number of shares issuable upon exercise of warrants previously granted to EIB was adjusted from 351,036 to 373,127.

Shareholders' Register

We are obligated to maintain an owners' register (DK: *ejerbog*). The owners' register is maintained by Computershare A/S (company registration number (CVR) no. 27088899), Lottenborgvej 26 D, 1., DK-2800 Kgs. Lyngby, Denmark, our Danish share registrar and transfer agent. It is mandatory that the owners' register is maintained within the European Union and that it is available to public authorities.

Pursuant to the Danish Companies Act public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to the Danish Companies Act, we will file registrations with the Public Owners' Register of the Danish Business Authority. Shareholders that exceed or fall below the ownership threshold must notify us and we will subsequently file the information with the Danish Business Authority. Reporting is further required upon passing or falling below thresholds of 5, 10, 15, 20, 25, 50, 90, and 100% or 1/3 or 2/3.

Articles of Association and Danish Corporate Law

With respect to our articles of association, the following should be emphasized:

Objects Clause

Our corporate object, as set out in article 1.2 of our articles of association, is to create advanced software that enables the development of novel immune therapies and vaccines.

Summary of Provisions Regarding the Board of Directors

Pursuant to our articles of association, our Board shall be elected by our shareholders at the general meeting and shall be composed of not less than three and no more than seven members. With respect to the duration of the term which our directors severally hold office, the board of directors is elected to serve for a term of one year subject to re-election at the next annual general meeting of shareholders or until their successors have been duly elected and qualified, subject to their earlier removal, retirement or death.

Currently, the board of directors consists of five members who are elected by the shareholders.

The board of directors shall appoint and employ executive management consisting of one to seven members to attend to our day-to-day management, and the board of directors shall determine the terms and conditions of their employment.

Voting Rights

Each shareholder is entitled to one vote for each share owned at the time of any general meeting. As compared with Danish citizens, there are no limitations under the articles of association or under Danish law on the rights of foreigners or non-Danish citizens to hold or vote our ordinary shares.

Dividend Rights

Our shareholders may at general meetings authorize the distribution of ordinary and extraordinary dividends. Our shareholders may not distribute dividends in excess of the recommendation from our board of directors and may only pay out dividends from our distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward.

Our shareholders are eligible to receive any dividends declared and paid out. However, we have not to date declared or paid any dividends and we currently intend to retain all available financial resources and any earnings generated by our operations for use in the business and we do not anticipate paying any dividends in the foreseeable future. The payment of any dividends in the future will depend on a number of factors, including our future earnings, capital requirements, financial condition and future prospects, applicable restrictions on the payment of dividends under Danish law and other factors that our board of directors may consider relevant.

See “Item 10.E. Taxation” for a summary of certain tax consequences in respect of dividends or distributions to holders of our ordinary shares or ADSs.

Pre-emptive Subscription Rights

Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. An increase in share capital can be resolved by the shareholders at a general meeting or by the board of directors pursuant to an authorization given by the shareholders. In connection with an increase of a company’s share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting and requires that such capital increases will be carried out as a cash contribution at market price.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations set forth above under the caption “Development of the Share Capital”.

Unless future issuances of new shares and/or pre-emptive rights are registered under the Securities Act or with any authority outside Denmark, United States shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights.

Rights on Liquidation

Upon a liquidation or winding-up of the Company, shareholders will be entitled to participate, in proportion to their respective shareholdings, in any surplus of assets remaining after payment of our creditors.

Limitations on Holding of Shares

There are no limitations on the right to hold shares under the articles of association or Danish law.

Disclosure Requirements

Pursuant to Section 55 of the Danish Companies Act, a shareholder is required to notify us when such shareholder’s stake represents 5% or more of the voting rights in our company or the nominal value accounts for 5% or more of the share capital, and when a change of a holding already notified entails that the limits of 5, 10, 15, 20, 25, 50, 90 or 100% and the limits of one-third and two-thirds of the share capital’s voting rights or nominal value are reached or are no longer reached. The notification shall be given within two weeks following the date when the limits are reached or are no longer reached. This also applies to beneficial holders of our ordinary shares, such as holders of the ADSs.

The notification shall provide information on the date of the acquisition or disposal of the shares, the full name, civil registration (CPR) number, and address of the shareholder or, in the case of an enterprise, registered office and business registration (CVR) number, the number of shares and their nominal value and share classes (if applicable) as well as information about the basis on which the calculation of the holdings has been made. In the event that the shareholder is a non-resident company or citizen of Denmark, the notification shall include documentation, which clearly identifies the owner. The company shall cause the notification to be entered in the owners’ register.

Pursuant to section 58a, we are obligated to collect and store for a period of at least five years certain information regarding the beneficial owners of shares in the Company. A beneficial owner is a physical person who ultimately holds or controls, directly or indirectly, a sufficient part of the ownership interests or voting rights or exercises control by other means, except for owners of companies whose ownership interests are traded on a regulated market or a similar market which is subject to a duty of disclosure in accordance with EU law or similar international standards.

The legal status of the notification obligations is not fully clarified in relation to ADS holders and an ADS holder may be subject to such obligations.

General Meetings

The general meeting of shareholders is the highest authority in all matters, subject to the limitations provided by Danish law and the articles of association. The annual general meeting shall be held in the Greater Copenhagen area not later than the end of May in each year.

At the annual general meeting, the audited annual report is submitted for approval, together with the proposed appropriations of profit/treatment of loss, the election of the board of directors and election of our auditors. In addition, the board of directors reports on our activities during the past year.

General meetings are convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice. A convening notice will also be forwarded to shareholders recorded in our owners' register, who have requested such notification and by publication in the Danish Business Authority's computerized information system and on the company's website.

At the latest, two weeks before a general meeting (inclusive of the day of the general meeting), we shall make the following information and documents available on our website.

- the convening notice,
- the documents that shall be presented at the general meeting, and
- the agenda and the complete proposals.

Shareholders are entitled to attend general meetings, either in person or by proxy and they or their proxy may be accompanied by one advisor. A shareholder's right to attend general meetings and to vote at general meetings is determined on the basis of the shares that the shareholder holds on the registration date. The registration date shall be one week before the general meeting is held. The shares which the individual shareholder holds are calculated on the registration date on the basis of the registration of ownership in the owners' register as well as notifications concerning ownership which the Company has received with a view to update the ownership in the owners' register. In addition, any shareholder who is entitled to attend a general meeting and who wishes to attend must have requested an admission card from us no later than three days in advance of the general meeting.

Any shareholder is entitled to submit proposals to be discussed at the general meetings. However, proposals by the shareholders to be considered at the annual general meeting must be submitted in writing to the board of directors not later than six weeks prior the general meeting.

Extraordinary general meetings must be held upon resolution of a general meeting to hold such a meeting or upon request of, the board of directors, our auditors or shareholders representing at least 1/20 of the registered share capital or such lower percentage as our articles of association may provide. Our articles of association do not state such a lower percentage.

Holders of ADSs are not entitled to directly receive notices or other materials and may not attend or vote at general meetings.

Resolutions in General Meetings

Resolutions made by the general meeting generally may be adopted by a simple majority of the votes cast, subject only to the mandatory provisions of the Danish Companies Act and our articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose or increase any obligations of the shareholders towards the company require unanimity.

Quorum Requirements

There are no quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Squeeze Out

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital and the corresponding voting rights to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company's share capital and the corresponding voting rights may, according to Section 70 of the same act, redeem the minority shareholder's shares. In the event that the parties cannot agree to the terms of redemption and the valuation basis of the redemption price, this shall be determined by an independent evaluator appointed by the court for the district in which the registered office of the company is situated.

Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law

The following comparison between Danish corporate law, which applies to us, and Delaware corporate law, the law under which many publicly listed companies in the United States are incorporated, discusses additional matters not otherwise described in this annual report. This summary is subject to Danish law, including the Danish Companies Act, and Delaware corporation law, including the Delaware General Corporation Law. Further, please note that as an ADS holder you will not be treated as one of our shareholders and will not have any shareholder rights.

Duties of Directors

Denmark. Public limited liability companies in Denmark are usually subject to a two-tier governance structure with the board of directors having the ultimate responsibility for the overall supervision and strategic management of the company in question and with an executive board/management being responsible for the day-to-day operations. Each Director and member of the executive board/management is under a fiduciary duty to act in the interest of the company but shall also take into account the interests of the creditors and the shareholders. Under Danish law, the members of the board of directors and executive management of a limited liability company are liable for losses caused by negligence whether shareholders, creditors or the company itself suffers such losses. They may also be liable for wrongful information given in the annual financial statements or any other public announcements from the company. An investor suing for damages is required to prove its claim with regard to the incurred loss, negligence and causation. Danish courts, when assessing negligence, have been reluctant to impose liability unless the directors and officers neglected clear and specific duties. This is also the case when it comes to liability with regard to public offerings or liability with regard to any other public information issued by the company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.

Terms of the Members of our Board of Directors

Denmark. Under Danish law, the members of the board of directors of a limited liability company are generally appointed for an individual term of one year (terms may have a maximum period of 4 years). There is no limit to the number of consecutive terms the directors may serve. Pursuant to our articles of association, our directors are appointed by the general meeting of shareholders for a term of one year. The election of directors is, according to our articles of association, an item that shall be included on the agenda for the annual general meeting.

At the general meeting, shareholders are entitled at all times to dismiss a director elected by the general meeting by a simple majority vote.

Pursuant to the Danish Companies Act, in a limited liability company that employed an average of at least 35 employees in the preceding three years, the employees are entitled to elect a minimum of two representatives and alternate members to the company's board of directors and up to one half the number of the shareholder elected directors. If the number of representatives to be elected by the employees is not a whole number, such number must be rounded up.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors but permits directorships to be divided into up to three classes, of relatively equal size, with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Director Vacancies

Denmark. Under Danish law, new directors are elected by the shareholders in a general meeting also in the event of vacancies. A general meeting will thus have to be convened in order to fill a vacancy on the board of directors. However, the board of directors may choose to wait to fill vacancies until the next annual general meeting of the company, provided that the number of remaining directors is more than two, and provided that the remaining directors can still constitute a quorum. It is only a statutory requirement to convene a general meeting to fill vacancies if the number of remaining members on the board is less than three.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless

(1) otherwise provided in the certificate of incorporation or bylaws of the corporation or (2) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-interest Transactions

Denmark. Under Danish law, directors may not take part in any matter or decision-making that involves a subject or transaction in relation to which the director has a conflict of interest with us.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy Voting by Directors

Denmark. In the event that a director in a Danish limited liability company is unable to participate in a board meeting, the elected alternate, if any, shall be given access to participate in the board meeting. Unless the board of directors has decided otherwise, or as otherwise is set out in the articles of association, the director in question may in special cases grant a power of attorney to another director, provided that this is considered safe considering the agenda in question.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Stockholder Rights

Notice of Meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall also be forwarded to shareholders recorded in our owners' register, who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

Delaware. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Voting Rights

Denmark. Each ordinary share confers the right to cast one vote at the general meeting of shareholders, unless the articles of association provide otherwise. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever our board of directors or our appointed auditor requires. In addition, one or more shareholders representing at least 1/20th of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is forwarded, the board of directors shall convene the general meeting within two weeks thereafter.

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are made in writing and forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda. Any business not included on the agenda may be transacted by the general meeting only if all shareholders' consent.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act.

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital to redeem his or her shares.

Similarly, a majority shareholder holding more than 90% of the company's share capital may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger or cross-border conversion are, according to Sections 286, 306 and 318 m of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit.

Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired, or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own share's if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover Provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares on name in the company's owners register and (iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares;
- owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder;
- A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

Inspection of Books and Records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company's books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then a shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation's books and records, for any proper purpose, during the corporation's usual hours of business.

Pre-emptive Rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company's share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting and requires that such capital increases will be carried out as a cash contribution at market price.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption "Development of the Share Capital."

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, United States shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights under United States securities law.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company's shareholders at a company's general meeting. Under the Danish Companies Act the general meeting may authorize the board of directors to resolve to distribute extraordinary dividends after presentation of a company's first financial statements. The authorization may be subject to financial and time restrictions. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as amounts stated as retained earnings in the Company's latest approved financial statements and reserves not being non-distributable under a statute or the Company's articles of association, less retained earnings. The decision to pay out extraordinary dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the extraordinary dividend payment shall be prepared. If extraordinary dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared.

Furthermore, it is possible under Danish law to distribute assets other than cash as dividends. If assets other than cash are distributed as dividends, a valuation report must be prepared. The valuation report must be prepared by one or more impartial valuation experts.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

Shareholder Vote on Certain Reorganizations

Denmark. Under Danish law, all amendments to the articles of association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the represented share capital. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers with the company as the transferor company and demergers with the company as the existing transferee if amendment of the articles of association for any purpose other than the adoption of the transferor company's name or secondary name as the transferee company's secondary name is required to be made. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to Governing Documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our shares is Computershare A/S, Lottenborgvej 26 D, 1., DK-2800 Kgs. Lyngby, Denmark. The Bank of New York Mellon serves as the depository, registrar and transfer agent for the ADSs.

10.C. Material Contracts

Except as otherwise disclosed in this annual report (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

10.D. Exchange Controls

There are no governmental laws, decrees, regulations, or other legislation in Denmark that may affect the import or export of capital, including the availability of cash and cash equivalents for use by Evaxion, or that may affect the remittance of dividends, interest, or other payments by Evaxion to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by Danish law or in the Articles on the right of non-residents to hold or vote shares.

10.E. Taxation

Danish Tax Considerations

The following discussion describes the material Danish tax consequences under present law of an investment in the ADSs representing our ordinary shares. The summary is for general information only and does not purport to constitute tax or legal advice. It is specifically noted that the summary does not address all possible tax consequences relating to an investment in the ADSs. The summary is based solely on the tax laws of Denmark in effect on the date of this annual report. Danish tax laws may be subject to change, possibly with retroactive effect.

The summary does not cover investors to whom special tax rules apply, and, therefore, may not be relevant, for example, to investors subject to the Danish Tax on Pension Yields Act (i.e., pension savings), professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and investors with tax liability on return on pension investments. The summary does not cover taxation of individuals and companies who carry on the business of purchasing and selling shares. The summary only sets out the tax position of the direct owners of the ADSs and further assumes that the direct investors are the beneficial owners of the ADSs and any dividends thereon. Sales are assumed to be sales to a third party.

Potential investors in the ADSs are advised to consult their tax advisors regarding the applicable tax consequences of acquiring, holding and disposing of the ADSs based on their particular circumstances.

Investors who may be affected by the tax laws of other jurisdictions should consult their tax advisors with respect to the tax consequences applicable to their particular circumstances as such consequences may differ significantly from those described herein.

Taxation of Danish Tax Resident Holders of the ADSs

It is currently not clear under the current Danish tax legislation or case law how the listed ADSs issued by Danish resident companies in general are to be treated for tax purposes, and therefore no level of assurance can be given on this matter. For the purpose of the below comments, it is assumed that Danish tax resident holders of the ADSs should be treated as holders of listed shares in the company for both Danish corporate law purpose and Danish tax purposes, even though the company's ordinary shares are not admitted to trading on a regulated market. Recent communications and binding rulings from the Danish Tax Assessment Council indicate that the holders of ADSs for Danish tax purposes are treated as holders of listed ordinary shares. The same communications and rulings indicate that the actual distribution of dividends on ADSs to Danish investors are considered dividends for Danish tax purposes. However, it should be emphasized that these communications and binding rulings are based on the actual facts and circumstances and terms and conditions of the depository agreement implying that a holder of ADSs might not be able to rely on said rulings, the position cannot therefore be said to be clear.

In the event that the holders of ADSs are not treated as holding listed shares, it is likely that they will be treated as either holding unlisted shares or financial instruments for tax purposes.

As described above, the below summary assumes that the holders of ADSs listed in the U.S. should be treated as holding listed ordinary shares in the company for Danish tax purposes, but if this is not the case, then this will impact the Danish tax treatment of the holders of ADSs, including in respect of the taxation of dividends paid to holders of ADSs.

Sale of the ADSs (Individuals) assuming treatment as listed shares under Danish tax law

For individual investors in 2025, gains from the sale of shares are included in the computation of the annual share income subject to 27% tax on the first DKK 67,500 (for cohabiting spouses, a total of DKK 135,000) and at a rate of 42% on share income exceeding DKK 67,500 (for cohabiting spouses over DKK 135,000). Such amounts are subject to annual adjustment and include all share income (i.e., all capital gains and dividends derived by the individual or cohabiting spouses, respectively). The realization principle applies for gains or losses included in income in the year of disposal.

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is generally determined using the average method (in Danish "gennemsnitsmetoden") as a proportionate part of the aggregate purchase price for all the shareholder's shares in a company (i.e. not the purchase price paid for each share).

Losses on the sale of listed shares can only be offset against other share income deriving from listed shares (i.e., dividends and capital gains on the sale of listed shares) and subject to the Danish tax authorities having received certain information concerning the ownership of the shares in due time. Unused losses will automatically be offset against a cohabiting spouse's share income deriving from listed shares and any additional losses can be carried forward and offset against future share income deriving from listed shares.

Sale of the ADSs (Companies) Assuming Treatment as Unlisted Shares under Danish Tax Law

For the purpose of taxation of sales of shares made by shareholders (companies), a distinction is made between Subsidiary Shares, Group Shares, Tax-Exempt Portfolio Shares and Taxable Portfolio Shares (note that the ownership threshold described below is applied on the basis of the number of all shares issued by a company, and not on the basis of the number of the ADSs issued):

“*Subsidiary Shares*” are generally defined as shares owned by a shareholder holding at least 10% of the nominal share capital of the issuing company.

“*Group Shares*” are generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or fulfill the requirements for international joint taxation under Danish law (i.e., the company is controlled by the shareholder).

“*Tax-Exempt Portfolio Shares*” are defined as shares not admitted to trading on a regulated market or multilateral trading facility owned by a shareholder holding less than 10% of the nominal share capital of the issuing company.

“*Taxable Portfolio Shares,*” which are defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are generally not included in the taxable income of the shareholder.

Special rules apply with respect to Subsidiary Shares and Group Shares to prevent certain holding company structures just as other anti-avoidance rules may apply. These rules will not be described in further detail.

Capital gains on listed Taxable Portfolio Shares are taxable at the general corporate tax rate of 22% and losses on such shares are generally deductible.

Gains and losses on listed Taxable Portfolio Shares are taxed under the mark-to-market principle irrespective of realization.

According to the mark to market principle, each year’s taxable gain or loss on Taxable Portfolio Shares is calculated as the difference between the market value of the shares at the beginning of the tax year and the market value of the shares at the end of the tax year. Hence, taxation will take place on an accrual basis even if no shares have been disposed of and no gains or losses have been realized.

A change of status from respectively Subsidiary Shares/Group Shares/Tax-Exempt Portfolio Shares to Taxable Portfolio Shares is for tax purposes considered a disposal of the shares and a reacquisition of the shares at market value at the time of change of status.

Dividends (Individuals)

As described above, the recent communications and binding rulings from the Danish Tax Assessment Council indicate that the holders of ADSs for Danish tax purposes are treated as holders of listed ordinary shares. The same communications and rulings indicate that the actual distribution of dividends on ADSs to Danish investors are considered dividends for Danish tax purposes. Provided that such distributions to Danish tax resident individual investors are treated as dividends, taxation as share income, as described above, will take place. All share income must be included when calculating whether the amounts described above are exceeded. Dividends paid to individuals are generally subject to 27% withholding tax.

Dividends (Companies)

For corporate investors, dividends paid (subject to the same uncertainty as described immediately above) on Subsidiary Shares and Group Shares generally are tax-exempt irrespective of ownership period.

Dividends paid on Tax-Exempt Portfolio Shares are partly taxable as 70% of the dividends received are included in the taxable income, which corresponds to an effective taxation of 15.4% irrespective of ownership period.

Dividends paid on Taxable Portfolio Shares are taxable at the general corporate rate of 22% and tax is generally withheld with 22%.

The actual withholding tax rate is as a starting point 27% but may be reduced (0%, 15.4%, 22%) if certain requirements are met. A claim for repayment may be made within two months, or the excess tax will be offset by the corporation's income tax for the year in question. The statute of limitation is three years.

Taxation of Shareholders Residing Outside Denmark

It is currently not clear under current Danish tax legislation or case law how the listed ADSs are to be treated for tax purposes, and therefore no level of assurance can be given on this matter. For the purpose of the below comments, it is assumed that non-Danish tax resident holders of the ADSs should be treated as holders of listed shares in our company for both Danish corporate law purposes and Danish tax purposes, even though our ordinary shares are not admitted to trading on a regulated market. Recent communications and binding rulings from the Danish Tax Assessment Council indicates that the holders of ADSs for Danish tax purposes are treated as holders of listed ordinary shares. The same communications and rulings indicate that the actual distribution of dividends on ADSs to Danish investors are considered dividends for Danish tax purposes. However, it should be emphasized that these communications and binding rulings are based on an individual analysis based on the actual facts and circumstances and terms and conditions of the depositary agreement implying that a holder of ADSs might not be able to rely on said rulings.

In the event that the holders of ADSs are not treated as holding listed shares in our company, it is likely that they will be treated as either holding unlisted shares or financial instruments for Danish tax purposes.

As described above, the below summary assumes that the holders of ADSs listed in the U.S. should be treated as holding listed ordinary shares in our company for Danish tax purposes, but if this is not the case, then this will impact the Danish tax treatment of the holders of ADSs, including in respect of the taxation of dividends paid to holders of ADSs.

Sale of the ADSs (Individuals and Companies)

Holders of the ADSs not resident in Denmark are normally not subject to Danish taxation on any gains realized on the sale of ADSs, irrespective of the ownership period, subject to certain anti-avoidance rules seeking to prevent that taxable dividend payments are converted to tax exempt capital gains.

No Danish share transfer tax or stamp duties should be payable on transfer of ADSs.

If an investor holds the ADSs in connection with a trade or business conducted from a permanent establishment in Denmark, gains on shares may be included in the taxable income of such activities pursuant to the rules applying to Danish tax residents as described above.

Dividends (Individuals)

As described above, the recent communications and binding rulings from the Danish Tax Assessment Council indicate that the holders of ADSs for Danish tax purposes are treated as holders of listed ordinary shares in the company. The same communications and rulings indicate that the actual distribution of dividends on ADSs to investors are considered dividends for Danish tax purposes. In principle the holders of the ADSs should therefore be entitled to apply for a refund of Danish withholding tax on dividends paid by the company. However, it remains uncertain how the Danish tax authorities will accept/handle this in practice and whether the holders of ADSs will in fact be entitled to apply for a refund of Danish withholding tax on dividends paid by the company.

If the holders of ADS for Danish purposes are treated as holders of the ordinary shares in the company and are entitled to apply for a refund of Danish withholding tax on dividends paid by the company, then the below should apply.

Dividends paid to individuals are generally subject to 27% withholding tax. The withholding tax is 44% for dividends paid to beneficial owners in "Blacklisted Jurisdictions". The 44% rate only applies to "Main Shareholders" which generally encompass individual shareholders holding more than 25% of the shares or 50% of the votes.

Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the holders of the ADSs are considered beneficial owners of the dividends according to the applicable double tax treaty between Denmark and the tax residence country of the ADS holder, the withholding tax rate under such double tax treaty may apply to the extent the tax residency of the ADS holder can be documented and to the extent it can be documented that the dividends are in fact paid onwards to the holder of the ADSs as the beneficial owner.

For holders of ADSs (as the beneficial owners of the dividends on the ordinary shares), if the withholding tax rate applied is higher than the applicable final tax rate (as reduced according to domestic law or an applicable double tax treaty) for the holder of ADSs, a request for a refund of Danish tax in excess hereof can be made in the following situations:

Reduction According to Tax Treaty

In the event that the ADS holder is a resident of a state with which Denmark has entered into a tax treaty, the holder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with approximately 80 countries, including the United States, Switzerland and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% tax rate.

Reduction According to Danish Tax Law

If the ADS holder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) of the company and the ADS holder is tax resident in a state which has a double tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters according to which the competent authority in the state of the ADS holder is obligated to exchange information with Denmark, dividends are subject to tax at a rate of 15%. If the ADS holder is a tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the ADS holder together with related ADS holders holds less than 10% of the nominal share capital of the company.

Note that the reduced tax rate does not affect the withholding rate, which is why the holder must claim a refund as described above in order to benefit from the reduced rate.

Where a non-resident of Denmark holds shares which can be attributed to a permanent establishment in Denmark, dividends are taxable pursuant to the rules applying to Danish tax residents described above.

The recent communications and binding rulings from the Danish Tax Assessment Council indicates that a holder of ADSs selling such ADSs back to the company should be exempt from withholding tax on the basis of a specific exception applying to shares in listed companies. It should be emphasized that these rulings are based on an individual analysis based on the actual facts and circumstances and terms and conditions of the depositary agreement implying that a holder of ADSs might not be able to rely on said rulings.

Dividends (Companies)

As described above, the recent communications and binding rulings from the Danish Tax Assessment Council indicates that holders of ADSs for Danish tax purposes are treated as holders of listed ordinary shares. The same communications and rulings indicate that the actual distribution of dividends on ADSs to investors are considered dividends for Danish tax purposes. In principle the holders of the ADSs should therefore be entitled to apply for a refund of Danish withholding tax on dividends paid by the company. However, it remains uncertain how the Danish tax authorities will accept/handle this in practice and whether the holders of ADSs will in fact be entitled to apply for a refund of Danish withholding tax on dividends paid by the company.

If the holders of ADS for Danish purposes are treated as holders of the ordinary shares in the company and are entitled to apply for a refund of Danish withholding tax on dividends paid by the company, then the below should apply.

Dividends paid to companies are generally subject to 27% withholding tax. The withholding tax is 44% for dividends paid on Group Shares and Subsidiary Shares held by beneficial owners in Blacklisted Jurisdictions as mentioned above.

Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the holders of the ADSs are considered beneficial owners of the dividends according to the applicable double tax treaty between Denmark and the tax residence country of the ADS holder, the withholding tax rate under such double tax treaty may apply to the extent the tax residency of the ADS holder can be documented and to the extent it can be documented that the dividends are in fact paid onwards to the holder of the ADSs as the beneficial owner.

For investors (as beneficial owners of the dividends on the ordinary shares), if the withholding tax rate applied is higher than the applicable final tax rate (as reduced according to domestic law or an applicable double tax treaty) for the investor, a request for a refund of Danish tax in excess hereof can be made.

Dividends from Subsidiary Shares are tax exempt provided the taxation of the dividends is to be waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the jurisdiction in which the company investor is resident. If Denmark is to reduce taxation of dividends to a foreign company under a tax treaty, Denmark will not — as a matter of domestic law — exercise such right and will in general exempt from imposing any withholding tax. Further, dividends from Group Shares — not also being Subsidiary Shares — are exempt from Danish tax provided the company investor is a resident of the European Union or the EEA and provided the taxation of dividends should have been waived or reduced in accordance with the Parent-Subsidiary Directive (2011/96/EEC) or in accordance with a tax treaty with the country in which the company investor is resident had the shares been Subsidiary Shares.

Dividend payments on both Tax-Exempt and Taxable Portfolio Shares will generally be subject to a tax rate of 22% irrespective of ownership period. While the actual withholding tax rate is as a starting point 27%, it can be reduced if certain requirements are met as described below. If the withholding tax rate applied is higher than the applicable final tax rate for the ADS holder, a request for a refund of Danish tax in excess hereof can be made by the ADS holder in the following situations:

Reduction According to Tax Treaty

In the event that the ADS holder is a resident of a state with which Denmark has entered into a double taxation treaty, the shareholder may generally, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the applicable treaty rate, which is typically 15%. Denmark has entered into tax treaties with a large number of countries, including the United States and almost all members of the European Union. The tax treaty between Denmark and the United States generally provides for a 15% rate.

Reduction According to Danish Tax Law

If the ADS holder holds less than 10% of the nominal share capital (in the form of ordinary shares in the company and not on the basis of the number of the ADSs issued) in the company and the ADS holder is resident in a jurisdiction which has a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax according to which the competent authority in the state of the ADS holder is obligated to exchange information with Denmark, dividends are generally subject to a tax rate of 15%. If the ADS holder is a tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the ADS holder together with related ADS holder holds less than 10% of the nominal share capital of the company. Note that the reduced tax rate does not affect the withholding rate, hence, in this situation the ADS holder must also in this situation claim a refund as described above in order to benefit from the reduced rate. Where a non-resident company of Denmark holds shares which can be attributed to a permanent establishment in Denmark, dividends are taxable pursuant to the rules applying to Danish tax residents described above.

The recent communications and binding rulings from the Danish Tax Assessment Council indicate that a holder of ADSs selling such ADSs back to the company should be exempt from withholding tax on the basis of a specific exception applying to shares in listed companies. It should be emphasized that these rulings are based on an individual analysis based on the actual facts and circumstances and terms and conditions of the depositary agreement implying that a holder of ADSs might not be able to rely on said rulings.

Share Transfer Tax and Stamp Duties

No Danish share transfer tax or stamp duties should be payable on transfer of the shares.

Certain Material U.S. Federal Income Tax Considerations

The following discussion describes certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires the ADSs and holds them as a capital asset (generally property held for investment) under the Internal Revenue Code of 1986, as amended from time to time, or the "Code". This discussion is based upon existing U.S. tax law (including the Code, its legislative history, existing, temporary and proposed United States Department of the Treasury Regulations promulgated thereunder, or the "Treasury Regulations", administrative and judicial interpretations thereof, and other published rulings, guidance, and court decisions) in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. No ruling has been sought from the Internal Revenue Service, or the "IRS", or any other taxing authority, with respect to any U.S. federal income tax consequences described below. In addition, because the authorities upon which this summary is based are subject to various interpretations, the IRS, other taxing authorities, and the U.S. courts could disagree with one or more of the positions taken in this summary. This summary is not binding on the IRS or any other taxing authority or court, none of which are precluded from taking a position that is different from or contrary to, any position taken in this summary and there can be no assurance that the IRS, other taxing authority, or a court will not take a contrary position. No opinion from U.S. legal counsel has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ADSs.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status including investors subject to special tax rules (such as, banks, and other financial institutions, insurance companies, broker-dealers in stocks, securities, currencies, or notional principal contracts, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass-through entities, tax-exempt organizations including private foundations and charitable remainder trusts, pension plans, persons that hold the ADSs or ordinary shares as part of a straddle, hedge, conversion, constructive sale, or other integrated investment or transaction as determined for U.S. federal income tax purposes, persons whose “functional currency” is not the USD, U.S. expatriates or former long-term residents of the United States, persons that directly, indirectly or constructively own 10% or more (by vote or value) of the Company, persons who acquired interests in the Company pursuant to the exercise of any employee share option or otherwise as compensation, or persons holding interests in the Company through partnerships or other pass-through entities).

This summary does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any U.S. state or local or non-U.S. taxing jurisdiction, the special tax accounting rules under Section 451(b) of the Code, or any U.S. estate, gift or alternative minimum tax consequences.

This summary is for general information purposes only and does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Holder as a result of the acquisition, ownership and disposition of the ADSs. In addition, this summary does not take into account the individual facts and circumstances of any particular U.S. Holder that may affect the U.S. federal income tax consequences to such U.S. Holder. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any particular U.S. Holder. Except as specifically set forth below, this summary does not discuss applicable tax reporting requirements.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of the ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or of any State thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust’s administration and one or more United States persons have the authority to control all substantial decisions of the trust or (ii) a valid election under applicable Treasury Regulations is in effect for the trust to be treated as a United States person.

If a partnership or other pass-through entity (including any entity or arrangement treated as a partnership or other pass-through entity for U.S. federal income tax purposes) holds the ADSs, the tax treatment of a person treated as a partner or other owner in the partnership or other pass-through entity for U.S. federal income tax purposes generally will depend on the status of the partner or other owner and the activities of the partnership or other pass-through entity. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, for U.S. federal income tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and non-U.S. income and other tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the PFIC (as defined below) rules discussed below under “— Passive Foreign Investment Company Considerations”, any distributions of cash or other property with respect to the ADSs (including any amounts withheld in respect thereof), generally will, to the extent made out of our current and accumulated earnings and profits as determined for U.S. federal income tax purposes, constitute dividends for U.S. federal income tax purposes. Generally, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a non-corporate U.S. Holder that constitute dividend income from a “qualified foreign corporation” will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock (or ADSs in respect of such stock) which is readily tradable on an established securities market in the United States. The ADSs are listed on The Nasdaq Capital Market, which is an established securities market in the United States. We anticipate that the ADSs should qualify as being regularly traded, but no assurances may be given in this regard. We anticipate that the ADSs should qualify as being regularly traded, but no assurances may be given in this regard. We therefore expect that dividends we pay with respect to the ADSs generally will constitute qualified dividend income, but no assurances may be given in this regard.

A U.S. Holder must include any Danish tax withheld from the dividend payment, as described above under “— Danish Tax Considerations — Taxation of Shareholders Residing Outside Denmark,” in the gross amount of any dividend paid even though the holder does not in fact receive it. The dividend is taxable to the holder when the depository receives the dividend, actually or constructively. Because we are not a U.S. corporation and do not expect to meet the dividends-received deduction eligibility criteria for non-U.S. corporations, the dividend is not expected to be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in a U.S. Holder’s income will be the USD value of the Danish Krone payments made, determined at the spot Danish Krone/USD rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into USD. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into USD will be treated as ordinary income or loss to the U.S. Holder and will not be eligible for the special tax rate applicable to qualified dividend income. The currency gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder’s capital invested in the Company, up to the holder’s adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in “— Gain on Sale, Exchange or Other Taxable Disposition of ADSs.”

Because we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles, all distributions paid will generally be treated as “dividends” for U.S. federal income tax purposes.

Dividends paid by the Company generally will be treated as income from foreign sources for U.S. foreign tax credit purposes and generally will constitute passive category income. A U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit in respect of any foreign withholding taxes imposed on dividends received on the ADSs, including the Danish tax withheld in accordance with the Treaty and paid over to the Danish taxing authority, which may, subject to such limitations, be creditable against a U.S. Holder’s U.S. federal income tax liability. A U.S. Holder who does not elect to claim a foreign tax credit for foreign tax withheld, may instead claim a deduction, for United States federal income tax purposes, in respect of such withholdings, but only for a year in which such U.S. Holder elects to do so for all creditable foreign income taxes. To the extent a refund of the tax withheld is available to a U.S. Holder under Danish law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against a U.S. Holder’s U.S. federal income tax liability. Investors are urged to consult their own tax advisors about the availability of any foreign tax credits or deductions in respect to their specific tax situations.

Sale, Exchange or Taxable Disposition of ADSs

Subject to the PFIC rules described below under “— Passive Foreign Investment Company Considerations”, a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the United States dollar value of the amount realized and the holder’s adjusted tax basis, determined in United States dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder’s holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are generally taxed at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder’s ability to deduct capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

We believe that we were not a PFIC for our 2025 taxable year but have not made a determination as to whether the Company will or will not be treated as a PFIC in the current taxable year and subsequent or prior taxable years. The determination of PFIC status is inherently factual, is subject to a number of uncertainties (including with respect to the market price of the ADSs, which may fluctuate considerably), and can be determined only annually after the close of the tax year in question. Additionally, the analysis depends, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. There can be no assurance that the Company will or will not be determined to be a PFIC for the current tax year or any prior or future tax year, and no opinion of legal counsel or ruling from the IRS concerning the status of the Company as a PFIC has been obtained or will be requested. U.S. Holders should consult their own U.S. tax advisors regarding our PFIC status.

If we were classified as a “passive foreign investment company”, or a “PFIC”, for U.S. federal income tax purposes in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. A non-U.S. corporation, such as the Company, will be classified as a PFIC for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of “passive” income (the “income test”) or (ii) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income (the “asset test”). For this purpose, cash and assets readily convertible into cash are categorized as passive assets and the Company’s goodwill and other unbooked intangibles are taken into account. Passive income generally includes, among other things, dividends, interest, rents, royalties, and gains from the disposition of passive assets. However, certain rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. For purposes of the PFIC test, we will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, at least 25% (by value) of the stock.

If we were a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime would apply to the U.S. Holder with respect to (i) any “excess distribution” (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder’s holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder’s holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder’s regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we were determined to be a PFIC, this tax treatment for U.S. Holders would apply also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “— Dividends.”

A U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the PFIC income and asset tests described above, unless the U.S. Holder elects to recognize gain via a “deemed sale” election, which will be taxed under the excess distribution rules as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the ADSs with respect to which such election was made will not be treated as ADSs in a PFIC.

Certain elections by a U.S. Holder would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below. These elections include a “qualified electing fund” or “QEF” election and a “mark-to-market” election, which is described in more detail below. We do not expect that a U.S. Holder would be able to make a QEF election with respect to the ADSs because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

In the event we are determined to be a PFIC, the rules applicable to PFICs described above would not apply to a U.S. Holder that makes a “mark-to-market” election with respect to the ADSs, but this election will be available with respect to the ADSs only if they meet certain minimum trading requirements to be considered “marketable stock” for purposes of the PFIC rules. Generally, ADSs will be treated as marketable stock if they are “regularly traded” on a “qualified exchange” within the meaning of applicable Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs will be considered marketable stock as long as they remain listed on The Nasdaq Capital Market and are regularly traded. We anticipate that the ADSs should qualify as being regularly traded, but no assurances may be given in this regard.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder's adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder's adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years and may be subject to certain other limitations. The U.S. Holder's adjusted tax basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to such U.S. Holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the ADSs cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we were a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above would apply to any mark-to-market gain recognized in the year the election is made.

A U.S. Holder of PFIC shares or ADSs must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund).

The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a mark-to-market election with respect to the ADSs.

Net Investment Income Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this net investment income tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable Treasury Regulations, exceeds \$100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

Dividend payments with respect to the ADSs and proceeds from the sale, exchange or other taxable disposition of the ADSs may be subject to information reporting to the IRS and possible U.S. backup withholding. In general, information reporting, including IRS Form 1099 reporting, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or other taxable disposition of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes other required certifications, or who is otherwise exempt from backup withholding. U.S. Holders that are required to establish their exempt status generally must provide such certification on IRS Form W-9. Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS, provided that the required information is timely furnished to the IRS. U.S. Holders are urged to consult their tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We are subject to certain of the information reporting requirements of the Exchange Act. As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our directors, executive management and principal shareholders are exempt from the reporting (until March 2026) and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of Form 6-K.

The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of this website is <http://www.sec.gov>. The company's website is www.evaxion.ai.

10.I. Subsidiary Information

Not applicable.

10.J. Annual Report to Security Holders

The Company intends to submit any annual report provided to security holders in electronic format as an exhibit to a current report on Form 6-K.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

See "Item 5.A. Operating and Financial Review and Prospects—Quantitative and Qualitative Disclosures about Market Risk."

Item 12. Description of Securities Other Than Equity Securities**12.A. Debt Securities**

Not applicable.

12.B. Warrants and Rights

Not applicable.

12.C. Other Securities

Not applicable.

12.D. American Depositary Shares Fees and Charges

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

- **Persons depositing or withdrawing shares or ADS holders must pay:**
- \$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)
- \$.05 (or less) per ADS
- A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs
- \$.05 (or less) per ADS per calendar year
- Registration or transfer fees
- Expenses of the depositary
- Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes
- Any charges incurred by the depositary or its agents
- **For:**
- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
- Cable and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to United States dollars
- As necessary
- As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement.

The methodology used to determine exchange rates used in currency conversions is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from the us in USD that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to The Rights of Security Holders And Use Of Proceeds

A.-D. Material Modifications to the Rights of Security Holders

Not applicable.

E. Use of Proceeds

Not applicable.

Item 15. Controls And Procedures

(a) Disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2025, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective as of December 31, 2025.

(b) Management's annual Report on internal control over financial reporting

Our management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Internal control over financial reporting is defined in rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board.

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO 2013) in the Internal Control-Integrated Framework. Based on its assessment and those criteria, our management with the participation of the Chief Executive Officer and Chief Financial Officer, determined that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2025.

(c) Attestation report of the registered public accounting firm

This annual report does not include an attestation report of the Company's registered public accounting firm because as an emerging growth company, we are exempt from this requirement.

(d) Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our board has determined that Mr. Lars Holtug qualifies to serve as an “audit committee financial expert” as defined under the SEC rules, and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Mr. Lars Holtug also qualifies as an independent director under the corporate governance standards of the Nasdaq listing requirements and the audit committee independence requirements of Rule 10A-3 of the Exchange Act. For more information see “Item 6. Directors, Senior Management and Employees – C. Board Practices – Committees of our Board of Directors – Audit Committee.”

Item 16B. Code of Ethics

Code of Business Conduct

We have adopted a code of business conduct and ethics, or code of conduct, which outlines the principles of legal and ethical business conduct under which we do business. The code of conduct applies to all of our directors and employees, including our executive management. The full text of the code of conduct will be made available on our website at evaxion.ai/investors/corporate-governance/. The information on, or that can be accessed through, our website is not part of and is not incorporated by reference into this Form 20-F. We have included our website address as an inactive textual reference only. Any amendments to the provisions of the code of conduct will be made only after approval by our board of directors or committees thereof and will be disclosed on our website promptly following the date of such amendment or waiver. Any waivers from the provisions of the code of conduct for the benefit of a director or a member of executive management will be made only after approval by our board of directors or committee thereof and will be disclosed in accordance with applicable securities laws and any waiver from the provisions of the code of conduct for other employees may be made by our compliance officer or by our board of directors or committee thereof.

Item 16C. Principal Accountant Fees and Services

The following table provides information regarding fees paid by us to EY Godkendt Revisionspartnerselskab for all services, for the years ended December 31, 2025, and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
	(USD in thousands)	
Audit fees	\$ 329	\$ 297
Audit related fees	106	190
Other fees	80	198
Total fees	\$ 515	\$ 685

In 2025 and 2024, audit fees relate to audit of the annual consolidated financial statements and for review services.

Audit Committee

Pre-Approval Policies and Procedures

Our audit committee’s specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of Evaxion include the approval of audit and non-audit services to be provided by the independent auditor before the auditor is engaged to render such services. The audit committee approves in advance the particular services or categories of services to be provided to Evaxion during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees

None.

Item 16E. Purchases of Equity Securities by The Issuer And Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance**Foreign Private Issuer Exemption**

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Kingdom of Denmark instead of those otherwise required under the Nasdaq Rules applicable to domestic issuers, we intend to follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we shall voluntarily follow most Nasdaq corporate governance rules that are applicable to Evaxion, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);
- exemption from Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of United States companies that are subject to the Exchange Act until March 2026; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require Board of Directors approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Except as stated above, we intend to substantially comply with the rules applicable to United States companies listed on The Nasdaq Stock Market. Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(e)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to Danish requirements in lieu of many of the Nasdaq corporate governance rules, and we relied on such rules with respect to a majority of independent directors and for our committees from May 2023 through December 2023, we intend to comply with the Nasdaq corporate governance rules applicable to foreign private issuers going forward. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer. In addition, we have opted to follow home country law instead of the Nasdaq Listing Rules that require that a listed company obtain shareholder approval for certain dilutive events, such as certain transactions other than a public offering involving issuances of a 20% or greater interest in the company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company may provide our shareholders with less protection than they would have as shareholders of a domestic U.S. company.

Accordingly, our shareholders and holders of ADSs will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq and the domestic reporting requirements of the SEC. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer. For an overview of our corporate governance principles, see the section titled "Description of Share Capital – Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law."

Evaxion Shareholder Rights Under Danish Law

Notice of Meeting

Denmark. According to the Danish Companies Act, general meetings in limited liability companies shall be convened by the board of directors with a minimum of two weeks' notice and a maximum of four weeks' notice as set forth in the articles of association. A convening notice shall also be forwarded to shareholders recorded in our owners' register, who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

Delaware. Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Voting Rights

Denmark. Each ordinary share confers the right to cast one vote at the general meeting of shareholders, unless the articles of association provide otherwise. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our subsidiaries do not confer the right to vote.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation

According to Section 73 of the Danish Companies Act, a minority shareholder may require a majority shareholder that holds more than 90% of the company's registered share capital to redeem his or her shares. Similarly, a majority shareholder holding may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than ten days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

Denmark. According to the Danish Companies Act, extraordinary general meetings of shareholders will be held whenever our board of directors or our appointed auditor requires. In addition, one or more shareholders representing at least 1/20th of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is forwarded, the board of directors shall convene the general meeting within two weeks thereafter.

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are made in writing and forwarded at the latest six weeks prior thereto. In the event that the proposal is received at a later date, the board of directors will decide whether the proposal has been forwarded in due time to be included on the agenda. Any business not included on the agenda may be transacted by the general meeting only if all shareholders' consent.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

Denmark. Under Danish law, it is permissible for shareholders to take action and pass resolutions by written consent in the event of unanimity; however, this will normally not be the case in listed companies and for a listed company, this method of adopting resolutions is generally not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

Denmark. The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemptions rights according to the Danish Companies Act, more than 90% of the company's share capital may, according to Section 70 of the same act, squeeze out the minority shareholders. In the event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the Danish Companies Act that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the Danish Companies Act, entitled to have their shares redeemed.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

Denmark. Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

Denmark. Danish limited liability companies may not subscribe for newly issued shares in their own capital. Such company may, however, according to the Danish Companies Act Sections 196-201, acquire fully paid shares of its own capital provided that the board of directors has been authorized thereto by the shareholders acting in a general meeting. Such authorization can only be given for a maximum period of five years and the authorization shall fix (i) the maximum value of the shares and (ii) the minimum and the highest amount that the company may pay for the shares. Shares may generally only be acquired using distributable reserves.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover Provisions

Denmark. Under Danish law, it is possible to implement limited protective anti-takeover measures. Such provisions may include, among other things, (i) different share classes with different voting rights, (ii) specific requirements to register the shares on name in the company's owners register and

(iii) notification requirements concerning participation in general meetings. We have currently not adopted any such provisions.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transaction;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption

Inspection of Books and Records

Denmark. According to Section 150 of the Danish Companies Act, a shareholder may request an inspection of the company’s books regarding specific issues concerning the management of the company or specific annual reports. If approved by shareholders with simple majority, one or more investigators are elected. If the proposal is not approved by simple majority but 25% of the share capital votes in favor, then a shareholder can request the court to appoint an investigator.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation’s books and records, for any proper purpose, during the corporation’s usual hours of business.

Pre-emptive Rights

Denmark. Under Danish law, all shareholders have pre-emptive subscription rights in connection with capital increases that are carried out as cash contributions. In connection with an increase of a company’s share capital, the shareholders may, by resolution at a general meeting, approve deviations from the general Danish pre-emptive rights of the shareholders. Under the Danish Companies Act, such resolution must be adopted by the affirmative vote of shareholders holding at least a two-thirds majority of the votes cast and the share capital represented at the general meeting and requires that such capital increases will be carried out as a cash contribution at market price.

The board of directors may resolve to increase our share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations described above under the caption “Development of the Share Capital.”

Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, United States shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights under United States securities law.

Delaware. Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the distribution of ordinary and extraordinary dividends requires the approval of a company’s shareholders at a company’s general meeting. Under the Danish Companies Act the general meeting may authorize the board of directors to resolve to distribute extraordinary dividends after presentation of a company’s first financial statements. The authorization may be subject to financial and time restrictions. The shareholders may not distribute dividends in excess of the recommendation from the board of directors and may only pay out dividends from our distributable reserves, which are defined as amounts stated as retained earnings in the Company’s latest approved financial statements and reserves not being non-distributable under a statute or the Company’s articles of association, less retained earnings. The decision to pay out extraordinary dividends shall be accompanied by a balance sheet, and the board of directors determine whether it will be sufficient to use the balance sheet from the annual report or if an interim balance sheet for the period from the annual report period until the extraordinary dividend payment shall be prepared. If extraordinary dividends are paid out later than six months following the financial year for the latest annual report, an interim balance sheet showing that there are sufficient funds shall always be prepared. Furthermore, it is possible under Danish law to distribute assets other than cash as dividends. If assets other than cash are distributed as dividends, a valuation report must be prepared. The valuation report must be prepared by one or more impartial valuation experts.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

Shareholder Vote on Certain Reorganizations

Denmark. Under Danish law, all amendments to the articles of association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the represented share capital. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers with the company as the transferor company and demergers with the company as the existing transferee if amendment of the articles of association for any purpose other than the adoption of the transferor company's name or secondary name as the transferee company's secondary name is required to be made. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company's business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to Governing Documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the Danish Companies Act and the articles of association. Resolutions concerning all amendments to the articles of association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder's ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation's certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is Computershare A/S, Lottenborgvej 26 D, 1., DK- 2800 Kgs. Lyngby, Denmark. Since the closing of our public offering, The Bank of New York Mellon has served as the depository, registrar and transfer agent for the ADSs.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J. Insider Trading Policies

The Company has adopted an insider trading policy 3.d. that is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to the Company. A copy is filed as Exhibit 11.1 to this annual report.

Item 16K. Cybersecurity

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft, fraud, extortion, harm to employees or customers, violation of privacy laws and other litigation and legal risk, and reputational risk.

We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. Our cybersecurity program is aligned with industry standards and best practices. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. We require third-party service providers with access to personal, confidential or proprietary information to implement and maintain comprehensive cybersecurity practices consistent with applicable legal standards and industry best practices.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share.

While we have not experienced any material system failures, accidents or security breaches to date, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the future. Any such unauthorized access or breach could materially harm our business, financial condition, results of operations and prospects.

PART III

Item 17. Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

Our audited consolidated financial statements are included in this annual report beginning at Page F-1.

EVAXION A/S

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Evaxion A/S

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Evaxion A/S (the Company) as of December 31, 2025, and 2024, the related consolidated statements of comprehensive loss, changes in equity (deficit) and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

EY Godkendt Revisionspartnerselskab

We have served as the Company's auditor since 2019.

Copenhagen, Denmark

March 5, 2026

EVAXION A/S

Consolidated Statements of Comprehensive Loss

	Note	Years Ended December 31,		
		2025	2024	2023
		(USD in thousands, except per share amounts)		
Revenue	5	\$ 7,528	\$ 3,344	\$ 73
Research and development	7, 8	(9,975)	(10,457)	(11,916)
General and administrative	7, 8	(6,787)	(7,619)	(10,354)
Operating loss		(9,234)	(14,732)	(22,197)
Finance income	10	4,616	6,500	963
Finance expenses	10	(3,997)	(3,123)	(1,681)
Net loss before tax		(8,615)	(11,355)	(22,915)
Income tax benefit	11	908	788	790
Net loss for the year		\$ (7,707)	\$ (10,567)	\$ (22,125)
Net loss attributable to shareholders of Evaxion A/S		\$ (7,707)	\$ (10,567)	\$ (22,125)
<i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax):</i>				
Exchange differences on translation of foreign operations		—	(14)	(57)
Exchange rate adjustments of investments in subsidiaries		(41)	(5)	3
<i>Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax):</i>				
Exchange differences on currency translation to presentation currency		406	197	(68)
Other comprehensive income/(loss) for the year, net of tax		\$ 365	\$ 178	\$ (122)
Total comprehensive loss		\$ (7,342)	\$ (10,389)	\$ (22,247)
Total comprehensive loss attributable to shareholders of Evaxion A/S		\$ (7,342)	\$ (10,389)	\$ (22,247)
Loss per share – basic and diluted	12	\$ (0.02)	\$ (0.20)	\$ (0.81)

The accompanying notes are an integral part of these consolidated financial statements.

EVAXION A/S

Consolidated Statements of Financial Position

	Note	December 31,	
		2025	2024
(USD in thousands)			
ASSETS			
Non-current assets			
Property and equipment, net	13	\$ 3,322	\$ 3,514
Government grants receivables, non-current		—	44
Leasehold deposits, non-current		185	162
Total non-current assets		3,507	3,720
Current assets			
Prepayments and other receivables	14	801	1,273
Tax receivables, current		866	1,540
Cash and cash equivalents	16	23,234	5,952
Total current assets		24,901	8,765
TOTAL ASSETS		\$ 28,408	\$ 12,485
EQUITY (DEFICIT) AND LIABILITIES			
Share capital			
Share capital	19	\$ 15,791	\$ 10,516
Other reserves		127,492	106,369
Accumulated deficit		(126,244)	(118,537)
Total equity (deficit)		17,039	(1,652)
Non-current liabilities			
Lease liabilities, non-current	17	1,607	1,620
Borrowings, non-current	18	5,347	8,008
Provisions	22	158	141
Total non-current liabilities		7,112	9,769
Current liabilities			
Lease liabilities, current	17	360	314
Derivative liability	6	287	—
Borrowings, current	18	190	159
Trade payables		2,186	2,968
Other payables	15	1,234	927
Total current liabilities		4,257	4,368
Total liabilities		11,369	14,137
TOTAL EQUITY (DEFICIT) AND LIABILITIES		\$ 28,408	\$ 12,485

The accompanying notes are an integral part of consolidated financial statements.

EVAXION A/S

Consolidated Statements of Changes in Equity (Deficit)

	Note	Other reserves				Accumulated deficit	Total equity (deficit)
		Share capital	Share premium	Share-based payments reserve	Foreign currency translation reserve		
(USD in thousands)							
Equity at December 31, 2022		\$ 3,886	\$ 80,727	\$ 13,186	\$ (3,651)	\$ (85,845)	\$ 8,303
Net loss for the period		—	—	—	—	(22,125)	(22,125)
Other comprehensive income		—	—	—	(122)	—	(122)
Share-based compensation	9	—	—	479	—	—	479
Issuance of shares for cash	19	2,013	7,155	—	—	—	9,168
Transaction costs	19	—	(432)	—	—	—	(432)
Equity (deficit) at December 31, 2023		\$ 5,899	\$ 87,450	\$ 13,665	\$ (3,773)	\$ (107,970)	\$ (4,729)
Net loss for the period		—	—	—	—	(10,567)	(10,567)
Other comprehensive income		—	—	—	178	—	178
Share-based compensation	9	—	—	357	—	—	357
Issuance of shares for cash	19	4,617	11,933	—	—	—	16,550
Non-cash effect from issue of investor warrants classified as derivative liability	6	—	(1,097)	—	—	—	(1,097)
Transaction costs	19	—	(2,344)	—	—	—	(2,344)
Equity (deficit) at December 31, 2024		\$ 10,516	\$ 95,942	\$ 14,022	\$ (3,595)	\$ (118,537)	\$ (1,652)
Net loss for the period		—	—	—	—	(7,707)	(7,707)
Other comprehensive income		—	—	—	365	—	365
Share-based compensation	9	—	—	342	—	—	342
Issuance of shares for cash	19	5,275	19,794	—	—	—	25,069
Non-cash effect from issue of investor warrants classified as derivative liability	6	—	1,221	—	—	—	1,221
Transaction costs	19	—	(1,908)	—	—	—	(1,908)
Forfeited warrants		—	228	(228)	—	—	—
Reclassification share-based compensation reserve		—	4,145	(4,145)	—	—	—
Loan conversion	18	—	1,309	—	—	—	1,309
Equity at December 31, 2025		\$ 15,791	\$ 120,731	\$ 9,991	\$ (3,230)	\$ (126,244)	\$ 17,039

The accompanying notes are an integral part of these consolidated financial statements.

EVAXION A/S

Consolidated Statements of Cash Flows

	Note	Years Ended December 31,		
		2025	2024	2023
				(USD in thousands)
Operating activities:				
Net loss for the year		\$ (7,707)	\$ (10,567)	\$ (22,125)
Adjustments for non-cash items:				
Reversal of finance income		(4,616)	(6,209)	(546)
Reversal of finance expense		3,997	2,967	1,622
Reversal of tax charge		(908)	(788)	(790)
Tax credit schemes accounted for as grants		—	(25)	(194)
Share-based compensation		307	357	479
Depreciation		615	607	615
Changes in working capital:				
Receivables		178	(167)	259
Prepayments		406	736	802
Contract liabilities		48	(45)	(200)
Trade payables, accrued expenses and other payables		(536)	(62)	762
Exchange rate translation effects on working capital items		(233)	58	(61)
Cash flows used in operations		(8,449)	(13,138)	(19,377)
Interest received		299	254	154
Interest paid		(107)	(56)	(65)
Income taxes received		1,632	—	1,597
Net cash used in operating activities		(6,625)	(12,940)	(17,691)
Investing activities:				
Purchase of property and equipment	13	(11)	—	(87)
Payment of non-current financial assets – leasehold deposits		(3)	(3)	(6)
Net cash used in investing activities		(14)	(3)	(93)
Financing activities:				
Proceeds from issuance of shares and exercise of warrants, less underwriter discounts	19	23,161	14,206	11,323
Exchange loss from repayment of borrowings		—	59	—
Repayment of borrowings		(399)	(805)	(371)
Proceeds from borrowings		(0)	(0)	65
Leasing installments	17	(352)	(331)	(326)
Net cash provided by financing activities		22,410	13,129	10,691
Net increase/ (decrease) in cash and cash equivalents		15,771	186	(7,093)
Cash and cash equivalents at January 1	16	5,952	5,583	13,184
Exchange rate adjustments on cash and cash equivalents		1,511	183	(508)
Cash and cash equivalents at December 31	16	\$ 23,234	\$ 5,952	\$ 5,583

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. General Company Information

Evaxion A/S (the “Company” or “Evaxion”) is a clinical-stage TechBio company developing novel vaccines with its proprietary, clinically validated and scalable AI platform, AI-Immunology™. The platform harnesses the power of artificial intelligence to decode the human immune system and develop novel vaccine candidates for cancer and infectious diseases for patients in the global market. Unless the context otherwise requires, references to the “Company,” “Evaxion,” “we,” “us,” and “our”, refer to Evaxion A/S and its subsidiaries.

Evaxion is a public limited liability company incorporated and domiciled in Denmark with its registered office located at Dr. Neergaards Vej 5f, DK-2970 Horsholm, Denmark.

On February 5, 2021, the Company completed an initial public offering (“IPO”), which resulted in the listing of ADSs representing the company’s ordinary shares, under the symbol “EVAX” in the United States on the Nasdaq Capital Market.

On January 14, 2025, the Company made effective a change to the ratio of ADSs to ordinary shares, DKK 1 nominal value (the “ADS Ratio”). The ratio has been changed from one ADS representing ten (10) ordinary shares to a new ADS Ratio of one ADS representing fifty (50) ordinary shares of the Company. Unless specified otherwise, all references in this annual report to ADS share and ADS per share data have been adjusted, including historical data which has been retroactively adjusted, to give effect to the ADS Ratio change.

The consolidated financial statements of Evaxion A/S and its subsidiaries (collectively, the “Group”) for the year ended December 31, 2025, were approved, and authorized for issuance, by the Board of Directors on March 5, 2026.

Emerging Growth Company Status

Evaxion is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The consolidated financial statements have been prepared in accordance with IFRS Accounting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”).

The Company has elected to take advantage of specified reduced reporting and regulatory requirements in contrast to those otherwise applicable generally to public companies. This provision includes the exemption from the auditor attestation requirement in the assessment of the Company’s internal control over financial reporting pursuant to Section 404 the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act.

Evaxion will remain an emerging growth company until the earliest of (i) the last day of the first fiscal year (a) following the fifth anniversary of the completion of the global offering, (b) in which its annual gross revenue totals at least \$1.235 billion or (c) when the Company is deemed to be a large accelerated filer, which means the market value of the Company’s ordinary shares that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (ii) the date on which the Company has issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Note 2. Liquidity and Going Concern Assessment

Management and the Board of Directors have assessed the Company’s ability to continue as a going concern and believe the Company has adequate resources to meet its obligations in the foreseeable future. With the Company’s current financial position, available funding, and projected cash flows, Management and the Board of Directors are confident that the Company will continue its operations for at least the next 12 months, and with our current strategic plans and forecasted cash burn, we have sufficient cash to finance operations into second half of 2027.

Accordingly, the annual report has been prepared on a going concern basis in accordance with applicable accounting standards.

We have considered potential risks and uncertainties, including market conditions, economic factors, and liquidity needs. After reviewing the Company’s financial forecast and access to capital, the Board does not anticipate material uncertainties that would cast significant doubt on the Company’s ability to continue as a going concern.

The Company monitors its funding situation closely to ensure that it has access to sufficient liquidity to meet its forecast cash requirements. Analyses are run to reflect different scenarios including, but not limited to, cash runway, human capital resources and pipeline priorities to identify liquidity risk. This enables Management and the Board of Directors to prepare for new financing transactions and/or adjust the cost base accordingly.

The Company's plan is to balance the funding of cash needs through capital market transactions, such as public offerings, at-the-market ("ATM") program, warrant exercises or other capital sources in case this is not covered by income from potential collaborations or licenses, thus assuring continued going concern.

The Company anticipates incurring additional losses until such time, if ever, it can complete its research and development activities and obtain sufficient out-licensing partnerships for its product candidates and generate revenues from such product candidates. Substantial additional financing will be needed by the Company to fund its operations and to continue development of product candidates.

Failure to raise capital or enter into such other arrangements when needed could have a negative impact on the Company's financial condition and its ability to pursue its business plans and strategies. If the Company is unable to raise additional capital when needed, it could be forced to delay, limit, reduce or terminate its product candidate development or grant rights to develop and market its product candidates.

Note 3. Summary of Accounting Policies

Basis of Preparation

The consolidated financial statements have been prepared in accordance with IFRS Accounting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates and requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 4.

The consolidated financial statements are presented in the Company's presentation currency, U.S. dollar ("USD") which is not the functional currency of the parent company. The Group's financial statements are presented in USD as the result of the Company's publicly listing the ADSs in the United States. The Company's functional currency is DKK for Denmark. The consolidated financial statements have been prepared on a going concern basis using a historical cost basis. All financial assets and liabilities are measured at amortized cost unless otherwise stated.

Basis of Consolidation

The consolidated financial statements of the Company comprise the consolidated statement of financial position as of December 31, 2025, and 2024, and the consolidated statement of comprehensive loss for the twelve months ended December 31, 2025, and 2024, and 2023. Subsidiaries are entities controlled by the Company. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and can affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. The accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Company. Control is reassessed whenever facts and circumstances indicate that there are changes of control.

All intra-Group assets and liabilities, equity (deficit), income, expenses, and cash flow relating to transactions between members of the Group are eliminated in full in the consolidated statements.

Currency Translation of Transactions and Balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized as financial income or financial expenses in the consolidated statements of comprehensive loss. Non-monetary items in foreign currency which are measured at cost at the consolidated statements of financial position date are translated using the exchange rates at the date of the transaction.

Translation of Foreign Operations

Assets and liabilities in the Company's functional currency, DKK and AUD, for Denmark and Australia, respectively, are translated to the Company's presentation currency at the exchange rate applicable on December 31 for the respective year. Income and expenses in the Company's functional currency are translated to USD at the average exchange rate which corresponds to an approximation of the exchange rates prevailing on each individual transaction date. Translation differences arising in the translation to presentation currency are recognized in other comprehensive income.

Revenue Recognition

The Company recognizes revenue in accordance with IFRS 15, *Revenue from Contracts with Customers*. To determine revenue recognition for agreements that the Company determines are within the scope of IFRS 15, the Company performs the following five steps:

- i. Identify the contract
- ii. Identify the performance obligations in the contract
- iii. Determine the transaction price
- iv. Allocate the transaction price to the performance obligations in the contract
- v. Recognize revenue when (or as) the entity satisfies a performance obligation

When contracts with customers are entered into, the goods and/or services promised in the contract are assessed to identify distinct performance obligations.

A promise in the agreement is considered a distinct performance obligation if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct); and
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

The transaction price is the amount of the consideration the Company expects to be entitled to in exchange for those goods or services. The transaction price may include up-front payments and milestone payments.

Licenses of Intellectual Property

If the license to the company's intellectual property is determined to be distinct from the other performance obligations identified in an out-licensing arrangement, the company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition

Milestone Payments

At the inception of each arrangement that includes development milestone payments, the company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Contract Work

Revenue from contract research and licenses that do not transfer the right of ownership to an intangible asset are recognized over time in line with the execution and transfer of the services. The percentage of completion is made up based on the stage of completion on each individual work in progress.

Research and Development Expenses

Expenses related to service agreements are recognized in the income statement when the related payments and milestone events in the corresponding collaboration agreements materialize. The expenses are included in research and development expenses.

Research and development expenses are primarily internal and external costs incurred in the development of the Company's product candidates, including personnel costs, share-based compensation, external research and development expenses, maintenance of the Company's patents, overhead allocation and enhancements and maintenance of the Company's technology platforms.

The research activities are comprised of activities performed before filing an IND or equivalent and necessary preclinical activities for such product candidates. All research expenses are recognized in the period in which they are incurred, and payments made prior to the receipt of goods or services to be used in research and development are deferred until the goods or services are received. The Company records accruals for estimated research and development costs, comprising payments for work performed by third-party contractors and others. Payments for these activities are based on the terms of the individual agreements, which may differ from the timing of the expense recognition of these costs, in which case they are reflected in the consolidated financial statements as either prepaid- or accrued expenses.

The development activities are comprised of the activities performed following the filing of an IND or equivalent clinical-enabling activities for such product candidates, including but not limited to, research and clinical development activities. In line with industry practice, internal and subcontracted development costs are expensed as incurred. Due to regulatory uncertainties and other uncertainties inherent in the development of new products, development expenses do not qualify for capitalization as intangible assets until marketing approval by a regulatory authority is obtained or considered highly probable. To date, the Company has not incurred any development costs which qualified for capitalization.

The Company's estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. The Company evaluates the estimates to determine if adjustments are necessary or appropriate based on information received.

CROs invoice the Company upon the occurrence of predetermined contractual or activity-based milestones; however, the timing of these invoices and the Company's related payments often do not correspond directly to the level of performance of contracted activities. To the extent payments are made by the Company in advance of the related activities performed by the CROs, they are included in prepayments to clinical research organizations and expensed when the activities are performed by the CROs. To the extent the payments are made by the Company following the performance of the related activities, the expense is accrued for as a payable to clinical research organizations.

Intellectual Property

The Company actively seeks to create, maintain and protect intellectual property and proprietary information and technology that is considered important to the Company's business, which includes seeking and maintaining patents covering proprietary technology, product candidates, proprietary processes and any other inventions that are commercially and / or strategically important to the Company's business development. These expenses are expensed as incurred and not capitalized as intangible assets until marketing approval by a regulatory authority is obtained or considered highly probable. The Company has not incurred any costs that qualify for capitalization.

Income From Government Grants

The Company receives grants for certain research and development activities. The grant income is recognized as a reduction of research and development expenses in the period in which the underlying expenditures were incurred and when there is reasonable assurance that the Company will comply with all conditions to receive the grant income. Government grants comprise direct grants and tax credits related to qualifying research and development costs in excess of the corporate tax rate. Tax credits in an amount up to the corporate tax rate are classified as income tax benefits.

General and Administrative Expenses

General and administrative expenses consist primarily of fees paid to external consultants and personnel costs, including share-based compensation for the Company's executive, finance, corporate and business development functions. In addition, general and administrative expenses also include depreciation and other expenses for the Company's corporate headquarters as well as other allocated overhead.

Share-Based Payments

The Company issues warrants as an incentive to employees and non-employees. The fair value of the warrants granted is recognized as an expense with a corresponding credit to share-based payments reserve. The fair value is expensed over the requisite service period of the awards. The expense recognition is based on an estimate of the number of warrants expected to vest. The estimate is reassessed regularly, and on a cumulative basis, the expense is equal to the fair value of the number of warrants which actually vest.

For employees and consultants providing services similar to employees of the Company, the fair value of the equity instruments is determined at the date of grant resulting in a fixed fair value at grant date that is not adjusted for future changes in the fair value of the equity awards that may occur over the service period. The grant date is defined as the date at which the parties agree to the contractual terms.

For consultants providing other services that are not similar to employees of the Company, the transactions are measured at the fair value of the services received unless this is not reliably measurable. In such cases, the transactions are measured at fair value of the equity instruments granted at the dates when the services are provided.

Modification of warrants which are beneficial are accounted for with their incremental value or over the shorter vesting period. Non-beneficial modifications such as an extension of the vesting period are not accounted for. Consequently, the original terms are deemed to continue to exist. The Company estimates the fair value of warrants using the underlying value of the Company's ordinary shares. Since the warrants granted before December 2020 are exercisable for nominal consideration, the warrants are valued using the fair value of the Company's ordinary shares on grant date less the exercise consideration. Warrants granted during 2025, and 2024 are valued using a Black-Scholes share option pricing model. The assumptions used in calculating the fair value of share-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The key assumption in this estimate is the fair value of the Company's ordinary share on the warrant grant date.

Accounting for Joint Operations - ExpreS2ion Biotechnologies ApS

In December 2022 the Company entered into a Vaccine Discovery Collaboration Agreement with ExpreS2ion Biotech Holding AB's affiliate ExpreS2ion Biotechnologies ApS ("ExpreS2ion") for the joint development of a novel cytomegalovirus (CMV) vaccine candidate.

In determining the accounting treatment for these types of arrangements, the Company carefully evaluates the relationship between the two parties in order to determine whether the arrangement is, in substance, a collaboration arrangement between the two parties (to be accounted for in accordance with IFRS 11), or rather, a vendor-customer contract (to be accounted for in accordance with IFRS 15).

Management has determined that ExpreS2ion does not meet the definition of a customer under IFRS 15. Consequently, the arrangement is classified as a collaboration arrangement and is accounted for as a joint operation in accordance with IFRS 11 resulting in the recognition of the Company's own income and expense and assets and liabilities, respectively.

In the first half of 2025, the collaboration agreement has ended, and Evaxion has taken the full ownership, responsibility and all rights of the asset (EVX-V1) and can potentially out-license it at our discretion.

Finance Income

Finance income consists primarily of foreign currency gains, and gains from changes in fair value of liability-classified warrants.

Finance Expense

Finance expenses consist primarily of foreign currency losses, losses from changes in fair value of liability-classified warrants, losses from changes in fair value of derivative liabilities, interest expense and related loan costs on the EIB Loan Agreement (as defined herein), and interest expense on leasing liabilities.

Income Tax

The income tax for the period comprises current and deferred tax, including prior-year adjustments and changes in provisions for uncertain tax positions. Tax is recognized in the consolidated statement of comprehensive loss, except to the extent that it relates to items recognized in equity (deficit).

Research and development tax credits are available to the Group under the tax laws of Denmark and Australia respectively, based on qualifying research and development spend as defined under those tax laws. Tax credits not exceeding the corporate tax rate are recognized as an income tax benefit. Tax credits in excess of the corporate tax rate are classified as government grants.

Accruals for uncertain tax positions and/or valuation of government grant receivables require management to make judgments of potential exposures. Accruals for uncertain tax positions and/or valuation of government grant receivables are measured using either the most likely amount or the expected value amount, depending on taxable amounts.

Deferred Taxes

Deferred tax is measured according to the liability method on all temporary differences between the carrying amount and the tax base of assets and liabilities. Where the tax value can be determined according to alternative tax rules, deferred tax is measured on the basis of the planned use of the asset or the settlement of the obligation.

Deferred tax assets are measured at the value at which they are expected to be utilized, either through elimination against tax on future earnings or through a set-off against deferred tax liabilities. Deferred tax assets are set off within the same legal tax entity and jurisdiction.

Uncertainties exist with respect to the interpretation of complex tax regulations and the amount and timing of future taxable income. Given the complexity of existing contractual agreements, differences arising between the actual results and the assumptions made, or future changes to such assumptions could necessitate future adjustments to tax income and expenses already recorded. As of December 31, 2025, and 2024, the Company has not recognized any provisions for uncertain tax positions resulting in a risk that the deferred tax asset related to warrants is lower than disclosed.

The Company recognizes deferred income tax assets if there is convincing evidence that sufficient taxable income will be available in the future against which the temporary differences and unused tax losses can be utilized. Management has considered future taxable income in assessing whether deferred income tax assets should be recognized and has concluded that the deferred income tax assets do not meet the criteria for recognition as assets in the consolidated statements of financial position.

Tax Receivables

Current tax assets for the current and prior periods are measured at the amount expected to be recovered from the taxation authorities, using the tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period.

Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Company recognizes lease liabilities for future remaining lease payments and right-of-use assets representing the right to use the underlying assets.

Leasehold Improvements and Loan From Lessor

The Company's lease contract comprises funding for the customization of the premises to the Company's specific needs. The payment is determined based on the actual costs incurred for the customization, a repayment period of 8 years and an interest rate of 6% per annum.

The Company has assessed whether this is a lease component, or a leasehold improvement funded by the lessor. We have considered the following factors:

- Which party designed the customization
- Which party had the right to direct changes to the work
- Who is taking on the economic risk of the cost price of the work

A third party has designed the project according to the Company's instructions, and the Company had the right to direct changes to the work during the construction period. Further, the Company has the full economic risk of the work due to 1:1 linkage between construction costs and payments to the lessor. Consequently, the Company has assessed that the customization is a leasehold improvement funded by the lessor and accordingly presented a leasehold improvement and a corresponding liability for the loan from the lessor.

Right-of-use Assets

The Company recognizes a right-of-use asset at the lease commencement date (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost less any accumulated depreciation and impairment losses and adjusted for certain remeasurements of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, lease payments made at or before the commencement date less any lease incentives received, initial direct costs incurred, and restoration costs.

Right-of-use assets are depreciated over the shorter of the lease term and the useful life of the right-of-use asset using the straight-line method. In addition, right-of-use assets are reduced by impairment losses, if any, and adjusted for certain remeasurements.

The Company's right-of-use assets are presented within property and equipment, net.

Lease Liabilities

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of the following payments, when applicable:

- Fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payments (linked to an index or interest rate);
- expected payments under residual value guarantees;
- the exercise price of purchase options, where exercise is reasonably certain;
- lease payments in optional renewal periods, where exercise of extension options is reasonably certain;
- and penalty payments for the termination of a lease, if the lease term reflects the exercise of the respective termination option.

The lease payments are discounted using the interest rate implicit in the lease if this rate can be readily determined. Otherwise, the Company's incremental borrowing rate is used, being the rate that the Company would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions. Generally, the Company uses its incremental borrowing rate as the discount rate.

Lease liabilities are subsequently measured at amortized cost using the effective interest method. In addition, the carrying amount of the lease liabilities are remeasured if there is a modification, a change in the lease term, or a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments).

Intangible Assets

The Company recognizes intangible assets for licenses. Licenses are measured at cost less cumulative amortization and impairment. Cost is measured at fair value of the consideration transferred with addition of transactions costs. If additional consideration is transferred to the seller due to meeting certain milestones, these payments are added to the cost price once the conditions for making the payments are met. As of December 31, 2025, the Company did not have an intangible asset balance.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Depreciation is recognized on a straight-line basis over the estimated useful lives of the assets, as follows:

Assets	Useful life
Properties	Shorter of lease term and useful life of the asset
Leasehold improvements	11 years
Other equipment	5 – 10 years

Impairment of Non-Financial Assets

Assets are tested for impairment annually, or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered impairment are reviewed for possible reversal of the impairment at the end of each reporting period. The Company has not recognized any impairment losses to date.

Provisions

Provisions are recognized when we have an existing legal or constructive obligation as a result of events occurring prior to or on the balance sheet date, and it is probable that the utilization of economic resources will be required to settle the obligation. Provisions are measured as the best estimate of the expense necessary to settle the obligation at the balance sheet date. Provisions that are estimated to mature after more than one year after the balance sheet date are measured at their present values, using a discount rate based on the Company's risk adjusted incremental borrowing rate.

Financial Instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial instruments are classified at initial recognition, including on the basis of the purpose for which the instrument was acquired and managed. This classification determines the valuation of the instruments.

(i) Non-Derivative Financial Assets

Non-derivative financial assets are recognized initially on the date they originate. The Company derecognizes non-derivative financial assets when the contractual rights to cash flows expire, or it transfers the right to receive cash flows in a transaction which transfers substantially all the risks and rewards of ownership of the asset. The Company's financial assets are initially recognized at fair value and subsequently measured at amortized cost less accumulated impairment losses.

The Company holds the following categories of non-derivative financial assets:

Receivables

Receivables (including lease deposits and receivables) represent the Company's right to an amount of consideration that is unconditional (i.e., only the passage of time is required before payment of the consideration is due). They are measured at amortized cost less impairment.

Prepayments include expenditures related to future financial periods and are measured at amortized cost.

Cash and Cash Equivalents

Cash is comprised of cash on hand and in bank deposit accounts. Cash equivalents are instruments with original maturities of 90 days or less, and are comprised of cash held in escrow accounts relating to the 2023 Securities Purchase Agreement.

(ii) Non-Derivative Financial Liabilities

Non-derivative financial liabilities comprise other payables which are measured initially at fair value and subsequently at amortized cost, unless otherwise noted below. The Company holds the following categories of non-derivative financial liabilities:

Trade Payables

Trade payables and accruals relate to the Group's purchase of products and services from various vendors in the normal course of business.

Other Payables

Other payables are comprised of payables to clinical research organizations, employee liabilities and other liabilities. The contract liabilities consist of CROs and vendor accruals. Employee cost liabilities comprise of provision for holiday allowance, provision for salaries and other employee-related provisions. Other liabilities consist of commitments and liabilities related to government grants received in advance.

EIB Loan

All loans and borrowings are classified as financial liabilities and are initially recorded at fair value less the value attributable to any separately accounted for embedded derivative. Further, considerations from the lender for other elements in the transaction are accounted for separately. After initial recognition, any such loans and borrowings are measured at amortized cost using the effective interest method, with the amortization recognized in finance costs.

EIB Warrants

Under the EIB Loan Agreement, EIB is entitled to an aggregate of 1,003,032 cash settled EIB Warrants with an exercise price of 1 DKK per warrant for all tranches (the "EIB Warrants"). On February 17, 2022, 351,036 EIB Warrants were issued to EIB as part of the drawdown of the first tranche of the EIB Loan. On October 3, 2024, the Company increased the number of shares issuable from the exercise of the EIB Warrants by 22,091 to 373,127 as an adjustment related to capital issuances that occurred during the year. The EIB Warrants are part of the overall return to EIB on the financing arrangement and are thus accounted for in accordance with IAS 32, *Financial Instruments: Presentation* and IFRS 9, *Financial Instruments*. The cost upon initial recognition is accounted for as transaction costs as it is directly linked to the drawdown on each individual tranche of the EIB Loan. EIB is entitled to elect net in cash settlement of its warrants at any time, and consequently a financial liability for the redemption amount is recognized.

The liability is measured initially at its fair value and is subsequently remeasured at the redemption amount. The redemption amount is equal to the current share price. The remeasurements are presented as finance expense or finance income in the consolidated statements of comprehensive loss.

(iii) Derivative Financial Instruments

Investor Warrants

Under the Securities Purchase Agreement with the 2023 SPA Investors, the Company issued warrants to purchase 9,726,898 ordinary shares. The 2023 SPA Investor Warrants vested immediately upon issuance with an exercise price of \$0.71 per ordinary share, and an expiration date of December 21, 2026. In accordance with IAS 32, the Company determined that the 2023 SPA Investor Warrants were precluded from equity classification and were determined to be derivative financial instruments, because while they contain no contractual obligation to deliver cash or other financial instruments to the holders other than the Company's own ordinary shares, the exercise price of the 2023 SPA Investor Warrants are in USD and not the Company's functional currency.

The 2023 SPA Investor Warrants are accounted for in accordance with IFRS 9 Financial Instruments and were determined to be classified as liabilities. The warrant liability was measured at fair value at initial recognition and subsequently remeasured at fair value each reporting date until either exercised or expired. The changes in the fair value of the 2023 SPA Investor Warrants during the reporting period were recognized as finance expense or finance income in the consolidated statements of comprehensive loss.

As part of the February 2024 Offering, the Company issued warrants to purchase 151,500 ADSs representing an aggregated 7,575,000 ordinary shares. The 2024 Investor Warrants vested immediately upon issuance, have an exercise price of \$20.00 per ADS, and expires five years from issuance. In accordance with IAS 32 Financial Instruments: Presentation, the Company determined that the 2024 SPA Investor Warrants were precluded from equity classification and were determined to be derivative financial instruments, because while they contain no contractual obligation to deliver cash or other financial instruments to the holders other than the Company's own ordinary shares, the exercise price of the 2024 Investor Warrants was in USD and not the Company's functional currency.

As announced on May 23, 2024, and on June 21, 2024, the Company entered into an amendment (the "2024 Warrant Amendment") to each of its 2023 SPA Warrants and 2024 Investor Warrants. The amendments convert the exercise price per ADS for the 2023 SPA Warrants from \$7.07 to DKK 47.99 and for the 2024 Investor Warrants from \$4.00 to DKK 27.52, subject to adjustment (not taking into account the ADS Ratio change). As the awards are no longer settled in foreign currency, the warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the derivative liability was reclassified to other reserves at the time of the amendment.

In connection with the January 2025 public offering, the Company issued warrants to purchase 3,997,361 ADSs, representing 199,868,050 ordinary shares. The 2025 Investor Warrants vested immediately upon issuance, have an exercise price of \$2.71 per ADS, and expires five years from the issuance date. Under IAS 32 the Company concluded that the 2025 Investor Warrants could not be classified as equity and should be accounted for as derivative financial instruments because their exercise price was denominated in USD rather than in the Company's functional currency, DKK.

As announced on May 27, 2025, the Company entered into an amendment to its 2025 Investor Warrants, with approximately 50% of the participating investors. The amendments convert the exercise price per ADS for the 2025 Investor Warrants from \$2.71 to DKK 19.15 on average. As the converted awards are no longer settled in foreign currency, the converted warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the converted portion of the derivative liability was reclassified to other reserves at the time of the amendment.

Segment Information

An operating segment is a part of the Company that conducts business activities from which it can generate revenue and incur costs, and for which independent financial information is available. Identification of segments is based on internal reporting to the chief operating decision maker ("CODM"). The CODM for the Company is the Chief Executive Officer. The Company does not divide its operations into different segments and the CODM operates and manages the Company's entire operations as one segment, which is consistent with the Company's internal organization and reporting system. The Company does not have any material non-current assets attributable to countries other than Denmark.

Shareholders' Equity (Deficit)

The share capital comprises the nominal amount of the company's ordinary shares, each at a nominal value of DKK 0.25.

Other reserves include the share premium comprising the amount received, attributable to shareholders' equity (deficit), in excess of the nominal amount of the shares issued at the company's capital increases, reduced by any expenses directly attributable to capital increases as well as translation reserves. Translation reserves include exchange rate adjustments of equity (deficit) and intragroup receivables forming part of the net investments in our group enterprises. Share-based payments reserves include the corresponding entries for share-based payments recognized in profit and loss arising from the Company's warrant program. Accumulated deficit includes the Company's accumulated profit and loss.

Loss Per Share

The calculation of basic loss per share is based on the Company's net loss for the year attributable to shareholders of Evaxion A/S and on the weighted average number of ordinary shares outstanding during the year. In calculating diluted loss per share, earnings and the average number of shares are adjusted for the dilutive effects of potential ordinary shares. Loss per share is not adjusted for any dilution that results in a loss per share that is lower than loss per ordinary share before dilution.

Reclassifications

During the period, The Company updated the presentation of specific equity balances to reflect the issuance of shares upon the exercise of warrants in a prior period. This resulted in a reclassification within equity from share-based payments reserve to share premium. This reclassification had no impact on total equity, profit or loss, or cash flows.

Certain prior year amounts in the consolidated statement cash flows were reclassified to conform with the current year's presentation.

Reclassification of operating activities includes the addition of line-items that configure both the total adjustments for non-cash items as well as changes in working capital. Reclassification of financing activities includes the netting of transaction costs related to the issuance of shares with the proceeds from the issuance of shares and exercise of warrants, less underwriter discounts. This reclassification did not impact total cash flows from operating, investing, or financing activities for any periods presented.

Standards Issued and Effective

There were a number of standards and interpretations which were issued and became effective at January 1, 2025, and have been adopted for these consolidated financial statements, including:

- Amendments to IAS 21 *Lack of Exchangeability*

The Company adopted the new standards listed above during the year ended December 31, 2025. None of the new standards listed above had a material impact on the Company's financial statements during the year ended December 31, 2025.

Standards issued but not yet effective

The following standards and interpretations which were issued but were not yet effective on December 31, 2025, and have not been adopted for these consolidated financial statements, including:

- Amendments to IFRS 9 & IFRS 7 *Classification and Measurement of Financial Instruments* (January 1, 2026)
- IFRS 18 *Presentation and Disclosure in Financial Statements* (January 1, 2027)

The Company expects to adopt these standards, updates and interpretations when they become mandatory. These standards are not expected to have a significant impact on disclosures or amounts reported in the Company's consolidated financial statements in the period of initial application and future reporting periods.

Note 4. Significant Accounting Judgements, Estimates, and Assumptions

The preparation of the consolidated financial statements in conformity with IFRS as issued by the IASB requires management to make judgements, estimates and assumptions that affect the application of policies and amounts reported in the consolidated financial statements and accompanying notes. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The critical accounting policies which involve significant estimates, assumptions or judgements, the actual outcome of which could have a material impact on the Company's results and financial position outlined below, are as follows:

Share-Based Compensation

Management determines costs for share-based payments using market-based valuation techniques. The fair value of the share awards is determined at the date of grant using generally accepted valuation techniques or valuation based on the Company's fundraising events. Assumptions are made and judgments are used in applying valuation techniques. Prior to the Company's IPO completed in February 2021, these assumptions and judgments include estimating the fair value for the underlying ordinary share on the warrant grant date, as well as the likelihood of liquidity events such as IPOs. Such judgments and assumptions are inherently uncertain. Changes in these assumptions affect the fair value estimates as well as the term applied to the expense recognition.

Subsequent to the Company's IPO completed in February 2021, determining the initial fair value and subsequent accounting for equity awards require significant judgment regarding expected life and volatility of an equity award; however, as a public listed company there is objective evidence of the fair value of an ordinary share on the date an equity award is granted. Refer to Note 9 for further details surrounding share-based compensation.

EIB Loan and EIB Warrant liability

In February 2022, the first tranche related to the Company's loan agreement with the European Investment Bank (EIB) was drawn down. As part of the loan arrangement warrants were granted to EIB.

The liability is initially recognized at fair value, net of transaction costs incurred (this includes the amount attributable to the warrants). The loan is subsequently measured at amortized cost using the effective interest method. The effective interest rate is determined based on the outstanding amount and the fixed interest payments during the period outstanding and the accumulated payment-in-kind interest payment to be paid upon repayment.

The warrants are considered a liability as they can be settled in cash and form part of the overall return to EIB on the financing arrangement and are thus accounted for in accordance with the financial instruments standards IAS 32 and IFRS 9. The liability is measured initially at its fair value. The cost upon initial recognition is accounted for as transaction costs as it is directly linked to the drawdown on each individual tranche of the EIB Loan. The warrant liability is subsequently remeasured at the redemption amount. Remeasurement of these warrants are based on observable market values.

In July 2025, the Company reached an agreement with EIB, where EIB converted €3.5 million of its €7 million loan to Evaxion into equity via a purchase of ordinary Evaxion warrants at a price of \$4.87, corresponding to a premium of 89% to the share price by market close the day before the announcement. The conversion was accounted for in accordance with IFRIC 19. Warrants issued as a result of the conversion were equity classified, and as the fair value of the warrants issued are lower than the carrying amount of the converted portion of the EIB loan, a gain upon settlement was recorded. Judgement was utilized in determining certain valuation inputs of the awarded warrants, and changes in these assumptions may affect the estimated fair value.

Investor Warrants

In December 2023, the Company entered into a Securities Purchase Agreement with the 2023 SPA Investors, for the issuance and sale in a private placement of the Company's ordinary shares, DKK 1 nominal value represented by ADSs and accompanying 2023 SPA Investor Warrants to purchase ordinary shares represented by ADSs. In accordance with IAS 32, the Company determined that the 2023 SPA Investor Warrants were derivative financial instruments because while they contain no contractual obligation to deliver cash or other financial instruments to the holders other than the Company's own ordinary shares, the exercise price of the 2023 SPA Investor Warrants were in USD and not the Company's functional currency. The 2023 SPA Investor Warrants were accounted for in accordance with IFRS 9 and were determined to be classified as liabilities.

In February 2024, the Company entered a 2024 Offering with certain investors, for the issuance and sale in a private placement of the Company's ordinary shares, DKK 1 nominal value represented by ADSs and accompanying 2024 Investor Warrants to purchase ordinary shares represented by ADSs. In accordance with IAS 32, the Company determined that the 2024 Investor Warrants were derivative financial instruments because while they contain no contractual obligation to deliver cash or other financial instruments to the holders other than the Company's own ordinary shares, the exercise price of the 2024 Investor Warrants were in USD and not the Company's functional currency. The 2024 SPA Investor Warrants were accounted for in accordance with IFRS 9 and were determined to be liability classified.

The warrant liability was measured at fair value at initial recognition and subsequently remeasured at fair value each reporting date until either exercised or expired. Significant judgment is made in respect to valuation of the warrants. The fair value of the warrants was determined using a Black-Scholes valuation model, considering relevant inputs, including the expected share price volatility, remaining contractual term, risk-free interest rate and expected dividend.

As a result of the 2024 Warrant Amendment, the exercise price of the 2023 SPA Investor Warrants and the 2024 Investor Warrant was converted from USD to DKK. As the awards are no longer settled in foreign currency, the warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the derivative liability was reclassified to other reserves at the time of the amendment.

In connection with the January 2025 public offering, the Company issued warrants to purchase 3,997,361 ADSs, representing 199,868,050 ordinary shares. The 2025 Investor Warrants vested immediately upon issuance, have an exercise price of \$2.71 per ADS, and expires five years from the issuance date. Under IAS 32 the Company concluded that the 2025 Investor Warrants could not be classified as equity and should be accounted for as derivative financial instruments because their exercise price was denominated in USD rather than in the Company's functional currency, DKK.

Judgement was utilized in determining certain valuation inputs of the awarded warrants, and changes in these assumptions may affect the estimated fair value. Refer to Note 6 for detailed information on the fair value measurement of the Investor Warrants, including the significant inputs, and the effect of changes in those inputs.

Leasehold Improvements and Loan From Lessor

A significant judgment was made in respect to determining whether customization of leased premises forms part of the lease or is a leasehold improvement funded by the lessor. See the section "Leasehold improvements and Loan from lessor" in Note 3.

There have been no other changes to the application of critical accounting judgments, or estimation uncertainties regarding accounting estimates.

Note 5. Revenue

In September 2024, the Company entered into an option and license agreement with MSD (the "MSD Option and License Agreement"). Under the terms of the agreement, Evaxion has granted MSD an option to exclusively license two preclinical vaccine candidates. Under the agreement, the Company has received an upfront fee of \$3.2 million.

In June 2025, the Company received funding support of nominal amount from the Gates Foundation to help the world eradicate polio (poliomyelitis) by exploring design options for a new and unique vaccine.

In September 2025, the Company out-licensed its vaccine candidate EVX-B3 to MSD (tradename of Merck & Co., Inc., Rahway, NJ, USA) as per the option and license agreement entered between the two companies in September 2024. The Company received a cash payment of \$7.5 million and will be eligible for future development, regulatory and sales milestone payments of up to \$592 million, as well as royalties on net sales. MSD will assume full responsibility and carry all costs for the further development of the EVX-B3 vaccine.

Note 6. Financial Instruments and Risk Management

Financial Risk Management and Risk Management Framework

In terms of financial risks, the Company has exposure to liquidity risk and market risk comprising foreign exchange risk. This note presents information about the Company's exposure to each of the above risks together with the Company's objectives, policies and processes for measuring and managing risks. The Company's Board of Directors monitors each of these risks on a regular basis and implements policies as and when they are required. Details of the current risk management policies are provided below.

Liquidity Risk

As of the date of the consolidated financial statements the Company, based on the Company's current financial position, available funding, and projected cash flows, Management and the Board is confident that the Company will have sufficient funds available to finance operations into the second half of 2027. Additionally, refer to Note 2 for further discussion of the Company's liquidity.

The Company's approach to managing liquidity is to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to its reputation.

The following are the contractual undiscounted outflows associated with the Company's financial liabilities in the current and prior year:

December 31, 2025						
(USD in thousands)						
	Carrying amount	Contractual cash flows	< 1 year	1– 5 years	>5 years	Total
			(USD in thousands)			
Borrowings	\$ 5,537	\$ 6,565	\$ 381	\$ 6,184	\$ —	\$ 6,565
Lease payables	1,967	2,495	374	1,571	550	2,495
Trade payables	2,186	2,186	2,186	—	—	2,186
Provisions	158	158	—	—	158	158
Other payables	129	129	129	—	—	129
Total	\$ 9,977	\$ 11,533	\$ 3,070	\$ 7,755	\$ 708	\$ 11,533

December 31, 2024						
(USD in thousands)						
	Carrying amount	Contractual cash flows	< 1 year	1– 5 years	>5 years	Total
			(USD in thousands)			
Borrowings	\$ 8,167	\$ 10,559	\$ 385	\$ 10,174	\$ —	\$ 10,559
Lease payables	1,934	2,544	325	1,370	849	2,544
Trade payables	2,968	2,968	2,968	—	—	2,968
Provisions	141	141	—	—	141	141
Other payables	67	67	67	—	—	67
Total	\$ 13,277	\$ 16,279	\$ 3,745	\$ 11,544	\$ 990	\$ 16,279

The financial liabilities include estimated or contractual interest rate payments.

Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The type of market risk that impacts the Company is currency risk. The Company does not currently have any loans or holdings that have a variable interest rate. Accordingly, the Company is not exposed to material interest rate risk.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The primary exposure derives from the Company's operating expenses paid in foreign currencies, mainly USD and Australian dollars. This exposure is known as transaction exposure. Any reasonable or likely movements in foreign exchange rates would not have a material impact on the Company's operating results. The Company's policy for managing foreign currency risks is to convert cash received from financing activities to currencies consistent with the Company's expected cash outflows.

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument, leading to a financial loss for the Company. The Company's exposure to credit risk is limited to deposits with banks with high credit ratings. Accordingly, the Company does not have material credit risk and no provision for credit risk is recognized.

Capital Management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Company raises capital from the issue of equity, grants or borrowings. On a regular basis, management receives financial and operational performance reports that enable management to assess the adequacy of resources on hand and the Company's liquidity position to determine future financing needs. For further information on financing needs refer to Note 2.

Fair Values

Financial instruments measured at fair value in the consolidated statements of financial position are grouped into three levels of fair value hierarchy. This grouping is determined based on the lowest level of significant inputs used in fair value measurement, as follows:

1. Level 1 – quoted prices in active markets for identical assets or liabilities.
2. Level 2 – inputs other than quoted prices included within Level 1 that are observable for the instrument, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
3. Level 3 – inputs for instruments that are not based on observable market data (unobservable inputs).

The following table summarizes the Company's financial liabilities, and the category using the fair value hierarchy. Note, the Company did not have any financial assets measured at fair value on a recurring basis, as of December 31, 2025, and 2024.

	Years Ended December 31, 2025		
	Level 1	Level 2	Level 3
	(USD in thousands)		
Financial liabilities at fair value			
2025 Investor Warrants	\$ —	\$ —	\$ 287
Total financial liabilities measured at fair value by level	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 287</u>
Financial liabilities measured at amortized cost			
EIB Loan	\$ —	\$ —	\$ 4,800
Loan from lessor	—	—	737
Total financial liabilities measured at amortized cost by level	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,536</u>
Financial liabilities measured at amortized cost			
EIB Loan	\$ —	\$ —	\$ 8,143
Loan from lessor	—	—	815
Total financial liabilities measured at amortized cost by level	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,958</u>

2024 and 2025 Investor Warrants

As part of the February 2024 Offering, the Company issued warrants to two investors with an exercise price based on the traded price prevailing as of the issue date. As set out in IAS 32, the warrants were classified as derivative financial instruments due to the exercise price being denominated in a currency other than the Company's functional currency, and therefore the fixed for fixed criteria was not met. As such, the warrants were deemed derivative liabilities at issuance, and the liabilities were measured and remeasured at their fair value.

As announced on May 23, 2024, and on June 21, 2024, the Company entered into an amendment to each of its 2023 SPA Warrants and 2024 Investor Warrants. The amendments convert the exercise price per ADS for the 2023 SPA Warrants from \$7.07 to DKK 47.99 and for the 2024 Investor Warrants from \$4.00 to DKK 27.52, subject to adjustment (not taking into account the ADS Ratio change). As the awards are no longer settled in foreign currency, the warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the derivative liability was reclassified to other reserves at the time of the amendment.

In connection with the January 2025 public offering, the Company issued warrants to purchase 3,997,361 ADSs, representing 199,868,050 ordinary shares. The 2025 Investor Warrants vested immediately upon issuance, have an exercise price of \$2.71 per ADS, and expires five years from the issuance date. Under IAS 32 the Company concluded that the 2025 Investor Warrants could not be classified as equity and should be accounted for as derivative financial instruments because their exercise price was denominated in USD rather than in the Company's functional currency, DKK. The fair value of the 2025 Investor Warrants were determined using a Black-Scholes valuation model, which included the following significant unobservable inputs:

	Years Ended December 31,	
	2025	2024
Exercise price	\$ 0.05	—
Remaining contractual term (in years)	2.04	—
Expected share price volatility	85%	—
Risk-free interest rate	3.47%	—
Expected dividends	—	—

As announced on May 17, 2025, the Company entered into an amendment to its 2025 Investor Warrants, with approximately 50% of the participating investors. The amendments convert the exercise price per ADS for the 2025 Investor Warrants from \$2.71 to DKK 19.15 on average. As the converted awards are no longer settled in foreign currency, the converted warrants now meet the fixed for fixed criteria under IAS 32. This resulted in a change of classification of the awards from liability classification to equity classification. Due to the classification change, the converted portion of the derivative liability was reclassified to other reserved at the time of the amendment.

The following table sets forth the changes to the Company's derivative liability related to the 2025 Investor Warrants:

	Total Derivative Liability (USD in thousands)
Carrying amount at January 1, 2025	\$ —
Initial recognition of derivative liability	3,929
Remeasurement of derivative liability	1,336
Exercise in period	(4,189)
Reclassification of derivative liability	(789)
Carrying amount at December 31, 2025	\$ 287

The initial recognition and the reclassification are offset against other reserves. The net amount from derivative liabilities recorded as a non-cash adjustment to share premium amounts to \$1.2 million and constitutes the difference between initial recognition \$3.9 million, the balance of the amended awards of \$0.8 million, amortization of the day one loss of the amended warrants and exercised warrants of \$0.2 million, and exercised warrants in the period of \$4.2 million.

EIB Warrants

The Company received the proceeds from the draw of the first tranche of the EIB Loan on February 17, 2022. In connection therewith, EIB received 351,036 EIB Warrants, at an exercise price of DKK 1 per warrant, which vested immediately, pursuant to the terms of a separate warrant agreement, the EIB Warrant Agreement. On October 3, 2024, the Company increased the number of shares issuable from the exercise of the EIB Warrants by 22,091 to 373,127 as an adjustment related to capital issuances that occurred during the year. The EIB Warrants are exercisable at any time after issuance either net in cash or through payment of the exercise price and receipt of shares. Therefore, the warrant liability is recognized in full upon issuance.

The Company issued warrants in connection with the EIB Loan Agreement. The EIB Warrants liability is measured in full upon issuance. The liability is measured initially at its fair value and is subsequently remeasured at the redemption amount. The liability is classified in Level 1 of the fair value hierarchy. The fair value of the warrants issued to EIB is currently lower than the exercise price and for that reason no liability is presented.

The following table sets forth the changes to the Company's EIB Warrant liability:

	Warrant Liability (USD in thousands)
Carrying amount at December 31, 2023	\$ 190
Remeasurement of warrant liability	(190)
Foreign currency translation	—
Carrying amount at December 31, 2024	\$ —
Remeasurement of warrant liability	—
Foreign currency translation	—
Carrying amount at December 31, 2025	\$ —

Note 7. Operating Activities

Research and Development Expenses

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Employee salary and benefit expenses, excluding share-based compensation	\$ 5,699	\$ 4,832	\$ 6,033
Share-based compensation expenses	167	101	377
Depreciation	315	305	340
External expenses	3,794	5,219	5,166
Total research and development expenses	<u>\$ 9,975</u>	<u>\$ 10,457</u>	<u>\$ 11,916</u>

During the years ended December 31, 2025, 2024, and 2023, the Company recognized a nominal amount, \$0.3 million and \$0.4 million, respectively, related to government grants as a reduction of research and development expenses.

General and Administrative Expenses

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Employee salary and benefit expenses, excluding share-based compensation	\$ 2,534	\$ 2,332	\$ 3,030
Share-based compensation expenses	140	256	102
Professional and other fees	3,812	4,729	6,947
Depreciation	301	302	275
Total general and administrative expenses	<u>\$ 6,787</u>	<u>\$ 7,619</u>	<u>\$ 10,354</u>

During the year ended December 31, 2025, general and administrative share-based compensation expenses included a nominal amount of share-based compensation expenses related to noncash payments of warrants to consultants for services rendered. There were no share-based compensation expenses to consultants recognized prior to 2025.

Note 8. Employees and Employee-Related Costs

The number of employees, including executive and non-executive directors, during the year was as follows:

	Years Ended December 31,		
	2025	2024	2023
Average number of full-time employees	45	45	55
Number of employees at end of period:			
Denmark and United States	46	46	49
Total employees, at end of period	46	46	49

Employee costs:

	Years Ended December 31,		
	2025	2024	2023
(USD in thousands)			
Wages and salaries	\$ 7,356	\$ 6,447	\$ 8,436
Cash bonus	629	604	393
Share-based compensation expenses	307	177	479
Other social security expenses	17	16	18
Other staff expenses	230	97	216
Total	\$ 8,539	\$ 7,341	\$ 9,542

	Years Ended December 31,		
	2025	2024	2023
(USD in thousands)			
<i>Total Employee costs classified as:</i>			
Research and development expenses	\$ 5,866	\$ 4,933	\$ 6,410
General and administrative expenses	2,673	2,408	3,132
Total	\$ 8,539	\$ 7,341	\$ 9,542

	Years Ended December 31,		
	2025	2024	2023
(USD in thousands)			
<i>Non-management employee benefit expenses classified as:</i>			
Research and development expenses	\$ 5,099	\$ 3,977	\$ 5,255
General and administrative expenses	1,397	1,289	1,870
Total	\$ 6,496	\$ 5,266	\$ 7,125

Remuneration to the Board of Directors and Executive Management

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
<i>Remuneration to the Executive Management:</i>			
Wages and salaries	\$ 1,518	\$ 1,595	\$ 1,802
Share-based compensation expenses	108	38	205
Total	1,626	1,633	2,007
<i>Remuneration to the Board of Directors:</i>			
Wages and salaries	356	384	360
Share-based compensation expenses	61	58	45
Total	417	442	405
<i>Remuneration to the Board of Directors and Executive Management classified as:</i>			
Research and development expenses	767	956	1,150
General and administrative expenses	1,277	1,119	1,262
Total	\$ 2,044	\$ 2,075	\$ 2,412

The Executive Management was comprised of four members as of December 31, 2025, as well as of December 31, 2024, and 2023.

Note 9. Share-Based Payments

Warrant Program

The Company's Articles of Association allow for the granting of equity compensation, in the form of equity settled warrants, to employees, and Scientific Advisory Board members who provide services similar to employees, members of executive management, and the board of directors. The warrants granted in 2018 or prior vested upon the closing of our initial public offering in February 2021 ("IPO"). The warrants granted in 2020 vest either gradually over 36 months or vest immediately. Vested warrants granted in 2020 are exercisable in certain exercise windows beginning in the second half of the year of 2021. Warrants granted until 2019 expire on December 31, 2036. Warrants granted in 2022, 2021 and 2020 expire on December 31, 2031. Warrants granted in 2025, and 2024 expire on December 31, 2031. For the years ended December 31, 2025, and 2024 the number of warrants outstanding as a percentage of outstanding ordinary shares was 1.6%, and 4.3%, respectively.

During 2025, the Company granted 3,872,407 warrants to its employees, members of its Board of Directors, and Executive Management team, of which 2,625,000 were granted to Chief Executive Officer, 125,000 were granted to Chief AI Officer, and 125,000 were granted to Chief Scientific Officer. All warrants granted vest over a period of 36 months.

The fair value of the warrants granted during 2025 at grant date amounted to \$0.3 million.

During 2024, the Company granted 538,460 warrants to its employees, members of its Board of Directors, and Executive Management team, of which 16,668 were granted to its Chief Executive Officer, 25,000 were granted to its Chief AI Officer, 50,000 were granted to its Chief Scientific Officer, and 50,000 were granted to its Chief Finance Officer. All warrants granted vest over a period of 36 months.

The fair value of the warrants granted during 2024 at grant date amounted to \$0.2 million.

The following schedule specifies the granted warrants:

	Number of warrants	Weighted Average Exercise Price/Share	Weighted Average Remaining Contractual Life (years)
Warrants granted as at December 31, 2023 ⁽¹⁾	2,738,473	USD 1.41	10
Warrants granted	538,460	USD 0.40	
Warrants exercised	—	—	
Warrants forfeited	(232,139)	USD 1.72	
Warrants cancelled	—	—	
Warrants granted as at December 31, 2024 ⁽¹⁾	3,044,794	USD 1.19	9
Warrants granted during 2025	3,872,407	USD 0.10	
Warrants exercised	—	—	
Warrants forfeited	(183,152)	USD 0.90	
Warrants cancelled	—	—	
Warrants granted as at December 31, 2025 ⁽¹⁾	6,734,049	USD 0.17 ⁽²⁾	7
Warrants exercisable as at December 31, 2023 ⁽¹⁾	2,007,123		
Warrants exercisable as at December 31, 2024 ⁽¹⁾	2,493,050		
Warrants exercisable as at December 31, 2025 ⁽¹⁾	3,500,721		

(1) The number of warrants excludes Investor Warrants and EIB Warrants referred to in Note 6.

(2) Based on exchange rate USD/DKK as of December 31, 2025.

The following table details amounts of share-based compensation expenses related to the warrant program included in the consolidated statements of comprehensive loss:

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Research and development expenses	\$ 167	\$ 101	\$ 377
General and administrative expenses	140	76	102
Total	\$ 307	\$ 177	\$ 479

Determination of fair value of warrants

Warrants are granted based on the average share price 30 days prior to the date of grant, and fair value comprises a time value which is significantly affected by the expected life and expected volatility. The expected life of a warrant is based on the assumption that the holder will not exercise until after the equity award is fully vested. Actual exercise patterns may differ from the assumption used herein. The expected volatility is based on peer group data and reflects the assumption that the historical volatility over a period similar to the life of the warrant is indicative of future trends, which may not necessarily be the actual outcome. The peer group consists of listed companies that management believes are similar to the Company in respect to industry and stage of development. Even with objective evidence of the fair value of an ordinary share, small changes in any other individual assumption or in combination with other assumptions could have resulted in significantly different valuations.

The following assumptions have been applied for the warrants issued during the years ended December 31, 2025, and 2024, and 2023:

	Years Ended December 31,		
	2025	2024	2023
Expected term (in years)	6.5	6.5	6.5
Risk-free interest rate	4.34%	4.71%	4.27%
Expected volatility	85%	85%	85%
Share price	\$ 0.06	\$ 0.42	\$ 0.70

The following schedule specifies the outstanding warrants as of December 31, 2025:

Outstanding program	Per warrant grant date fair value (DKK)	Number of warrants outstanding	Average exercise price per warrant (DKK)	Remaining term to maturity (years)
Granted prior to 2023		2,184,917		
Grant (January 2023)	9.17	7,479	USD 1.94	6
Grant (September 2023)	4.27	100,000	USD 1.02	6
Grant (December 2023)	3.61	269,605	USD 0.75	6
Grant (May 2024)	2.23	440,332	USD 0.40	6
Grant (February 2025)	2.09	1,231,716	USD 0.50	6
Grant (November 2025)	0.50	2,500,000	USD 0.74	6
Granted at December 31, 2025		<u>6,734,049</u>		
Warrants exercisable at December 31, 2025		<u>3,500,721</u>		

The following schedule specifies the outstanding warrants as of December 31, 2024:

Outstanding program	Per warrant grant date fair value (DKK)	Number of warrants outstanding	Average exercise price per warrant (DKK)	Remaining term to maturity (years)
Granted prior to 2023		2,186,778		
Grant (January 2023)	9.17	10,000	USD 1.94	7
Grant (September 2023)	4.27	100,000	USD 1.02	7
Grant (December 2023)	3.61	275,969	USD 0.75	7
Grant (May 2024)	2.23	472,047	USD 0.40	7
Granted at December 31, 2024		<u>3,044,794</u>		
Warrants exercisable at December 31, 2024		<u>2,493,050</u>		

EVAXION A/S
Notes to the Consolidated Financial Statements

The Board of Directors and Executive Management holding of share awards for the years ended December 31, 2023, 2024, and 2025 is shown below:

	Warrants held when becoming or leaving as a member of management					Warrants held when becoming or leaving as a member of management					Warrants held when becoming or leaving as a member of management				
	December 31, 2022	Granted	Exercised	Forfeited	December 31, 2023	Granted	Exercised	Forfeited	December 31, 2024	Granted	Exercised	Forfeited	December 31, 2025		
Steven Projan	51,631	—	—	—	51,631	—	—	—	51,631	—	—	—	51,631		
Roberto Prego	43,747	5,000	—	—	48,747	20,000	—	—	68,747	25,000	—	—	93,747		
Marianne Søgaard	113,487	75,000	—	—	188,487	40,000	—	—	228,487	125,000	—	—	353,487		
Lars Holtug	9,583	5,000	—	—	14,583	20,000	—	—	34,583	25,000	—	—	59,583		
Niels Iversen Møller ⁽⁵⁾	3,750	8,125	—	—	11,875	20,000	—	—	31,875	12,500	—	—	44,375		
Lars Aage Staal Wegner ⁽¹⁾	—	—	—	—	—	608,188	—	—	608,188	—	17,708	—	625,896		
Board of Directors in total	222,198	93,125	—	—	315,323	608,188	100,000	—	1,023,511	608,188	205,208	—	1,228,719		
Lars Aage Staal Wegner	808,188	—	(200,000)	—	608,188	(608,188)	—	—	—	—	—	—	—		
Helen Tayton Martin ⁽²⁾	—	—	—	—	—	—	—	—	—	2,500,000	—	—	2,500,000		
Birgitte Rono	99,376	12,500	—	—	111,876	50,000	—	—	161,876	125,000	—	—	286,876		
Erik Heegaard ⁽⁶⁾	122,564	—	—	—	122,564	—	—	(23,424)	99,140	—	—	—	99,140		
Andreas Holm Mattsson	35,000	6,250	—	—	41,250	25,000	—	—	66,250	125,000	—	—	191,250		
Bo Karmark ⁽⁷⁾	61,667	—	—	—	61,667	—	—	(30,185)	31,482	—	—	—	31,482		
Jesper Nyegaard Nissen ⁽⁴⁾	45,883	12,500	—	—	58,383	50,000	—	(62,267)	46,066	—	—	—	46,066		
Per Norlén ⁽⁸⁾	53,125	—	—	(37,150)	15,975	—	—	—	15,975	—	—	—	15,975		
Christian Kanstrup ⁽³⁾	—	169,167	—	—	169,167	—	16,668	—	185,835	—	125,000	—	310,835		
Executive Management in total	1,225,803	0	200,417	(200,000)	1,189,020	(608,188)	141,668	(115,876)	606,624	—	2,875,000	—	3,481,624		

- (1) Mr. Wegner joined the Board of Directors as of April 16, 2024.
- (2) Dr. Tayton-Martin was appointed CEO of Evaxion A/S as of November 24, 2025.
- (3) Mr. Kanstrup stepped down as CEO and member of the Executive Management team as of June 30, 2025.
- (4) Mr. Nissen resigned as Chief Operating Officer effective October 30, 2024.
- (5) Mr. Iversen Møller stepped down from the Board of Directors effective June 30, 2024.
- (6) Mr. Heegaard resigned from Chief Medical Officer of the company effective March 2024.
- (7) Mr. Karmark resigned as the Chief Financial Officer of the Company effective March 1, 2024.
- (8) Mr. Norlén resigned as the Chief Executive Officer effective September 1, 2023.

Note 10. Financial Income and Expenses

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Financial income:			
Interest income, bank	\$ 249	\$ 254	\$ 151
Interest income, other	50	—	3
Change in fair value of derivative liability	1,091	5,492	—
Change in fair value of warrant liability	—	190	636
Foreign exchange gains	658	564	173
Gain on conversion of EIB loan	2,568	—	—
Total financial income	<u>4,616</u>	<u>6,500</u>	<u>963</u>
Financial expenses:			
Interest expenses	—	—	(1)
Interest expenses, lease liabilities	(152)	(161)	(172)
Change in fair value of derivative liability	(2,383)	(1,653)	(110)
Change in fair value of warrant liability	—	(125)	(244)
Interest expenses, loan from lessor	(724)	(801)	(724)
Foreign exchange losses	(738)	(383)	(430)
Total financial expenses	<u>(3,997)</u>	<u>(3,123)</u>	<u>(1,681)</u>
Net financial items	<u>\$ 619</u>	<u>\$ 3,377</u>	<u>\$ (718)</u>

Note 11. Income Taxes

(a) Analysis of charge/(credit) for the year:

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Income tax benefit	\$ 908	\$ 788	\$ 790
Total income tax benefit for the year	<u>\$ 908</u>	<u>\$ 788</u>	<u>\$ 790</u>

On December 31, 2025, the Company had net tax loss carry-forwards in Denmark of \$23.2 million (2024: \$20.4 million) for income tax purposes, all of which can be carried forward infinitely according to Danish Corporate Income Tax Act. As of December 31, 2025, the Company did not have any tax loss carry-forwards in any other tax jurisdictions.

The benefit from income taxes for each year includes a tax credit for research and development expenditures at the applicable tax rate under the Danish Tax Assessment Act and Australian tax legislation, respectively.

(b) Reconciliation of effective tax rate to Danish statutory tax rate

	Years Ended December 31,		
	2025	2024	2023
Statutory corporate income tax rate in Denmark	22%	22%	22%
Non-deductible income / (expenses)	(3)%	5%	(1)%
Non-taxable income / (expenses)	—%	—%	—%
Additional tax deduction R&D expenses	2%	2%	1%
Tax credit research and development expenditures	—%	(7)%	(4)%
Change in deferred tax asset not capitalized	(11)%	(15)%	(14)%
Total effective tax rate	10%	7%	4%

(c) Deferred tax in the consolidated statements of financial position

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Deferred Tax Positions:			
Warrants	\$ —	\$ —	\$ 275
Loss carry forward	23,158	20,429	19,022
Other items	(156)	(131)	(126)
Deferred tax assets not recognized	(23,002)	(20,298)	(19,171)
Total Deferred Tax	\$ —	\$ —	\$ —

Under Danish tax legislation, the value of warrants to employees is income tax exempt subject to meeting certain conditions. The value of income tax exempt warrants is not tax deductible for the issuer. There is currently uncertainty in respect of the extent to which the conditions for being tax exempt are met and consequently the extent to which a tax deduction will be available for the company. Consequently, the deferred tax asset disclosed above is subject to uncertainty and there is a risk that the amount disclosed above is not tax deductible in full.

Note 12. Basic and Diluted Loss Per Share

Basic loss per share is calculated by dividing the net loss attributable for the year to shareholders of Evaxion A/S by the weighted average number of ordinary shares outstanding during the year. As net losses from continuing operations were recorded in the years 2025, 2024, and 2023, the dilutive potential shares are anti-dilutive for the earnings per share calculation.

	2025	2024	2023
	(USD in thousands, except share amounts and per share amounts)		
<i>Loss per share before and after dilution</i>			
Net loss attributable to shareholders of Evaxion A/S	\$ (7,707)	\$ (10,567)	\$ (22,125)
Weighted-average number of ordinary shares outstanding	320,406,391	53,644,483	27,335,829
Loss per share before and after dilution	\$ (0.02)	\$ (0.20)	\$ (0.81)

The following potential shares are anti-dilutive and are therefore excluded from the weighted average number of shares for the purpose of diluted loss per share:

	Years Ended December 31,		
	2025	2024	2023
Warrants ⁽¹⁾	141,860,674	62,579,819	12,816,407

(1) The number of warrants presented includes warrants granted for share-based payments, the EIB Warrants, and Investor Warrants outstanding as of each year end period.

Note 13. Property and Equipment, Net

	Property	Other Equipment	Leasehold Improvements	Total
	(USD in thousands)			
Cost at December 31, 2024	\$ 2,531	\$ 1,357	\$ 1,656	\$ 5,544
Additions during the year	—	11	—	11
Exchange rate adjustments	322	169	206	697
Cost at December 31, 2025	2,853	1,537	1,862	6,252
Depreciation at December 31, 2024	\$ (788)	\$ (746)	\$ (496)	\$ (2,030)
Depreciation for the year	(254)	(197)	(164)	(615)
Exchange rate adjustments	(116)	(101)	(68)	(285)
Depreciation at December 31, 2025	(1,158)	(1,044)	(728)	(2,930)
Carrying amount at December 31, 2025	\$ 1,695	\$ 493	\$ 1,134	\$ 3,322
Carrying amount of right-of-use assets at December 31, 2025	\$ 1,695	\$ —	\$ —	\$ 1,695

	Property	Other Equipment	Leasehold Improvements	Total
	(USD in thousands)			
Cost at December 31, 2023	\$ 2,681	\$ 1,438	\$ 1,754	\$ 5,873
Exchange rate adjustments	(150)	(81)	(98)	(329)
Cost at December 31, 2024	2,531	1,357	1,656	5,544
Depreciation at December 31, 2023	\$ (585)	\$ (581)	\$ (364)	\$ (1,530)
Depreciation for the year	(244)	(206)	(158)	(608)
Exchange rate adjustments	41	41	26	108
Depreciation at December 31, 2024	(788)	(746)	(496)	(2,030)
Carrying amount at December 31, 2024	\$ 1,743	\$ 611	\$ 1,160	\$ 3,514
Carrying amount of right-of-use assets at December 31, 2024	\$ 1,743	\$ —	\$ —	\$ 1,743

Depreciation included in the consolidated statement of comprehensive loss:

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Research and development expenses	\$ 314	\$ 305	\$ 340
General and administrative expenses	301	303	275
Total depreciation included in the consolidated statement of comprehensive loss	615	608	615
Total accumulated depreciation of right-of-use assets at December 31,	\$ 1,215	\$ 788	\$ 585

Note 14. Prepayments and Other Receivables

	December 31,	
	2025	2024
	(USD in thousands)	
VAT receivables	\$ 185	\$ 216
Prepayments	616	955
Receivables from collaboration partners	—	37
Other receivables	—	65
Total prepayments and other receivables	\$ 801	\$ 1,273

Note 15. Other Payables

	December 31,	
	2025	2024
	(USD in thousands)	
Employee cost liabilities	\$ 1,105	\$ 860
Other liabilities	129	67
Total other payables	\$ 1,234	\$ 927

Note 16. Cash and Cash Equivalents

	December 31,	
	2025	2024
	(USD in thousands)	
Cash and cash equivalents	\$ 23,234	\$ 5,952
Total cash and cash equivalents	\$ 23,234	\$ 5,952

Reconciliation of Liabilities from Financing Activities

(USD in thousands)	December 31, 2024	Cash flows	Accumulated interest	Transaction Costs	Conversion	Exchange rate adjustment	December 31, 2025
Lease liabilities	\$ 1,934	\$ (352)	\$ 152	\$ —	\$ —	233	\$ 1,967
Borrowings	8,167	(399)	618	—	(3,890)	1,041	5,537
Provisions	141	—	—	—	—	17	158
Total liabilities from financing activities	\$ 10,242	\$ (751)	\$ 770	\$ —	\$ (3,890)	\$ 1,291	\$ 7,662

(USD in thousands)	December 31, 2023	Cash flows	Accumulated interest	Transaction Costs	Conversion	Exchange rate adjustment	December 31, 2024
Lease liabilities	\$ 2,222	\$ (331)	\$ 161	\$ —	\$ —	\$ (118)	\$ 1,934
Borrowings	8,648	(805)	703	—	—	(379)	8,167
Provisions	149	—	—	—	—	(8)	141
Total liabilities from financing activities	\$ 11,019	\$ (1,136)	\$ 864	\$ —	\$ —	\$ (505)	\$ 10,242

(USD in thousands)	December 31, 2022	Cash flows	Accumulated interest	Transaction Costs	Additions	Exchange rate adjustment	December 31, 2023
Lease liabilities	\$ 2,255	\$ (326)	\$ 172	\$ —	\$ 45	\$ 76	\$ 2,222
Borrowings	8,000	(306)	638	—	65	251	8,648
Provisions	144	—	—	—	—	5	149
Total liabilities from financing activities	\$ 10,399	\$ (632)	\$ 810	\$ —	\$ 110	\$ 332	\$ 11,019

Note 17. Leases

Leases

In October 2020, the Company entered into a lease for approximately 1,356 square meters, which is allocated on 839 square meters of office space, and 518 square meters of laboratory space in Hørsholm, Denmark. The commencement date for the lease of the 839 square meters of office space was February 1, 2021, and the lease continues for a term of 10 years from that date. The commencement date for the additional laboratory space was August 13, 2021, and the lease continues for a term of 10 years with a subsequent 12-month cancellation notice period. The lease agreement contains an early termination provision which would trigger a termination fee of \$2.7 million. Throughout the term, the lease is subject to annual increases ranging from two to four percent on the annual lease payment amount. The Company had one lease in Copenhagen, Denmark as of December 31, 2025.

EVAXION A/S
Notes to the Consolidated Financial Statements

For the years ended December 31, 2025, and 2024, the expense recognized in operating expense related to short term and variable lease payments not included in the lease liabilities was immaterial. For the years ended December 31, 2025, and 2024, the Company recognized \$0.3 million, and \$0.2 million respectively, of depreciation expense related to its right-of-use lease asset in operating expense. For the years ended December 31, 2025, and 2024, the Company recognized \$0.2 million, and \$0.2 million, of interest expense related to its lease liabilities. The Company recognized a total of \$0.4 million, and \$0.4 million related to lease expenses in the consolidated statements of comprehensive loss for the years ended December 31, 2025, and 2024.

Set out below are the carrying amounts of the Company's right-of-use assets and lease liabilities and the movements during the period:

	<u>Right-of-Use Asset</u>	<u>Lease Liabilities</u>
	(USD in thousands)	
At December 31, 2024	\$ 1,743	\$ 1,934
Additions	—	—
Depreciation	(254)	—
Interest Expense	—	152
Payments	—	(352)
Depreciation revaluation	—	—
Translation	206	233
At December 31, 2025	<u>\$ 1,695</u>	<u>\$ 1,967</u>
	<u>Right-of-Use Asset</u>	<u>Lease Liabilities</u>
	(USD in thousands)	
At December 31, 2023	\$ 2,096	\$ 2,222
Additions	—	—
Depreciation	(203)	—
Interest Expense	—	161
Payments	—	(331)
Translation	(150)	(118)
At December 31, 2024	<u>\$ 1,743</u>	<u>\$ 1,934</u>

The total cash outflow for leases were \$0.4 million and \$0.3 million during the years ended December 31, 2025 and 2024, respectively.

Note 18. Borrowings

Loan From Lessor

In October 2020, the Company entered into a lease for approximately 1,356 square meters, which is allocated on 839 square meters of office space, and 518 square meters of laboratory space in Hørsholm, Denmark. In addition to the ordinary lease payments, the Company obtained financing from DTU Science Park A/S ("DTU") for rebuilding the laboratory facility and engineering building to match the Company's needs. The Company will repay the \$1.3 million financing at a fixed interest rate of 6% over 8 years. If the lease is terminated due to default by the Company before the outstanding balance, including interest accrued, has been repaid, the remaining balance is due immediately. The finance liability is recorded at amortized cost, which approximates fair value at the time of issuance. For the years ended December 31, 2025, and 2024 interest expense related to the loan from lessor was a nominal amount, \$0.1 million and \$0.1 million, respectively.

As a result of the structure of the DTU financing this amount is not included as *Purchase of property, plant and equipment* within the consolidated statements of cash flows.

EIB Loan

In August 2020, the Company executed the EIB Loan, for a principal amount of €20.0 million, divided into three tranches of tranche 1 in the amount of €7.0 million, tranche 2 in the amount of €6.0 million and tranche 3 in the amount of €7.0 million. Under the EIB Loan Agreement, the tranche balances are due six years from their respective disbursement dates.

During the year ended December 31, 2021, the Company initiated the draw of the first tranche of the EIB Loan Agreement. The Company received the proceeds from the draw of the first tranche of €7.0 million (approximately \$7.8 million) on February 17, 2022. The Company will repay the first tranche of the EIB Loan at a fixed interest rate of 3% per annum and a payment-in-kind interest rate of 4% per annum. The loan is amortized to maturity using an effective monthly interest rate of 0.79%. For the years ended December 31, 2025, and 2024, interest expense related to the EIB Loan was \$0.6 million, and \$0.7 million, respectively. The loan is repayable in full six years after drawing down. The two remaining tranches have become void as of December 31, 2023.

In July 2025, the Company reached an agreement with EIB, where EIB converted €3.5 million of its €7 million loan to Evaxion into equity via a purchase of ordinary Evaxion warrants at a price of \$4.87 per warrant, corresponding to a premium of 89% to the share price by market close the day before the announcement. As a result of the conversion, a gain was recognized in the amount of \$2.6 million, calculated as the difference between the carrying amount of the converted portion of the EIB loan and the fair value of the warrants issued of \$1.3 million.

Borrowings are summarized as follows:

	Years Ended December 31,		
	2025	2024	2023
	(USD in thousands)		
Loan from lessor	\$ 737	\$ 815	\$ 1,022
EIB Loan	4,800	7,352	7,626
Total Borrowings	5,537	8,167	8,648
Less: Borrowings, current portion	(190)	(159)	(159)
Total Borrowings, net of current portion	\$ 5,347	\$ 8,008	\$ 8,489

Note 19. Capital Structure and Financial Matters

Share Capital – Ordinary Shares

Capital Transactions

January 14, 2025, the Company made effective a change to its ratio of ADSs to its ordinary shares, DKK 1 nominal value (the “ADS Ratio”). The ratio has been changed from one ADS representing ten (10) ordinary shares to a new ADS Ratio of one ADS representing fifty (50) ordinary shares of the Company. Unless specified otherwise, all references in this annual report to ADS share and ADS per share data have been adjusted, including historical data which has been retroactively adjusted, to give effect to the ADS Ratio change.

January 17, 2025, an extraordinary general meeting of Evaxion was held, where it was approved to reduce our share capital by nominal DKK 58,980,417 from nominal DKK 78,640,556 to nominal DKK 19,660,139 to cover loss. Furthermore, it was approved to reduce the nominal value of the shares from nominal DKK 1 per share to nominal DKK 0.25 per share, and our Article of Association were amended accordingly.

January 31, 2025, the Company closed its public offering of an aggregate of 3,997,361 of its ADSs and warrants to purchase up to 50% of the ADSs offered at a combined public offering price of \$2.71 per ADS with one accompanying warrant for each two ADSs, with gross proceeds of \$10.8 million. The Company registered aggregate share capital increases of nominal DKK 49,967,012.50 with the Danish Business Authority, with effective date of January 31, 2025, corresponding to an aggregate increase in the Company’s share capital to nominal DKK 78,332,151.50. This reflected issuances of 199,868,050 shares in connection with the public offering.

In October 2025, the Company registered \$2.7 million capital increase from exercise of 48,407,150 investor warrants from the January 2025 Public Offering.

In November 2025, the Company registered \$0.1 million capital increase from exercise of 1,875,000 investor warrants from the January 2025 Public Offering.

As of December 31, 2025, the Company's share capital of DKK 104.3 million consists of 417,010,756 ordinary shares.

JonesTrading Sales Agreement

On October 3, 2022, the Company entered into an At-The-Market (ATM) Issuance Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading") under which the Company could sell up to an aggregate of \$14.4 million of its ordinary shares represented by ADSs. The Company agreed to pay JonesTrading commission equal to 3% of the gross proceeds of the sales price of all ADSs sold through them as sales agent under the Sales Agreement. The offering of the Company's ADSs pursuant to the Sales Agreement will terminate at the earliest of (1) the sale of all of the ordinary shares subject to the Sales Agreement, or (2) termination of the Sales Agreement by the Company or JonesTrading. The Company and JonesTrading may terminate the sales agreement at any time upon ten days prior notice. JonesTrading may terminate the Sales Agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in their judgment, may make it impracticable or inadvisable to market or sell the Company's ADSs or a suspension or limitation of trading the Company's ADSs on The Nasdaq Capital Market.

January 24, 2025, the Company sold 696,400 ADSs at an average price of USD \$7.1776 per ADS. The ADSs were sold in an at-the-market (ATM) offering pursuant to the terms and subject to the conditions contained in that certain Capital Demand Sales Agreement between the Company and Jones Trading Institutional Services LLC dated October 3, 2022. After deducting fees and expenses, total proceeds to the Company from the sales of the ADSs were approximately \$4.85 million.

In September 2025, the Company sold 1,018,000 ADSs at an average price of USD \$4.3931 per ADS. The ADSs were sold in an at-the-market (ATM) offering pursuant to the terms and subject to the conditions contained in that certain Capital Demand Sales Agreement between the Company and Jones Trading Institutional Services LLC dated October 3, 2022. After deducting fees and expenses, total proceeds to the Company from the sales of the ADSs were approximately \$4.3 million.

December 10, 2025, the Company filed a prospectus supplement to the Prospectus Supplement dated March 26, 2025, and Prospectus dated March 24, 2025. As of the date hereof, the aggregate market value of the Company's ordinary shares represented by ADSs held by non-affiliates ("public float"), calculated in accordance with General Instruction I.B.5 of Form F-3 under the Securities Act of 1933, as amended, was approximately \$75.9 million, which was calculated based on 344,711,416 ordinary shares (which would be represented by 6,894,228 ADSs) outstanding and held by non-affiliates as of November 4, 2025, at a price of \$11.01 per ADS as of October 15, 2025, which was the highest closing price of the ADSs on The Nasdaq Capital Market within 60 days of the filing of this Prospectus Supplement.

The Company filed the Prospectus Supplement to amend the Prospectus to update the public float, and indicate that, because the public float is above \$75.0 million, the Company is no longer subject to the sales limitations of General Instruction I.B.5 of Form F-3 with respect to the Registration Statement of which the Prospectus, as amended by the Prospectus Supplement, forms a part. Since the filing of the Registration Statement, the Company has sold \$4,472,175.80 of ADSs pursuant to the Sales Agreement. Accordingly, because the Company no longer is subject to the sales limitations of General Instruction I.B.5, they may offer and sell up to an additional \$45.52 million of ADSs pursuant to the Sales Agreement and Prospectus.

2023 Securities Purchase Agreement

On December 18, 2023, the Company entered into a Securities Purchase Agreement with a group of certain investors including all members of the Company's Management and Board of Directors, and MSD Global Health Innovation Fund, a corporate venture capital arm of Merck & Co., Inc., Rahway, NJ, USA, for the issuance and sale in private placement of 9,726,898 of ordinary shares, DKK 1 nominal value represented by ADSs, and accompanying 2023 SPA Investor Warrants to purchase up to 9,726,898 ordinary shares represented by ADSs at a purchase price of \$0.54 per ordinary share. The 2023 SPA Investor Warrants are exercisable immediately upon issuance and expire three years after the closing date of the private placement and have an exercise price equal to \$0.71 per share. The gross proceeds to the Company from the private placement were \$5.3 million, with up to an additional \$6.8 million of gross proceeds in the event of cash exercise of the 2023 SPA Investor Warrants, before deducting offering expenses payable by the Company. Of the initial gross proceeds to the Company, \$2.6 million was allocated to the 2023 SPA Investor Warrants issued. Refer to Note 6 for additional information on the 2023 SPA Investor Warrants.

February 2024 Offering

In February 2024, the Company completed a public offering through which the Company offered 151,500 ADSs representing an aggregated 7,575,000 ordinary shares, DKK 1 nominal value per share, together with warrants to purchase up to 151,500 ADSs representing 7,575,000 ordinary shares. The public offering price for each ADS and accompanying warrant is \$20.00. The warrants have an exercise price per ADS of DKK 137.6 and are immediately exercisable for a term of five years from the date of issuance. As part of the public offering, the Company offered prefunded warrants to purchase up to 598,500 ADSs representing 29,925,000 ordinary shares. The public offering price for each ADS and accompanying prefunded warrant is \$20.00. The prefunded warrants have an exercise price per ADS of \$1.4537 and are immediately exercisable for a term of five years from the date of issuance. After deducting fees and expenses, total proceeds to the Company from the public offering were approximately \$8.4 million. During the six months ended June 30, 2024, 599,500 prefunded warrants to purchase ADSs were exercised for total proceeds of approximately \$0.9 million.

January 2025 Public Offering

January 31, 2025, the Company closed its public offering of an aggregate of 3,997,361 of its ADSs and warrants to purchase up to 50% of the ADSs offered at a combined public offering price of \$2.71 per ADS with one accompanying warrant for each two ADSs, with gross proceeds of \$10.8 million. The Company registered aggregate share capital increases of nominal DKK 49,967,012.50 with the Danish Business Authority, with effective date of January 31, 2025, corresponding to an aggregate increase in the Company's share capital to nominal DKK 78,332,151.50. This reflected issuances of 199,868,050 shares in connection with the public offering.

Debt conversion of EIB loan

In connection with the conversion of the EIB loan on July 2025, 38,450,000 warrants were issued. The issued warrants were fair valued at 0.2164 DKK per warrant using the Black-Scholes valuation model considering relevant inputs, including the expected share price volatility, remaining contractual term, risk-free interest rate and expected dividends. The warrants are equity classified, and the total fair value amounted to \$1.3 million.

considering relevant inputs, including the expected share price volatility, remaining contractual term, risk-free interest rate and expected dividend

At year end 2025 and 2024, due to issue of shares and warrant exercise, the outstanding share capital was nominal DKK 104,252,689 and DKK 70,130,556, respectively.

The following are changes in the Company's share capital for the years ended December 31, 2024 and 2025:

	Number of Ordinary Shares	Share Capital (DKK in thousands)
Share capital, December 31, 2023	37,897,780	37,898
Capital increase January 2024 (exercised warrants)	9,216	9
Capital increase at January 26, 2024 (JonesTrading sales agreement)	2,633,550	2,634
Capital increase at February 3, 2024 (JonesTrading sales agreement)	4,450,000	4,450
Capital increase at February 5, 2024 (JonesTrading sales agreement)	3,125,000	3,125
Capital increase February 2024 (exercised warrants)	1,975,000	1,975
Capital increase February 2024 (exercised warrants)	2,060,000	2,060
Capital increase April 2024 (exercised warrants)	1,960,000	1,960
Capital increase July 2024 (exercised warrants)	1,640,000	1,640
Capital increase at August 12, 2024 (JonesTrading sales agreement)	10,000	10
Capital increase at September 4, 2024 (JonesTrading sales agreement)	10,000	10
Capital increase at September 5, 2024 (JonesTrading sales agreement)	10,000	10
Capital increase September 2024 (exercised warrants)	1,070,000	1,070
Capital increase at September 30, 2024 (JonesTrading sales agreement)	316,180	316
Capital increase at September 30, 2024 (JonesTrading sales agreement)	253,830	254
Capital increase October 2024 (exercised warrants)	1,240,000	1,240
Capital increase December 2024 (exercised warrants)	4,840,000	4,840
Capital increase December 2024 (exercised warrants)	6,630,000	6,630
Share capital, December 31, 2024	70,130,556	70,131
Capital increase at January 8, 2025 (exercised warrants)	6,360,000	6,360
Capital increase at January 16, 2025 (exercised warrants)	2,150,000	2,150
Capital decrease at January 17, 2025	0	(58,980)
Capital increase at January 27, 2025 (JonesTrading)	34,820,000	8,705
Capital increase at January 31, 2025 (public offering)	177,451,100	44,363
Capital increase at January 31, 2025 (public offering)	22,416,950	5,604
Capital increase at February 5, 2025 (exercised warrants)	2,500,000	625
Capital increase at September 26, 2025 (JonesTrading)	50,900,000	12,725
Capital increase at October 3, 2025 (exercised warrants)	21,705,100	5,426
Capital increase at October 7, 2025 (exercised warrants)	1,325,150	331
Capital increase at October 8, 2025 (exercised warrants)	1,625,000	406
Capital increase at October 9, 2025 (exercised warrants)	1,875,000	469
Capital increase at October 9, 2025 (exercised warrants)	1,875,000	469
Capital increase at October 10, 2025 (exercised warrants)	922,500	231
Capital increase at October 10, 2025 (exercised warrants)	137,500	34
Capital increase at October 15, 2025 (exercised warrants)	2,025,000	506
Capital increase at October 16, 2025 (exercised warrants)	6,479,400	1,620
Capital increase at October 17, 2025 (exercised warrants)	5,350,000	1,338
Capital increase at October 20, 2025 (exercised warrants)	400,000	100
Capital increase at October 20, 2025 (exercised warrants)	1,875,000	469
Capital increase at October 21, 2025 (exercised warrants)	2,025,000	506
Capital increase at October 22, 2025 (exercised warrants)	200,000	50
Capital increase at October 24, 2025 (exercised warrants)	275,000	69
Capital increase at October 28, 2025 (exercised warrants)	312,500	78
Capital increase at November 4, 2025 (exercised warrants)	1,875,000	469
Share capital, December 31, 2025	417,010,756	104,253

The Company's share capital consists of the following ordinary shares:

	December 31,	
	2025	2024
	(USD in thousands)	
Authorized, issued and fully paid		
417,010,756 (2024: 70,130,556) ordinary shares of DKK 0.25 each (2024: ordinary shares of DKK 1 each)	\$ 15,791	\$ 10,516
Total share capital	\$ 15,791	\$ 10,516

The Company's ordinary shares shall confer on the holders thereof the right to receive notice of, attend and vote at general meetings of the Company.

Executive Management's and Board of Director's holding of shares

At December 31, 2025, the board of directors and executive management held the following shareholdings in the Company (including 60-Day-Exercisable Warrants):

	2025	2024	2023
Number of ordinary shares owned			
Helen Tayton-Martin	277,778	—	-
Thomas Frederik Schmidt	968,600	—	-
Birgitte Rønø	262,871	187,170	148,123
Andreas Holm Mattsson	6,330,118	4,289,341	4,267,931
Executive Management in total	7,839,367	4,476,511	4,416,054
	2025	2024	2023
Number of ordinary shares owned			
Roberto Prego	726,169	561,156	539,069
Lars Holtug	483,391	179,978	157,891
Marianne Søgaard	6,473,997	1,777,471	1,684,547
Lars Aage Staal Wegner	837,900	681,842	-
Board of Directors in total	8,521,457	3,200,447	2,381,507

Note 20. Related Party Transactions

The Company's related parties are comprised of significant shareholders of the Company, the executive management group, the board of directors and the close members of the family of these people.

The Company has not granted any loans, guarantees, or other commitments to or on behalf of any of the members in the board of directors or executive management. Other than the remuneration and other transactions relating to the board of directors or executive management and capital increases on the same terms as other investors, no other significant transactions have taken place with the board of directors or executive management for the years ended December 31, 2025, and 2024.

Note 21. Commitments and Contingencies

Legal Proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Evaxion is aware) that may have or have had in the recent past (covering the 12 months immediately preceding the date of this annual report), significant effects on Evaxion's financial position or profitability.

Contractual Obligations

The contractual obligations are similar individually and, in the aggregate, not material to the future financial position, operating profit or cash flow.

At December 31, 2025, the Company had the following contractual commitments which fall due as follows:

	December 31, 2025					Total
	(USD in thousands)					
Contractual cash flows	< 1 year	1– 2 years	2– 5 years	>5 years		
	(USD in thousands)					
Purchase obligations	\$ —	\$ 79	\$ 68	\$ 111	\$ —	\$ 258
Total	\$ —	\$ 79	\$ 68	\$ 111	\$ —	\$ 258

The purchase obligations consists of a rental agreement on facility equipment as well as IT & Security services.

At December 31, 2024, the Company had the following contractual commitments which fall due as follows:

	December 31, 2024					Total
	(USD in thousands)					
Contractual cash flows	< 1 year	1– 2 years	2– 5 years	>5 years		
	(USD in thousands)					
Purchase obligations	\$ —	\$ 81	\$ 51	\$ 51	\$ —	\$ 183
Total	<u>\$ —</u>	<u>\$ 81</u>	<u>\$ 51</u>	<u>\$ 51</u>	<u>\$ —</u>	<u>\$ 183</u>

The purchase obligations consist of rental agreement on facility equipment as well as IT & Security services.

Note 22. Provisions

The Company is required to restore the lease premises of its office and laboratory space in Hørsholm, Denmark to its original condition at the end of the lease term. A provision is recognized for the present value using a discount rate based on the Company's risk adjusted incremental borrowing rate of the estimated expenditure required to remove any leasehold improvements. These costs have been capitalized as part of the cost of leasehold improvements and are amortized over the lease term.

Changes in the provision balance during the year ended December 31, 2025, are as follows:

	Provisions (USD in thousands)
Carrying amount at January 1, 2025	\$ 141
Currency adjustment	17
Carrying amount at December 31, 2025	<u>\$ 158</u>

Changes in the provision balance during the year ended December 31, 2024, are as follows:

	Provisions (USD in thousands)
Carrying amount at January 1, 2024	\$ 149
Currency adjustment	(8)
Carrying amount at December 31, 2024	<u>\$ 141</u>

Note 23. Fees to Auditors

The following table presents the fees to our independent registered public accounting firm, EY Godkendt Revisionspartnerselskab, recognized in general and administrative expenses in the consolidated statements of comprehensive loss for the years ended December 31, 2025, and 2024. This note was prepared in accordance with the requirements of the Danish Financial Statements Act:

	Years Ended December 31,	
	2025	2024
	(USD in thousands)	
Audit fees	\$ 329	\$ 297
Audit related fees	106	190
Other fees	80	198
Total fees	<u>\$ 515</u>	<u>\$ 685</u>

Audit Fees

Audit fees consist of fees billed for professional services rendered by EY for the audit of our annual consolidated financial statements or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those fiscal years.

Audit-Related Fees

Audit-related fees consist of assurance and related services performed by EY that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit-Related fees."

Other Fees

Other fees consist of services provided by EY for other permitted services, including fees for work performed by EY in connection with the Company's capital raises.

Note 24. Events After the Reporting Period

No events have occurred after the reporting date that would influence the evaluation of these consolidated financial statements.

Item 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Form	Date	Incorporated by Reference Number	File Number	Provided Herewith
1.1	Articles of Association currently in effect (including English translation)	6-K	11/18/2025	1.1	001-39950	
2.1	Form of Deposit Agreement among the Registrant, the depository and holders and beneficial owners of the American Depositary Shares	F-6	01/12/2021	1	333-252038	
2.2	Form of Specimen American Depositary Receipt (included in Exhibit 2.1)					
4.1	CAF®09b Supply, Patent Know How & Trademark License Agreement dated November 30, 2020, between Statens Serum Institut and Evaxion Biotech A/S	F-1	01/08/2021	10.1	333-251982	
4.2	Finance Contract between European Investment Bank and Evaxion Biotech A/S dated August 6, 2020	F-1	01/08/2021	10.2	333-251982	
4.3	Lease Agreement dated October 2, 2020 between Evaxion Biotech A/S and DTU Science Park A/S.	F-1	01/08/2021	10.3	333-251982	
4.4	Clinical Trial Collaboration and Supply Agreement by and among Evaxion Biotech A/S, MSD International GmbH and MSD International Business GmbH, subsidiaries of Merck & Co., Inc., (known collectively as MSD outside the United States and Canada) (Incorporate by Reference to Exhibit 99.2 to Form 6-K filed with the Commission on October 25, 2021).	6-K	10/25/2021	99.2	001-39950	
4.5	Purchase Agreement dated June 7, 2022, between Evaxion Biotech A/S and Lincoln Park Capital Fund, LLC	6-K	06/07/2022	10.1	001-3950	
4.6	Registration Rights Agreement dated June 7, 2022, between Evaxion Biotech A/S and Lincoln Park Capital Fund, LLC	6-K	06/07/2022	10.2	001-3950	
4.7	Capital on Demand™ Sales Agreement dated October 3, 2022 between Evaxion Biotech A./S and JonesTrading Institutional Services LLC	6-K	10/04/2022	1.1	001-3950	
4.8	Agreement for the Issuance and Subscription of Notes	6-K	08/04/2023	10.1	001-39950	
4.9	Form of Securities Purchase Agreement	6-K	12/21/2023	10.1	001-39950	
4.10	Form of Investment Agreement	6-K	12/21/2023	10.2	001-39950	
4.11	Form of Registration Rights Agreement	6-K	12/21/2023	10.3	001-39950	
4.12	Engagement Agreement, by and between the Company and H.C. Wainright & Co., LLC, dated as of September 27, 2023, as amended	F-1/A	01/31/2024	1.1	333-276505	

4.13	Form of Placement Agent Warrant	F-1/A	01/30/2024	4.6	333-276505	
4.14	Form of Securities Purchase Agreement	6-K	02/05/2024	99.1	001-39950	
4.15	Form of Series A Warrant	6-K	02/05/2024	99.3	001-39950	
4.16	Form of Prefunded Warrant	6-K	02/05/2024	99.2	001-39950	
4.17	Amendment to Warrants	6-K	06/24/2024	10.1	001-39950	
4.18	Option and License Agreement	6-K	10/01/2024	10.1	001-39950	
4.19	Co-Ownership Agreement	6-K	07/02/2024	10.1	001-39950	
4.20	License Agreement	6-K	07/02/2024	10.1	001-39950	
4.21	Form of Securities Purchase Agreement	F-1/A	01/30/2024	10.1	333-276505	
4.22	Form of Pre-funded warrants for this offering	F-1/A	12/17/2024	4.7	333-283304	
4.23	Form of Ordinary warrants	F-1/A	12/17/2024	4.8	333-283304	
8.1	List of Subsidiaries of the Registrant	F-1/A	11/03/2021	21.1	333-260493	
11.1	Insider Trading Policy					X
12.1	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
12.2	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
13.1	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
13.2	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
15.1	Consent of EY Godkendt Revisionspartnerselskab					X
97.1	Clawback Policy					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the nline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema					
101.CAL	Inline XBRL Taxonomy Extension Schema Calculation Linkbase					
101.DEF	Inline XBRL Taxonomy Extension Schema Definition Linkbase					
101.LAB	Inline XBRL Taxonomy Extension Schema Label Linkbase					
101.PRE	Inline XBRL Taxonomy Extension Schema Presentation Linkbase					
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101)					

Signatures

Evaxion A/S hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Evaxion A/S	/s/ Helen Tayton-Martin
<hr/>	
Name:	Helen Tayton-Martin
Title:	Chief Executive Officer
Date:	March 5, 2026
	/s/ Thomas Frederik Schmidt
<hr/>	
Name:	Thomas Frederik Schmidt
Title:	Chief Financial Officer
Date:	March 5, 2026

EVAXION

INTERNAL RULES ON

INSIDER TRADING POLICY

INTERNAL RULES

ON INSIDER TRADING POLICY

(Company registration no. (CVR) 31762863)

PREAMBLE

Evaxion Biotech A/S (the "Company") and, together with its subsidiaries, the "Group") has American Depositary Shares ("ADSs") representing ordinary shares of the Company listed on The NASDAQ Capital Market, New York. These internal rules apply to these ADSs as well as financial instruments attached to the ADSs, including warrants, convertible notes or debentures and similar securities.

These internal rules have been established to provide for compliance with the United States securities laws, as applied to the Company, and cover:

- (i) the dissemination of Inside Information (as defined below) for the purpose of preventing Inside Information from becoming available to others than those needing such information; and
- (ii) management's and other employees' transactions with securities issued by the Company.

1. PURPOSE

- 1.1 This set of internal rules governs the Group's members of the Board of Directors and Executive Management and its other employees and the Company for the purpose of ensuring that the prohibition against insider trading, price manipulation and speculation is not violated.

2. INSIDE INFORMATION

- 2.1 "Inside Information" means information, which

- is of a precise nature, meaning information that
 - (a) indicates a set of circumstances which exists, or may reasonably be expected to come into existence, or an event which has occurred or may reasonably be expected to do so,
 - (b) if there is a substantial likelihood that a reasonable investor would consider the information important in making an investment decision regarding the purchase or sale of a company's securities, or if the information would significantly alter the total mix of information already known about a company, or
 - (c) is specific enough to enable a conclusion to be drawn as to the possible effect of that set of circumstances or event on the market price of the relevant securities;
- has not been made public; and
- relates to (a) the Company, (b) the Company's securities, (c) a Company partner or collaborator or (d) market conditions which, if it were made public, would be likely to have a significant effect on the market price of one or more securities.

- 2.2 Information shall be considered as published once, for the market, there has been general and relevant dissemination hereof, which will include that it must be widely disseminated in a manner making it generally available to investors through (i) a report filed with the Securities and Exchange Commission (the “SEC”), (ii) a press release distributed through a widely circulated news or wire service, such as Dow Jones, Bloomberg, Business Wire, PR Newswire, or Thomson Reuters; (iii) a news conference to which the public is granted access and for which advance notice is given; (iv) a simultaneous webcast of a news conference or analyst conference call; (v) posting of the information on the company’s website; and (vi) making available to the public a replay of the company’s news conference or conference call or through media such as Dow Jones, Thomson Reuters Economic Services, The Wall Street Journal or the Associated Press. The circulation of rumours, even if accurate and reported in the media, does not constitute effective public dissemination.
- 2.3 Information shall not be regarded as published until two business days after the day on which the relevant information is disseminated to the public. Consequently, information shall be treated as Inside Information until that time.
- 2.4 Non-published information, to the extent the information is of a precise nature and may be expected to have significant impact on the market price, regarding the matters listed below (including considerations and negotiations relating thereto) shall always be considered Inside Information:
- considerable profit or loss on single transactions;
 - conclusion or termination/cancellation of major co-operation agreements or contracts;
 - major investments;
 - material new products;
 - notice of issuance of patents;
 - results of the Company’s or a Company partner’s or collaborator’s re-research and development activities, preclinical testing or clinical trials.
 - legal proceedings taken out by or against the Company and/or the Group in the event that the outcome hereof is considered to have material impact;
 - major, new markets or lapse of the same;
 - purchase or sale of major fixed assets, including real estate;
 - information related to any offering (actual or proposed) of the Company’s securities;
 - major expansion, changes or limitations to the activities of the Company and/or the Group;
 - business cycle fluctuations of significant importance to the Company and/or the Group;
 - liquidation, suspension of payments, bankruptcy petition, etc.;
 - proposals for merging with another company;
 - proposals for material amendments of the articles of association;
 - transfer of a controlling interest in the Company and/or the Group, which the Board of Directors (the “Board”) or Executive Management is involved in or has knowledge of.

In addition, any non-published information regarding the following matters comprised by the Company's specific and/or continuous duty of disclosure must always be regarded as Inside Information until it has been made public:

- substantial changes in earnings or liquidity;
- interim results and balances, including interim financial reports and budgets, and tax affairs;
- changes to the management and audit and changes in the Company's auditors or a notification from its auditors that the Company may no longer rely on the auditors' audit report;
- the establishment of or material changes to incentive schemes.

Finally, all other information that, considering the nature and contents of such information, is considered as confidential or which by the management of the Company is declared to be confidential, shall be considered Inside Information. Note that both positive and negative information can be material. U.S. securities regulators and stock market investigators will scrutinize a questionable trade after the fact with the benefit of hindsight. A member of the Board or Executive Management or employee may incur personal liability if he or she buys, sells, or makes certain other transfers, including gifts or donations, of any Company securities during a period when the member of the Board or Executive Management, or employee is aware of Material Nonpublic Information about the Company. It is possible that members of the Board or Executive Management, or employees of the Company by virtue of their position and access to certain material information, may, under U.S. laws, be presumed to know such information before it is released to the public.

3. INSIDER LIST

- 3.1 The Company shall prepare and, on a continuous basis, update a list (the Insider List) of all persons working for the Group and who regularly or in isolated circumstances have access to Inside Information directly or indirectly relating to the Group as further described in the Company's Internal Rules on Dissemination of Inside Information.

4. TRADE IN SECURITIES ISSUED BY THE COMPANY

- 4.1 Persons who are subject to these internal rules may only purchase, sell, subscribe, exercise etc. securities of the Company, and financial instruments attached thereto, during a period of two (2) weeks from the date of publishing of the Company's annual report or interim financial report. The 2-week trade window starts on the third full trading day after the day when any of the Company's annual report or interim financial report has been published. The chairperson (the "Chair") of the Company's Board may, if necessary, decide to fully or partly close the said 2-week window, which decision will be communicated to relevant persons by e-mail. As mentioned in clause 2.2 above information shall not be regarded as published until the relevant information has been disseminated to the public.

- 4.2 Purchase, sale or subscription of shares etc. may not take place outside the 2-week period, unless the Chair of the Board has approved the transaction in advance. Such approval may only be granted in special circumstances, e.g. with respect to subscription of employee-owned shares; exercising of subscription rights; share options or similar, where the right may only be exercised within a fixed deadline, which the rights holder has no influence on.
- 4.3 The request to the Chair of the Board pursuant to clause 4.2 shall be specific and include the reason for the request. Purchase and sale outside the 2-weeks period may under no circumstances take place within three (3) weeks prior to publication of an interim financial report or annual financial report.
- 4.4 The prohibition against trading outside the 2-week period applies to members of the Board and members of the Executive Management for a period of six months and employees for a period of three months after the expiry of the appointment or employment, respectively.
- 4.5 Any trade must be notified to the Executive Management no later than two (2) business days after the trade is confirmed stating the nature of the trade, the number of shares etc. concerned and the date of the trade.
- 4.6 Regardless of the above including whether or not permission has been obtained or whether the trade window is open, the prohibition against insider trading applies if the person in question is in possession of Inside Information.
- 5. PROHIBITION AGAINST SPECULATION**
- 5.1 Pursuant to Section 113 of the Danish Companies Act (in Danish: *selskabsloven*), members of the Board and the Executive Management may not engage in speculative transactions involving shares in the Company or in other companies in the Group.
- 5.2 The Company considers it improper and inappropriate for any member of the Board and the Executive Management, as well as any other employee of the Company to engage in short-term or speculative transactions in the Company's securities. Therefore, it is the Company's policy that members of the Board and the Executive Management and other employees may not engage in any of the following transactions:
- **Short-term Trading.** An employee's short-term trading of the Company's securities may be distracting to the employee and may unduly focus the employee on the Company's short-term stock market performance instead of the Company's long-term business objectives. For these reasons, no member of the Board or Executive Management or employee of the Company who purchases Company securities in the open market may sell any Company securities of the same class during the six months following the purchase.

- **Short Sales.** Short sales of the Company's securities evidence an expectation on the part of the seller that the securities will decline in value, and therefore signal to the market that the seller has no confidence in the Company or its short-term prospects. In addition, short sales may reduce the seller's incentive to improve the Company's performance. For these reasons, short sales of the Company's securities are prohibited by this Policy.
- **Hedging Transactions.** Certain forms of hedging or monetization transactions, such as forward sale contracts, allow a member of the Board or Executive Management or an employee to lock in much of the value of his or her securities holdings, often in exchange for all or part of the potential for upside appreciation in the securities. These transactions allow the member of the Board or Executive Management or employee to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the member of the Board or Executive Management or employee may no longer have the same objectives as the Company's other shareholders. Therefore, all member of the Board or Executive Management and employees are prohibited from engaging in any such transactions.
- **Margin Accounts and Pledges.** Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of Material Nonpublic Information or otherwise is not permitted to trade in the Company's securities, member of the Board or Executive Management and employees are prohibited from holding the Company's securities in a margin account or pledging Company securities as collateral for a loan.
- **Other Transactions.** The Company cannot possibly cover all potential transactions, trades, or types of products that may be developed in the future under this policy; accordingly, the Company reserves the right from time to time to review and consider whether to include additional transactions, types of products, and/or certain trading arrangements as prohibited under this policy. During review of the terms of any such transaction or product, or the facts and circumstances surrounding the proposed transaction, that is undertaken as part of the pre-clearance process, the Company may determine that the transaction, product, or trade is not appropriate, and the Company may refuse to clear such transaction to proceed.

6. PROHIBITION AGAINST INSIDER TRADING

- 6.1 The purchase, sale and recommendation to purchase or sell shares in the Company and of financial instruments attached to these shares, including warrants, convertible debentures and similar securities, may not be performed by any person while in possession of Inside Information.

- 6.2 Providing material nonpublic information to another person who may trade or advise others to trade on the basis of that information is known as “tipping” and is illegal. Tipping violates the securities laws of both Denmark and the USA and can result in the same civil and criminal penalties that apply to insider trading, even though the person in question did not trade and did not gain any benefit from another's trading. Therefore, it is prohibited to “tip” or provide material nonpublic information concerning the Company or any other company or otherwise make unauthorized disclosure or use of this information, regardless of whether the person profits or intends to profit by the tipping, disclosure, or use of such information, to any person other than a member of the Board or Executive Management or employee of the Company, unless required as part of that your regular duties for the Company and authorized by the Compliance Officer, if any.
- 6.3 The Group's member of the Board or Executive Management and employees shall in connection with any purchase or sale of shares etc. carefully observe the prohibition against insider trading and tipping.
- 6.4 The legal prohibition against insider trading does not apply to buying or selling of shares etc. conducted in the discharge of an obligation, provided that the obligations have become due at the time of the transaction and where the said obligation results from an agreement concluded before the person concerned possessed Inside Information.
- 6.5 The prohibition against insider trading and tipping set out in clause 6.1 and 6.2 applies'
- (i) to all persons with Inside Information, regardless of whether or not these persons are included on the Insider List;
 - (ii) at all times and regardless of whether or not the Company's management and/or employees would otherwise have been allowed to perform such transactions, including within the 4-weeks period mentioned in item 4.1.

7. PROHIBITION AGAINST PRICE MANIPULATION

- 7.1 Price manipulation or attempts hereof may not take place. "Price manipulation" shall mean acts covered by nos. (i)-(iv) which are likely to influence the price of the securities in a direction deviating from their value on the market through:
- (i) dissemination of information through the media or other methods likely to give false or misleading signals as to the supply of, demand for, or price of securities;
 - (ii) transactions or orders to trade likely to give false or misleading signals as to the supply of, demand for or price of securities;
 - (iii) transactions or orders to trade which employ fictitious devices or any other form of deception or contrivance; or
 - (iv) transactions or orders to trade through which secure, by a person, or persons acting in collaboration, the price of one or several securities at an abnormal or artificial level.

Price manipulation may, for example, include

- (i) sending out an expression of opinion through the media regarding a security or an issuer of a security after having previously acquired a certain amount of the relevant security if, at a later time, profit is gained from the impact of the opinions voiced on the price of the security, and if the conflict of interest is not disclosed to the public in a proper and effective manner no later than at the time said expression of opinion is sent out;
- (ii) the buying or selling of securities at the close of the market with the effect of misleading investors acting on the basis of closing prices; or
- (iii) conduct by a person, or persons acting in collaboration, to secure a dominant position over the supply of or demand for a security which has the effect of fixing, directly or indirectly, purchase or sale prices of the security at an abnormal or artificial level or creating other unfair trading conditions for the transaction.

8. SANCTIONS

- 8.1 If a person suspects that these internal rules have been violated, including violation of the prohibition against insider trading, price manipulation or speculation, the person in question shall immediately inform the Chair of the Board thereof.
- 8.2 A violation of these rules may be a criminal offence and may seriously harm the Company. Furthermore, a violation of these rules may have disciplinary consequences in the form of a warning and in aggravated cases instant dismissal, and regardless of the Company's wish to protect its employees, the Company may be obliged to report such violation and violating person(s) to the police and regulatory authorities.
- 8.3 Abuse of Inside Information (any violation of the prohibition against insider trading or the prohibition against price manipulation) may be punishable by a fine or imprisonment. Penalties under U.S. securities laws in the form of civil and/or criminal penalties, including imprisonment of up to 20 years and criminal fines (no matter how small the profit gained or loss avoided) of up to USD \$5 million per violation and civil fines of up to three times the gain or loss avoided, regardless of whether the relevant person financially benefited.

For a company (as well as possibly any supervisory person) that fails to take appropriate steps to prevent insider trading, penalties can consist of (i) a civil penalty of the greater of (a) \$1 million, and (b) three times the profit gained or loss avoided by the person as a result of the violation; and (ii) a criminal fine of up to \$25 million.

Employees of the Company who violate this Policy will also be subject to disciplinary action by the Company, which may include termination of employment, regardless of whether the employee's non-compliance results in a violation of law.

The consequences of and penalties for insider trading for the Company and for those members of the Board or Executive Management and employees that are subject to the securities laws in jurisdictions outside the U.S. can also be severe. You are required to comply fully with the securities laws in any jurisdiction to which you are subject. If you have any questions about the securities laws that apply to you, please contact the Company's Chief financial Officer.

9. ANNUAL UPDATE

9.1 The Board shall on a regular basis and at least once a year review and reconsider the contents of these internal rules.

10. EFFECTIVE DATE, ETC.

10.1 Adopted by the Board of Directors on 17 December 2020, amended 7 December 2022, amended 31 August 2023, amended June 13, 2024.

10.2 Immediately upon the adoption of these internal rules, a copy shall be handed out to each person who is subject to these internal rules.

10.3 A copy of these internal rules will be handed over to the Danish Financial Supervisory Authority (in Danish: *Finanstilsynet*) upon its request.

Members of the Board of Directors:

Marianne Søgaard

Lars Holtug

Roberto Prego

Lars Staal Wegner

Members of the Executive Management:

Helen Tayton-Martin

Andreas Holm Mattsson

Thomas Frederik Schmidt

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Helen Tayton-Martin, certify that:

1. I have reviewed this annual report on Form 20-F of Evaxion A/S (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 5, 2026

By: /s/ Helen Tayton-Martin

Name: Helen Tayton-Martin

Title: Chief Executive Officer

**CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thomas Frederik Schmidt, certify that:

1. I have reviewed this annual report on Form 20-F of Evaxion A/S (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 5, 2026

By: /s/ Thomas Frederik Schmidt

Name: Thomas Frederik Schmidt

Title: Chief Financial Officer

**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002***

In connection with the Annual Report on Form 20-F of Evaxion A/S (the "Company") for the year ended December 31, 2025, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Helen Tayton-Martin, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2026

By: /s/ Helen Tayton-Martin
Name: Helen Tayton-Martin
Title: Chief Executive Officer

**CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002***

In connection with the Annual Report on Form 20-F of Evaxion A/S (the "Company") for the year ended December 31, 2025, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Thomas Frederik Schmidt, as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2026

By: /s/ Thomas Frederik Schmidt
Name: Thomas Frederik Schmidt
Title: Chief Financial Officer

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-255064) Pertaining to the Incentive Scheme of Evaxion A/S,
- (2) Registration Statement (Form F-1 No. 333-266050) of Evaxion A/S,
- (3) Registration Statement (Form F-1 No. 333-276505) of Evaxion A/S,
- (4) Registration Statement (Form F-1 No. 333-279153) of Evaxion A/S,
- (5) Registration Statement (Form F-1 No. 333-283304) of Evaxion A/S
- (6) Registration Statement (Form F-3 No. 333-285778) of Evaxion A/S, and
- (7) Registration Statement (Form F-1 No. 333-291685) of Evaxion A/S;

of our report dated March 5, 2026, with respect to the consolidated financial statements of Evaxion A/S included in this Annual Report (Form 20-F) of Evaxion A/S for the year ended December 31, 2025.

/s/ EY Godkendt Revisionspartnerselskab

Copenhagen, Denmark

March 5, 2026

EVAXION

EVAXION A/S

INCENTIVE COMPENSATION RECOUPMENT POLICY

- 1. Introduction.** The Board of Directors (the “**Board**”) of Evaxion A/S (the “**Company**”) believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company’s pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of Incentive-Based Compensation in the event the Company is required to prepare a Restatement resulting from noncompliance with financial reporting requirements under the federal securities laws (this “**Policy**”). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the “**Exchange Act**”), and the corresponding listing standards adopted by The NASDAQ Stock Market (“**Nasdaq Requirements**”).
- 2. Recoupment.** If the Company is required to prepare a Restatement, the Board shall, unless the Board’s Compensation Committee (the “**Compensation Committee**”) or, in the absence of the Compensation Committee, a majority of the independent directors serving on the Board, determines it to be Impracticable, take Reasonably Prompt Action to recoup all Recoverable Compensation from any Covered Person. Subject to applicable law, the Board may seek to recoup Recoverable Compensation by requiring a Covered Person to repay such amount to the Company; by adding “holdback” or deferral policies to incentive compensation; by adding post-vesting “holding” or “no transfer” policies to equity awards; by set-off of a Covered Person’s other compensation; by reducing future compensation; or by such other means or combination of means as the Board, in its sole discretion, determines to be appropriate. This Policy is in addition to (and not in lieu of) any right of repayment, forfeiture, or off-set against any Covered Person that may be available under applicable law or otherwise (whether implemented prior to or after adoption of this Policy). The Board may, in its sole discretion and in the exercise of its business judgment, determine whether and to what extent additional action is appropriate to address the circumstances surrounding any Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.
- 3. Administration of Policy.** The Board shall have full authority to administer, amend, or terminate this Policy and intends that this Policy will be applied to the fullest extent of the law. The Board shall, subject to the provisions of this Policy, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. All determinations and interpretations made by the Board shall be final, binding and conclusive. The Board may delegate any of its powers under this Policy to the Compensation Committee of the Board or, subject to the Nasdaq Requirements and the provisions of this Policy, any subcommittee or delegate thereof. This Policy and all controversies arising from or relating to this Policy shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its conflicts of law principles. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the U.S. Securities and Exchange Commission (the “**SEC**”) and any applicable Nasdaq Requirement. For the avoidance of doubt, the enforcement of this Policy is not dependent on if or when any applicable restated financial statements are filed with the SEC.

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4. **Acknowledgement by Executive Officers.** The Board shall provide notice to and seek written acknowledgement of, and agreement to be bound by, this Policy from each Executive Officer in the form of Appendix A (“**Acknowledgement**”); provided that the failure to provide such notice or obtain such Acknowledgement shall have no impact on the applicability or enforceability of this Policy.

5. **No Indemnification.** Notwithstanding the terms of any of the Company’s organizational documents, any corporate policy or any contract, no Covered Person shall be indemnified by the Company against the loss of any Recoverable Compensation. Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation that is granted, paid or awarded to a Covered Person from the application of this Policy or that waives the Company’s right to recovery of any Recoverable Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date of this Policy).

6. **Disclosures.** The Company shall make all disclosures and filings with respect to this Policy and maintain all documents and records that are required by the applicable rules and forms of the SEC (including, without limitation, Rule 10D-1 promulgated under the Exchange Act) and any Nasdaq Requirement.

7. **Effective Date.** This Policy shall be effective as of the date it is adopted by the Board (the “**Effective Date**”) and shall apply to Incentive-Based Compensation that is Received on or after October 2, 2023.

8. **Amendment.** The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect any amendments or other changes to Section 10D of the Exchange Act or any Nasdaq Requirement.

9. **Definitions.** In addition to terms otherwise defined in this Policy, the following terms, when used in this Policy, shall have the following meanings:

“**Applicable Period**” means the three completed fiscal years, including any Transition Period, immediately preceding the earlier of: (i) the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement.

“**Covered Person**” means any person who receives Recoverable Compensation.

“**Executive Officer**” means the Company’s president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policymaking functions for the Company. Executive officers of the Company’s parent(s) or subsidiaries are deemed Executive Officers of the Company if they perform such policy making functions for the Company.

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“Financial Reporting Measure” means the measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return (“**TSR**”) are also considered Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the SEC.

“Impracticable” means, after exercising a normal due process review of all the relevant facts and circumstances and taking all steps required by Exchange Act Rule 10D-1 and any applicable Nasdaq Requirement, the Compensation Committee or, in the absence of the Compensation Committee, a majority of the independent directors serving on the Board, determines that recovery of the Incentive-Based Compensation is impracticable because: (i) it has determined, after making a reasonable attempt to recover such Incentive-Based Compensation, documented such reasonable attempt to recover and provided that documentation to The NASDAQ Stock Market, that the direct expense that the Company would pay to a third party to assist in recovering the Incentive-Based Compensation would exceed the amount to be recovered; (ii) it has concluded that the recovery of the Incentive-Based Compensation would violate home country law adopted prior to November 28, 2022 and has received a legal opinion from home country counsel stating that the recovery would result in such a violation; or (iii) it has determined that the recovery of Incentive-Based Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to the Company’s employees, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

“Incentive-Based Compensation” means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

“Reasonably Prompt Action” means that each of the Company, its directors and its officers act in a manner that is consistent with the exercise of their applicable fiduciary duties to safeguard the assets of the Company, including the time value of any potential Recoverable Compensation.

“Received” means Incentive-Based Compensation received in the Company’s fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

“Recoverable Compensation” means all Incentive-Based Compensation (calculated on a pre-tax basis) Received on or after the Effective Date by a person: (i) after beginning service as an Executive Officer; (ii) who served as an Executive Officer at any time during the performance period for that Incentive-Based Compensation (whether or not such Executive Officer is serving at the time the Recoverable Compensation is required to be repaid to the Company); (iii) while the Company had a class of securities listed on a national securities exchange or national securities association; and (iv) during the Applicable Period, that exceeded the amount of Incentive-Based Compensation that otherwise would have been Received had the amount been determined based on the Financial Reporting Measures, as reflected in the Restatement. With respect to Incentive-Based Compensation based on stock price or TSR, when the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the amount must be based on a reasonable estimate of the effect of the Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received.

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“Restatement” means an accounting restatement of any of the Company’s financial statements due to the Company’s material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“Transition Period” means any transition period in the Company’s financial statements that is the result of a change in the Company’s fiscal year within or immediately following the relevant three completed fiscal year period; *provided, however*, a transition period between the last day of the Company’s previous fiscal year and the first day of its new fiscal year that comprises a period of nine (9) to twelve (12) months shall be deemed to be a completed fiscal year for purposes of this Policy.

Adopted by the Board on June 13, 2024.

Appendix A

AGREEMENT AND ACKNOWLEDGEMENT OF POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

By my signature below, I, as an Executive Officer of Evaxion A/S (the “**Company**”), acknowledge and agree that:

1. I have received and read the attached Incentive Compensation Recoupment Policy (the “**Policy**”).
2. I am a Covered Person as defined in the Policy.
3. I will be bound by all of the terms and conditions of the Policy, Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC, and any applicable Nasdaq Requirements both during and after my employment with the Company, including, without limitation, by promptly repaying or returning any Recoverable Compensation to the Company as determined in accordance with the Policy and this Acknowledgement.

Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Policy.

Signature: _____

Printed Name: _____

Date: _____