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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, 2021

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 Biotech A/S

(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

Dr. Neergaards Vej 5f DK-2970 Hoersholm, Denmark
(Address of principal executive offices)
Lars Staal Wegner, MD
Chief Executive Officer
Evaxion Biotech A/S
Dr. Neergaards Vej 5f DK-2970 Hoersholm Denmark
Tel: +45 53 53 18 50
E-mail: lsw@evaxion-biotech.com
(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:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value DKK 1 per share	EVAX	The Nasdaq Stock Market LLC
Ordinary Shares, nominal value of DKK 1 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, 2021 was:

Title of each class	Number of Shares Outstanding at December 31, 2021
Ordinary share, nominal value DKK1 per share (including shares underlying American Depository Shares)	23,203,808

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 ☒

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 ☐ Non-accelerated Filer ☒
Emerging growth company ☒

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. ☐

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:

- "ADSs" are to our American Depositary Shares, each of which represents one ordinary share of Evaxion Biotech 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 Biotech A/S and our wholly owned subsidiaries;
- "Group" are to the consolidated entities of Evaxion Biotech 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 1 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, 2021 and 2020 and for the years ended December 31, 2021, 2020 and 2019 (our "audited consolidated financial statements"), prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

Our financial information is presented in our presentation currency, U.S. Dollar, or USD. Our parent Company's functional currency is the Danish Krone, or DKK. Certain Danish Krone amounts in this annual report have been translated solely for convenience into USD at an assumed exchange rate of DKK 6.5612 per $1.00, which was the official exchange rate of such currencies as of December 31, 2021 rounded to four decimal places.

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 actually 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, 2021. 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 actually 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 ™ 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 "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "should," "target," "would" 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 a number of 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 of 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 pre-clinical 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;
- 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 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 and foreign countries;
- adverse effects on our business condition and results for operation from the global COVID-19 pandemic, including the pace of global economic recovery from the pandemic;
- 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 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 AI-immunology company with only two product candidates currently in clinical trials.

- We have a limited operating history and no immunotherapy drug has been approved using our technology, and none may ever be approved.

- 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.

- 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.

- Pharmaceutical product development is inherently uncertain, and there is no guarantee that any of our product candidates will receive marketing approval.

- The global pandemic caused by COVID-19 and variants such as Delta and Omicron, as well as the pace of global economic recovery from the pandemic, has affected our business and if the pandemic continues it could materially adversely impact our business, including delays in our clinical trials, supply chain operation, regulatory timelines and commercial activities.

- The effects of the recent 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.

- 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.

- 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.

- 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.

- 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 in the conduct of significant aspects of our pre-clinical 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.

- 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 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

We are a clinical-stage biotechnology company with no pharmaceutical products approved for commercial sale. Our business faces significant risks. You should carefully consider all of 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 or results of operations 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 our other SEC filings. 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 in each year since our inception in 2008, including net losses of $24.5 million, $15.0 million, and $11.2 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had accumulated deficit of $50.4 million.

We have devoted most of our financial resources to research and development, including our pre-clinical and clinical development activities and the development of our AI platform technologies, PIONEER, EDEN and RAVEN. To date, we have financed our operations primarily through the sale of equity securities, issuance of convertible debt instruments and through private and governmental grants. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, collaborations and grants. We believe that the cost and expense of late stage clinical testing, regulatory and marketing approval and commercialization of products for such disease indications are beyond the resources of all but the large biopharmaceutical and pharmaceutical companies. Therefore, we intend to develop our product candidates through Phase 2b clinical trials and then enter into partnership arrangements with these large biopharmaceutical and pharmaceutical companies to conduct late stage clinical trials, regulatory and marketing approval and commercialization of our product candidates. We have not yet entered into any such partnership agreements and may be unable to do so on economically viable terms, if at all. As a result, late stage clinical trials as well as pivotal clinical trials for our product candidates have not been commenced and even if such trials are commenced in the near future, it will be several years, if ever, before we have a product candidate ready for commercialization by one of our partners. Even if our future partners obtain regulatory approval to market a

product candidate, our future revenues will depend upon the size of any markets in which our product candidates receive such approval, upfront, milestone and any other payments we receive from our future partners, and our future partners' ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of, and our partners' ability to obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating substantial revenues in the near term from any of our commercialization partnerships we may establish.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- continue or expand our research or development of our programs in pre-clinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional pre-clinical studies or clinical trials for our product candidates and seek to identify and validate additional product candidates;
- continue to invest in our AI platforms to identify novel therapies;
- change or add to internal and external manufacturing capacity or capability;
- change or add more suppliers;
- add more infrastructure to our quality control, quality assurance, legal, accounting, compliance and other groups to support our operations;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company;
- create additional infrastructure to support our product development, including expansion of sites in Denmark and new sites in the United States;
- acquire or in-license other technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

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

- completing research and pre-clinical development, and successfully progressing our product candidates through clinical development, including through Phase 2b clinical trials for both immuno-oncology and infectious disease product candidates to validate our AI platforms;
- seeking, negotiating and obtaining agreements with future partners, if any, on favorable terms for the completion of clinical trials, and United States and non- United States marketing approvals and commercialization of our product candidates;

- further development of the manufacturing capabilities of, and our relationships with, third-party manufacturers in order to provide adequate (in amount and quality) products and services to support clinical development of our product candidates;
- our future partners obtaining market acceptance of our product candidates as treatment options;
- our future partners launching and commercializing our product candidates for which marketing approval and reimbursement have been obtained;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and attracting, hiring and retaining qualified personnel.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the market price of the ADSs could decline.

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Form 20-F:

- delays or failures in advancement of existing or future product candidates into clinical trials;
- failures in further development of our AI platforms;
- the ability of our future partners to manufacture and commercialize our product candidates;
- our ability to manage our growth;
- the outcomes of research programs, pre-clinical studies and clinical trials, and other product development or approval processes conducted by us and/or our future partners;
- the ability of our future partners to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with partners;
- our contractual or other obligations to provide resources to fund our product candidates;
- our operations in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business outside of Denmark, including the conduct of clinical trials in multiple locations;
- our and our partners' consistent ability to have our products and product candidates manufactured by third parties;
- our ability to develop programs to fit into a clinical work-flow and treatment regimen;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;

- our and our partners' ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our and our partners' ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our future partners' ability to obtain additional capital that may be necessary to develop and commercialize products under our collaboration agreements;
- business interruptions such as power outages, strikes, acts of terrorism, pandemics or natural disasters; and
- our ability to use our net operating loss, or NOL, carryforwards to offset future taxable income.

Due to the various factors mentioned above, and others, the projected financial information included in this Form 20-F should not be relied upon as indications of our future operating performance.

The net losses we incur may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause the market price of the ADSs to decline. While as a general matter we intend to periodically report on the status of our product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, we may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosures of any milestones related to any of our product candidates that are managed by our partners. Any disclosure by a partner of data that are perceived as negative, whether or not such data are related to other data that we or others release, may have a material adverse impact on the market price of the ADSs or overall valuation. The market price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or the EMA, the Australian Therapeutic Goods Administration, or the TGA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Even if we are able to generate revenues from our agreements with future partners, if any, we may not become profitable and may need to obtain additional funding to continue operations.

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 unused tax loss carryforwards for corporate taxes, though we have not recognized deferred tax assets related to such loss carryforwards for IFRS reporting purposes. In general, NOL carryforwards in Denmark do not expire. They are, however, subject to review and possible adjustment by the Danish tax authorities. Furthermore, under current Danish tax laws, certain substantial changes in our ownership structure and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income. In addition, we may in the future have United States federal and state NOL carryforwards in the United States, and other jurisdictions where we maintain a subsidiary.

We may not be able to utilize a material portion of our NOLs or credits in either Denmark, the United States, or other jurisdictions where we maintain a subsidiary or otherwise engage in business. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and our recognition could be subject to challenge by taxing authorities. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years. Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. As described above, we have incurred significant net

losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We do not know whether or when we will generate the taxable income necessary to utilize our NOL or credit carryforwards.

We will need 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, reduce or terminate our product development programs, commercialization efforts or other operations.

As of December 31, 2021 we had $32.2 million in cash and cash equivalents. The net proceeds from our IPO completed in February 2021 was $25.3 million, based on the initial public offering price of $10.00 per ADS, after deducting underwriting discounts and commissions and offering expenses payable by us. The net proceeds from our follow-on offering completed in November 2021 was $24.9 million, based on the public offering price of $7.00 per ADS after deducting underwriting discounts and commissions and offering expenses payable by us.

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 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, or the 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, or the 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 draw down of the first tranche of the EIB loan Agreement amounting to €7.0 million. We received the proceeds from the draw down of the first tranche of the EIB loan of €7.0 million on February 17, 2022. We expect that the net proceeds from our IPO, our follow-on offering, the proceeds from draws on amounts available under the EIB Loan and our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the date of this Form 20-F. However, our operating plan may change as a result of many 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 capital to achieve our goals. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable 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 pre-clinical or nonclinical 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 commercial 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; and

- 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.

To date, we have financed our operations primarily through the sale of equity securities, issuance of convertible debt instruments 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 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, licensing arrangements, and other product development arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our product candidates. In addition, 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. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our securityholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, our shareholders' ownership interest will be diluted. In addition, we may enter into credit facilities from time to time, which may be secured, to fund certain of our operations. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through sales of assets or other collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek future partners for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the market price of the ADSs to decline, and negatively impact our ability to fund operations

Any additional financing that we could seek may not be available on favorable terms or at all. For example, while the potential impact and duration of the COVID-19 pandemic on the global economy and our business in particular may be difficult to assess or predict, the pandemic has resulted in, and may continue to result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our future plans and our ability to execute our strategy could be adversely affected, which in turn could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

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.

As of December 31, 2021, we had 61 full-time equivalent employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As a growing biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and develop our product candidate will depend in part on our ability to effectively manage the future development and expansion of our company.

Risk factors

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operations and investors may lose confidence in our financial reports and the market price of the ADSs could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined by the JOBS Act. We do not expect to have our independent registered public accounting firm attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our company's annual consolidated financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our financial statements for the year ended December 31, 2021, we continued to be in the process of designing and implementing controls to monitor and provide oversight over the design and operating effectiveness of internal control over financial reporting in order to comply with the requirements of Section 404 of the Sarbanes-Oxley Act. We determined that management failed to implement certain components of the COSO framework, including elements of the control environment, information and communication, control activities and monitoring activities. Therefore, we have assessed that we lacked sufficient internal controls to support effective financial reporting as of December 31, 2021, which constitutes a material weakness.

To remediate this material weakness, we will continue to make further progress on the design and operating effectiveness of our internal controls over financial reporting, including the monitoring, oversight and evaluation of our internal controls. We will allocate more internal resources to internal controls and intend to engage external advisors to provide training and to reassess and redesign processes and develop new controls as appropriate including assisting with the evaluation and documentation of the risk assessment, design and operating effectiveness of our internal controls over financial reporting and assist with the remediation of any deficiencies.

Additionally, in the years ended December 31, 2020 and 2019, we had identified a material weakness in our internal control over financial reporting, which remained unremediated as of December 31, 2021. The unremediated material weakness identified relates to the lack of accounting and supervisory personnel that possess an appropriate level of technical accounting experience and training, and their lack of supervision over third party service providers in areas such as books and records, financial controlling, and financial statements preparation.

To remediate this previously identified material weakness, we retained an advisory firm to provide additional depth and breadth to our technical accounting and financial reporting capabilities and are taking steps such as the hiring of additional finance staff. Also, during 2021, we hired four additional accounting personnel with financial statement closing experience and technical IFRS knowledge for the purposes of timely and reliable financial reporting in accordance with IFRS and the requirements set forth by the SEC. In addition, we recently announced that we have hired a new Chief Financial Officer who has considerable public company experience.

While we intend to implement our plans to remediate these material weaknesses, we cannot predict the success of such plans or if they will result in remediation of these material weaknesses or that additional material weaknesses will not be identified in the future. If we are unable to remediate these material weaknesses or if we experience additional material weaknesses in the future or otherwise continue to fail in maintaining an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations. Our investors may lose confidence in the accuracy and completeness of our financial reports, the market price of the ADSs could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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

We do not carry insurance for all categories of risk that our business may encounter, and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If our future partners obtain marketing approval for any product candidates that we or our future partners may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts, if at all. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our future partners may develop. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Board, our board committees or our management team.

Risks Related to our Business and Industry

Our AI approach to the discovery and development of product candidates is novel and unproven, and we do not know whether we or our partners, if any, will be able to develop any products of commercial value.

We are leveraging our PIONEER, EDEN and RAVEN AI platform technologies to create a pipeline of cancer immunotherapies and bacterial and viral infectious disease product candidates for patients whose diseases have not been adequately addressed to date by other approaches, and to design and conduct efficient clinical trials with a potentially greater likelihood of success. While we believe that applying our AI platform technologies to create medicines for defined patient populations may potentially enable drug research and clinical development that is more efficient than conventional drug research and development, our approach is both novel and unproven and, therefore, the cost and time needed to develop our product candidates is difficult to predict. Our efforts may not result in the discovery and development of commercially viable medicines. We may also be incorrect about the effects of our product candidates on the diseases of our targeted patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in clinical effect, time savings, higher success rates or reduced costs as we expect and, if not, we may not attract future partners or develop new drug candidates as quickly or cost effectively as expected and therefore our future partners may not be able to commercialize our approach as originally expected.

Our AI approach may fail to help us discover and develop additional product candidates.

Any drug discovery that we are conducting using our AI platform technologies may not be successful in identifying compounds that have commercial value or therapeutic utility. Our AI platform technologies may initially show promise in identifying potential product

candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including:

- we may not be successful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for pre-clinical and clinical development, our ability to develop product candidates and generate revenue in future periods could be compromised, which could result in significant harm to our financial position and adversely impact the market price of the ADSs;
- compounds found through our AI platform technologies may not demonstrate efficacy, safety or tolerability;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and 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 capable of being manufactured at an acceptable cost and speed; or
- we may not be able to scale up manufacturing of patient-specific therapies to a commercial scale.

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

Our business requires sophisticated computer systems and software. Some of the technologies are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no guarantee that we will be able to develop, acquire, enhance, deploy or integrate new technologies, that these new technologies will meet our needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render our AI platform technologies obsolete. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance features of our AI platform technologies in response to an ever-changing patient population. We may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of our AI platform technologies, limiting our ability to identify new product candidates. Any of these failures could have a material adverse effect on our operating results and financial condition.

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.

As with most biological and vaccine products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, have compromised immune and other systems and be receiving numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us, our future partners or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, the TGA or comparable regulatory authorities. Results of clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our product candidates, we, our future partners, the FDA, the EMA, the TGA, competent authorities of the European Union member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which clinical trials of our product candidates are conducted, or a Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials. The FDA, the EMA, the TGA or comparable regulatory authorities could also order us or our future partners to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our or our partners' clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect that we or our future partners may have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate

training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

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 have contracted with and are expected to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us, our future partners or the FDA, EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and may have a detrimental impact on the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

In addition, even if our future partners successfully advance one or more of our product candidates into and through late stage clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be discovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we, our future partners or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of products derived from one or more of our product candidates;
- our future partners may be required to recall products derived from one or more of our product candidates or change the way such products are administered to patients;
- additional restrictions may be imposed on the marketing of the products derived from one or more of our product candidates or the manufacturing processes for such products or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- our future partners may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we or our future partners could be sued and held liable for harm caused to patients;
- the products derived from one or more of our product candidates may become less competitive; and
- our reputation may suffer.

Any of the foregoing 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.

Pre-clinical development, including the timeline from target identification to clinical development, is uncertain. Our pre-clinical 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 on a timely basis or at all and would have an adverse effect on our business.

A portion of our product pipeline is in pre-clinical development and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for product candidates, we must complete extensive pre-clinical studies, including IND-enabling Good Laboratory Practice toxicology testing that supports our planned INDs in the United States or similar applications in the EMA, the TGA and other jurisdictions. We must also complete extensive work on CMC activities (including collecting yield, purity and stability data) to be included in the IND filing or other equivalent regulatory filing. CMC activities for a new category of medicines require extensive manufacturing processes and analytical development, which are uncertain and lengthy. For instance, issues have occurred as we scale up our manufacturing and may occur in the future. In addition, we may have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our pre-clinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of pre-clinical studies or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our pre-clinical testing and studies and cannot predict if the FDA, the EMA, the TGA or other regulatory authorities will accept the results of our pre-clinical testing or our proposed clinical programs or if the outcome of our pre-clinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our pre-clinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Additionally, while we have demonstrated our ability to move from target identification to clinical development within as little as 18 months with our EVX-02 product candidate, which is now in Phase 1/2a trial, no assurance can be given that we will be able to do the same with other product candidates in various phases of clinical development and trials in the future.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our or our future partners control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We and our future partners may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our future partners also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our future partners conduct that could delay or prevent us or our future partners from successfully developing our product candidates, including:

- the FDA, EMA, other regulators, IRBs DSMBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;

- we or our future partners may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies;

- or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;

- the outcome of our pre-clinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;

- we and our future partners may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;

- in an effort to optimize product features, we or our future partners may continue to make changes to our product candidates after we or our future partners commence clinical trials of a product candidate which may require us or our future partners to repeat earlier stages of clinical testing or delay later-stage testing of the product candidate;

- clinical trials of any of our product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we or our future partners may decide, or regulators may require us or our future partners, to conduct additional nonclinical studies or clinical trials, or we or our future partners may decide to abandon product development programs;

- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;

- pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval;

- our product candidates may have undesirable side effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us, our investigators, our future partners, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;

- the number of trial participants required for clinical trials of any product candidates may be larger than we or our future partners may anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than we or our future partners anticipate due to perceived adverse effects, limited patient populations, competitive trials or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we or our future partners anticipate;

- our third-party contractors and our future partners may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;

- regulators may elect to impose a clinical hold, or we, our investigators, our future partners, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;

- the cost of pre-clinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we or our future partners anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;

- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies that are perceived as similar to ours; and

- the FDA, the EMA, the TGA or other regulatory authorities may require us or our future partners to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

In addition, the regulatory agencies may conduct inspections of clinical trial sites. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in development, approval and failure to commercialize the potential product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us, our future partners, the FDA, the EMA, the TGA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the DSMB. We may in the future be delayed in gaining clearance from the FDA, the EMA, the TGA or other regulators to initiate clinical trials through, among other things, the imposition of a clinical hold in order to address comments from such regulators on our or our partners' clinical trial design or other elements of our or our partners' clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA, the EMA, the TGA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit, or adequate benefit-risk ratio, from using a product candidate; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We or future partners could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. We and our future partners must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA, the EMA, the TGA and regulatory authorities in other jurisdictions have limited experience with commercial development of product candidates developed using our PIONEER AI technology platform. The FDA may require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our or our partners' ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be certain.

Significant pre-clinical or nonclinical testing and studies or clinical trial delays for our product candidates also could allow our competitors to bring products to market before our future partners do, potentially impairing our future partners 'ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

If we or our future partners encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We and our future partners depend on enrollment of participants in the clinical trials for our product candidates. In the past, we and our future partners have found, and we or our future partners may in the future find, it difficult to enroll participants in clinical trials, which could delay or prevent clinical trials of our product candidates. Identifying and qualifying participants to participate in clinical trials of our product candidates is critical to our and our future partners' success. The timing of our and our future partners clinical trials depends on the speed at which we and our future partners can recruit trial participants to participate in testing our product candidates. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our and our partners' ability to advance the development of our product candidates. If trial participants are unwilling to participate in our or our partners' studies because of negative publicity from adverse events in the clinical trials or other clinical trials of similar product candidates, or those related to a specific therapeutic area, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product candidates, or termination of the clinical studies altogether.

We and our future partners may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete clinical trials of our product candidates in a timely manner. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;

- size of the patient population;
- eligibility criteria for the study in question;
- proximity and availability of clinical trial sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our and our partners' ability to obtain and maintain participant informed consent; and
- the risk that participants enrolled in clinical trials will not complete a clinical trial.

In addition, our and our partners' clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of trial participants available to us and our future partners because some trial participants who might have opted to enroll in our or our partners' clinical trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, we and our future partners will likely conduct some of our or our partners' clinical trials at the same clinical trial sites that some of our and our partners' competitors use, which will reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Moreover, because in some cases our product candidates represent a departure from more traditional methods for disease treatment and prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other new therapies rather than enroll trial participants in any future clinical trial involving patient-specific product candidates. Additionally, if new product candidates, such as gene editing therapies, show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our or our future partners' clinical trials.

A variety of risks associated with conducting research and clinical trials in the United States and other countries outside of Denmark and marketing our product candidates, if approved, by our future partners internationally could materially adversely affect our business.

While clinical trials of EVX-01, our lead product candidate are currently being conducted only in Denmark and Australia, we expect that clinical trials or commercialization of our product candidates, if approved, may take place globally. Accordingly, we expect that we and our future partners will be subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in a particular country and shipping the product candidate to the patient in other countries;
- import and export requirements and restrictions;

- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling in other countries;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Denmark;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in Denmark, Australia and other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as do Denmark and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities in other countries; and
- business interruptions resulting from geopolitical actions, including war and terrorism, such as the recent invation of Ukraine by Russia and the resulting armed conflict as well as for natural disasters and pandemics such as those caused by COVID-19 and variants such as Delta and Omicron.

These and other risks associated with our international operations and our collaborations with our future partners may materially adversely affect our ability to attain or maintain profitable operations.

Interim top-line and preliminary data from studies or trials that we and/or our future partners announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we and/or our future partners may publish interim top-line or preliminary data from pre-clinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We and/or our future partners may also make assumptions, estimations, calculations and conclusions as part of the analyses of data, and we and/or our future partners may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we and/or our future partners report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we and/or our future partners may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including the FDA, the EMA, the TGA and other regulatory agencies, may not accept or agree with our and/or our partners' assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we and/or our future partners choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we and/or our future partners determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we and/or our future partners report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Results of pre-clinical studies and clinical trials of our product candidates may not be predictive of future trial results.

Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier pre-clinical studies or clinical trials. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we and/or our future partners cannot be certain that we and/or our future partners will not face similar setbacks. Even if our or our partners' clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our pre-clinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our EVX-01 cancer immunotherapy product candidate and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in pre-clinical mouse studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. Even if we and/or our future partners are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

Our planned clinical trials or those of our future partners may reveal significant adverse events not seen in our pre-clinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Some of our product candidates may need to be co-administered with other developmental therapies or approved medicines. Such combinations may have additional side effects, which may be difficult to predict in future clinical trials.

If significant adverse events or other side effects are observed in any of our and/or our future partners' current or future clinical trials, we and/or our future partners may have difficulty recruiting trial participants to any of our and/or our partners' clinical trials, trial participants may withdraw from trials, or we and/or our future partners may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, and/or our future partners, the FDA, the EMA, the TGA or other applicable regulatory authorities, ethics committees or an IRB may impose a clinical hold on, or suspend or terminate, clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, an unfavorable benefit-risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

We and/or our future partners may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of our product candidates.

Some of our product candidates may require the use of companion diagnostic tools. If safe and effective use of a biologic product depends on an *in vitro* companion diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an *in vitro* companion diagnostic may be placed on the market only if it conforms to certain "essential requirements" and bears the *Conformité Européenne* Mark, or CE Mark, and the conformity assessment process to obtain the CE Mark can be lengthy.

For our patient-specific immunotherapy candidates, the FDA and similar regulatory authorities outside of the United States such as the EMA or the TGA, may require the development and regulatory approval of a companion diagnostic assay as a condition to approval. The FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional individualized therapeutic candidates. We do not have experience or capabilities in developing or commercializing companion diagnostics and plan to rely in large part on third parties to perform these functions. Companion diagnostic assays are subject to regulation by the FDA and other comparable regulatory authorities in other jurisdictions as medical devices and require separate regulatory approval prior to the use of such diagnostic assays with our therapeutic candidates. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with our therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we and/or our future partners may be unable to identify patients with the specific profile targeted by our product candidates for enrollment in our clinical trials. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability to conduct additional clinical trials or obtain regulatory approval.

The FDA, EMA, TGA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we and/or our future partners may address in the future. For instance, we and/or our future partners may apply our technology to develop therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we and/or our future partners may conduct for our programs. Further, even if we and/or our future partners do achieve the pre-specified criteria, our and/or our partners' trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we and/or our future partners achieve statistically significant results on that endpoint, if we and/or our future partners do not do so on the secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

The FDA, EMA, TGA or other comparable regulatory authorities may disagree with our and/or our future partners' regulatory plan and we and/or our future partners may fail to obtain regulatory approval of our product candidates.

If the results of our and/or our future partners' clinical trials are sufficiently compelling, we and/or our future partners intend to discuss with the FDA, the EMA, the TGA or other regulatory authorities, submission of a BLA, EMAA, AMAA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere, an European Union marketing authorization, an Australian marketing authorization or other regulatory authorization for our product candidates. However, we and/or our future partners do not have any agreement or guidance from the FDA that our and/or our partners' regulatory development plans will be sufficient for submission of a BLA, EMAA, AMAA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere for any of our product candidates. The FDA, EMA, TGA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, EMA, TGA or other regulatory agencies may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA, EMA, TGA or other regulatory agencies that are more accelerated than those available for regular approvals. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, EMA, TGA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our and/or our future partners' clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA, the TGA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we and/or our future partners may be unable to demonstrate to the satisfaction of the FDA, the EMA, the TGA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the TGA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we and/or our future partners may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA, the TGA or comparable regulatory authorities may disagree with our and/or our future partners' interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA, the TGA or comparable regulatory authorities to support the submission of a BLA, EMAA, AMAA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA, the TGA or comparable regulatory authorities will inspect our and/or our future partners manufacturing facilities and may not approve our and/or our partners' facilities; and
- the approval policies or regulations of the FDA, the EMA, the TGA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We and/or our future partners may not be able to file INDs with the FDA, clinical trial applications with the competent authorities of European Union member states, clinical trial applications with the competent authorities in Australia or similar applications with other comparable regulatory authorities to commence additional clinical trials on the timelines we and/or our future partners expect, and even if we and/or our future partners are able to, one or more of these regulatory authorities may not permit us to proceed.

The timing of filing on our product candidates is dependent on further pre-clinical, clinical and manufacturing success. We and/or our future partners cannot be sure that filing of an IND or IND amendment with the FDA, a clinical trial application with the competent authorities of European Union member states, a clinical trial application with the competent authorities in Australia or similar application with other comparable regulatory authorities will result in the FDA, the competent authorities of European Union member states, the competent authorities in Australia or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, no assurance can be given that such regulatory authorities will not change their requirements in the future.

We and/or our future partners may seek orphan drug designation for some or all of our product candidates across various indications, but we and/or our future partners may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We and/or our future partners may seek for orphan drug designation in the United States and other jurisdictions, such as the European Union, where a similar designation may be available for our product candidates. In the United States, under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application, or NDA, or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union and Australia with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we and/or our future partners obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union and Australia with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we and/or our future partners may seek orphan drug designation for our product candidates, we may never receive such designations.

We and/or our future partners may seek breakthrough therapy or fast-track designation for one or more of our product candidates, but we and/or our future partners may not receive such designations. Even if we and/or our future partners do receive such designations, it may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that such product candidates will receive marketing approval.

We and/or our future partners may seek a breakthrough therapy designation in the United States and other jurisdictions, such as the European Union, where a similar designation may be available, for one or more of our product candidates. In the United States, a breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we and/or our future partners believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification, or it may decide that the time period for FDA review or approval will not be shortened.

We and/or our future partners may also seek Fast Track Designation in the United States and/or a Conditional Market Authorization, or CMA, in the European Union for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we and/or our future partners believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, 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 we develop will be regulated as biologics in the United States and elsewhere and therefore they may be subject to competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, 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-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 pre-clinical 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 that is 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 under applicable international regulatory requirements. The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to eventually market any of our product candidates in any other jurisdiction, we and/or our future partners must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional pre-clinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union, Australia and other jurisdictions' regulatory approval processes involve all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we and/or our future partners fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Even if we and/or our future partners receive regulatory approval of our product candidates, we and/or our future partners will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we and/or our future partners fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if we and/or our future partners obtain regulatory approval in a jurisdiction, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

If we and/or our future partners fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our and/or our partners' ability to commercialize any approved products and generate revenues.

If any of our product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval. Product candidates we and/or our future partners may develop may be associated with an adverse immune response or other serious adverse events, undesirable side effects or unexpected characteristics. In addition to serious adverse events or side effects caused by any of our product candidates, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our product candidates could be suspended or terminated.

If in the future, we and/or our future partners are unable to demonstrate that such adverse events were caused by factors other than our product candidates, the FDA, the EMA, the TGA or other regulatory authorities could order us to cease further development of, or deny approval of, any of our product candidates for any or all targeted indications. Even if we and/or our future partners are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we and/or our future partners elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product sale revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our and/or our partners' ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, if we and/or our future partners successfully obtain regulatory approval for a product candidate, the FDA, the EMA, the TGA or other regulatory authority could require us to adopt a REMS or a risk management plan, or RMP, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we, our future partners or others later identify undesirable side effects caused by any product that we and/or our future partners develop based on one or more of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals or revoke licenses of such product;
- regulatory authorities may require additional warnings on the label;
- we and/or our future partners may be required to change the way a product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients and their children; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we and/or our future partners may identify and develop based on one or more of our product candidates and could have a material adverse impact on our business, financial condition, results of operations and prospects.

If we and/or our future partners are successful in gaining approval for any of our product candidates, we and/or our future partners will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA, the EMA, the TGA and other regulatory authorities for compliance with Current Good Manufacturing Practices, or cGMP, and adherence to commitments made in the BLA. If we, our future partners or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we and/or our future partners, as applicable, are not successful in discovering, developing and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop and, through our future partners, potentially commercialize additional product candidates beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own AI technology platforms to engage in drug and target discovery efforts, exploring potential collaborations for the development of new product candidates, and in-licensing delivery technologies. Identifying new product candidates requires substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we and/or our future partners may fail to successfully develop and commercialize such product candidates for many reasons, including the following:

- our AI technology platforms may not successfully identify potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

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

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency has fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, has had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process its regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

If the FDA becomes unable to continue its current level of performance, we and/or our future partners could experience delays and setbacks for our product candidates and for any approvals we and/or our future partners may seek which could adversely affect our business.

Our business, operations and clinical development plans and timelines have been affected by the COVID-19 pandemic and if the pandemic continues our business operations could be adversely affected by the COVID-19 pandemic and other health epidemics or pandemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others.

Our business has been and could be further adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party CMOs, CROs and other third parties upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then COVID-19 has spread worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the United States government ordered the closure of all non-essential businesses, imposed social distancing measures, "shelter-in-place" orders and restrictions on travel between the United States, Europe, Australia and other countries. The global pandemic and government measures taken in response have also had a significant impact on businesses and commerce worldwide, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended across a variety of industries; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance on conducting clinical trials during the pandemic, which was updated in July 2020, January 2021 and August 2021. The guidance describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report (or as a separate document) contingency measures implemented to manage the trial and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic-related trial disruptions by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or trial, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial. In its most recent update to this guidance, the FDA addressed questions received from clinical practitioners who are adapting their operations in a pandemic environment. These questions focused on, among other things, when to suspend, continue or initiate a trial and how to submit changes to protocols for INDs and handle remote site monitoring visits. There is no assurance that this guidance governing clinical trials during the pandemic will remain in effect or, even if it does, that it will help address the risks and challenges enumerated above.

Other potential impacts of the COVID-19 pandemic on our ongoing clinical trial include patient dosing and trial monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trial, interruption or delays in the operations of the FDA, the EMA, the TGA and other similar regulatory agencies, or other reasons related to the COVID-19 pandemic.

If the COVID-19 pandemic continues, other aspects of our ongoing clinical trial and future planned clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, clinical trial site data monitoring and efficacy, safety and translational data collection, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our trials or we may have to pause enrollment or we may choose to or be required to pause enrollment and/or patient dosing in our ongoing or planned clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue. Patients may need to withdraw due to COVID-19 infections or experience increased adverse events and deaths in our clinical trials due to COVID-19 related infections.

In addition, we depend on a global supply chain, including timely shipment of patient specimens and ingredients, to manufacture product candidates used in our pre-clinical studies and clinical trials. Quarantines, “shelter-in-place” and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other epidemics, could impact personnel at third-party manufacturing facilities in the United States, Europe and other countries, or the availability or cost of materials, any of which factors, either individually or collectively, could disrupt our supply chain.

Additionally, it has been widely reported that there has been a global shortage of microchips that has been affecting almost every industry, which has impacted the production of machinery and final products. This shortage could adversely impact our suppliers ability to meet their contractual obligations to provide us with necessary products and materials. If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Replacing or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our business, including our pre-clinical studies and clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, have been and may continue to be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. For example, some patients, may not be able to attend follow-ups and comply with trial protocols. These challenges have and, in the future, may continue to also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

While we have not closed our offices, many of our employees, including members of our executive management, have periodically worked remotely during the COVID-19 pandemic and a number of our employees have contracted COVID-19 requiring them to miss a number of days of work while recovering, which, if either of these situations continue, may adversely affect our business operations.

In the event that government authorities were to enhance current restrictions, our employees who currently are not working from home may no longer be able to access our facilities, including our laboratories and our operations may be further limited or curtailed. An increase in the number of personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. Further, any such enhanced restrictions may also impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. We may also face difficulties in obtaining access to manufacturing slots for our product candidates. For example, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950,

or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

In addition, personnel working from home could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. Further, we and our third-party service providers, including our CROs, the clinical trial sites, our manufacturers and suppliers, may experience staffing shortages as a result of personnel contracting COVID-19 and its variants such as Delta and Omicron.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic has resulted in significant disruption of global financial markets, resulting in an economic downturn that could continue to significantly impact our business and operations and may reduce our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of the ordinary shares and ADSs.

Further, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on employee resources that would otherwise be focused on the conduct of our pre-clinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- refusal of the FDA or other regulatory authorities to accept data from clinical trials in these affected geographies; and
- shipment of patient specimens / biological material across county boarders and nationally.

These and similar, and perhaps more severe, disruptions in our operations could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we continue to monitor the COVID-19 situation closely. Finally, initially, the outbreak of COVID-19 led to steep declines in the Dow Industrial Average and other domestic and international stock indices at the end of February and during March and April 2020. While the markets have rebounded since then, recent concerns over the “Delta variant” and the “Omicron variant” and the impact they may have on the United States and global economies, have led to “risk-off” sessions in the global markets.

The trading prices for our ADS and the shares of other biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic and the trading prices for our ADSs could continue to experience high volatility. As a result, we may face difficulties raising additional capital through sales of our ADSs or any such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the COVID-19 could materially and adversely affect our business and the value of our ADSs.

To the extent the COVID-19 pandemic adversely affects our business, results of operations, cash flows, financial condition and/or prospects, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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

The recent 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. Potential ramifications include disruption of the supply chain including research activities and complications with the conduct of ongoing and future clinical trials of our product candidates, including patient enrollment. We and our collaborators rely on global networks of contract research organizations and clinical trial sites to enroll patients. Delays in research activities or in the conduct of our clinical trials could increase associated costs and, depending upon the duration of any delays, require us to find alternative suppliers at additional expense. In addition, the conflict between Russia and the Ukraine has had significant ramifications on global financial markets, which may adversely impact our ability to raise capital on favorable terms or at all.

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

We and/or our future partners may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we, and/or our future partners or any of the third-party manufacturers we and/or our future partners work with encounter such difficulties, our and/or our future partners' ability to supply materials for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are novel and complex. Specifically, due to the nature of our patient-specific immunotherapies and novel delivery technologies, we and/or our future partners may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and we and/or our future partners may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This may in the future result in our and/or our future partners' having to resupply batches for pre-clinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our and/or our future partners' ability to continue the clinical trial for that product candidate or require us and/or our future partners to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional pre-clinical or clinical supply.

For patient-specific therapies, we and/or our future partners may encounter issues with our and/or our future partners' ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As we and/or our future partners continue developing new manufacturing processes for our drug substances and drug products for infectious diseases, the changes we and/or our future partners implement to manufacturing process may in turn impact specification and stability of our drug products. Changes in our manufacturing processes may lead to failure of lots and this could lead to substantial delays in our clinical trials. Our product candidates for infectious diseases may prove to have a stability profile that leads to a lower than desired shelf life of the final approved immunotherapy. This poses risk in supply requirements, wasted stock and higher cost of goods.

We and/or our future partners may be dependent on a number of equipment providers who are also implementing novel technology. Further, we and/or our future partners may develop custom manufacturing equipment for certain of our product candidates. If such equipment malfunctions or we and/or our future partners encounter unexpected performance issues, we and/or our future partners could encounter delays or interruptions to clinical and commercial supply.

Due to the number of different programs, we and/or our future partners may have cross contamination of products inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our product candidates. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that we and/or our future partners run the risk of contaminating the process each time we and/or our future partners reopen a container to use remaining supplies.

As we and/or our future partners scale the manufacturing output for particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our product candidates from clinical stage studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Due to continuous improvement in manufacturing processes, we and/or our future partners may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as six- or 12-month stability testing. That may require resupplying clinical material or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We and/or our future partners may utilize a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our product candidates. Further, one or more of our programs may have a single source of supply for raw materials and excipients. Additionally, we and our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments, such as recent events in Ukraine and Russia, or other geopolitical uncertainty. If we and/or our our future partners and manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to manufacture our products, or to make our product candidates available for clinical trials could be jeopardized. Any such delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We and/or our future partners may learn that any or all of our product candidates are less stable than desired. We and/or our future partners may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

Certain of our product candidates are uniquely manufactured for each patient and we and/or our future partners may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we, and/or our future partners or any of the third-party manufacturers with whom we and/or our future partners contract encounter these types of difficulties, our and/or our future partners' ability to provide our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we and/or our future partners may be unable to maintain a commercially viable cost structure.

Using our PIONEER AI platform technology, we identify and custom design product candidates that are unique and tailored specifically for each patient. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor;
- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud, to assist with the design of the patient-specific product candidate, which software must be maintained and secured;

- effective design of the patient-specific product candidate;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and
- our reliance on single-source suppliers.

One or more of our future partners may continue to evolve their manufacturing equipment. This equipment may not function as designed, which may lead to deviations in the drug products being produced. This can lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up the manufacturing facilities or build new facilities before our future partners can begin to meet any commercial demand if one or more of our product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

As certain of our product candidates may be manufactured for each individual patient, we and/or our future partners will be required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, analyze results of such patient's genomic analysis, and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Production of our patient-specific product candidates developed using our PIONEER AI platform technology involves a novel micro-batch production process based on a one patient per batch level, which necessarily increases the need for vigilant systems to be employed in order to avoid any such mix-ups We have in the past experienced one case of a product mix-up, which did not result in any adverse effects on the patient. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Our or our future partners' inability to manufacture or have manufactured sufficient quantities of our product candidates, or our or our future partners' failure to comply with applicable regulatory requirements, would materially and adversely affect our business.

Manufacturing is a vital component of our patient-specific immunotherapy approach as well as our bacterial vaccines. All manufacturing must be performed in compliance with cGMP regulations. We expect to rely on external CMOs for the manufacture of our product candidates and at this time, we have limited redundancy among our manufacturing capabilities. For our patient-specific immunotherapies, we and/or our future partners do not maintain product reserves due to the patient-specific nature of our product candidates. If any of our manufacturing facilities or the facilities of our CMOs experiences difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our and/or our future partners'

clinical development programs may be delayed or suspended until we and/or our future partners can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

Our CMOs' facilities are subject to various regulatory requirements and will be subject to inspection by the FDA, EMA or other regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities in other jurisdictions, we and or our future partners may not be able to rely on our CMOs' manufacturing facilities for the manufacture of our product candidates. If the FDA, EMA or another comparable regulatory authority finds our facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we and /or our future partners may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Additionally, we and/or our future partners may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we and/or our future partners were to encounter any of these difficulties, our and/or our future partners' ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

We are, and our future partners shall be subject to regulatory and operational risks associated with the physical and digital infrastructure at both our future partners' internal manufacturing facilities and at those of external service providers.

We may engage CMOs that have facilities with a high level of digitization for clinical manufacturing relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to delay in supply or shutdown of our CMOs or our future partners facilities. Any disruption in our CMOs or our future partners' manufacturing capabilities could cause delays in production capacity for drug substances or drug products, impose additional costs, or may require us to identify, qualify and establish relationships with additional CMOs with alternative manufacturing sites, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As the development and commercial capacity for our or our future partners' product candidates and products expand, we and/or our future partners may need to establish additional manufacturing capabilities and expand to other locations or geographies, which may lead to regulatory delays or prove costly. If we or our future partners fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel, and generally manage our growth effectively, the development and production of our product candidates could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in our infrastructure.

Certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Certain of our product candidates require specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. These suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

Our product candidates are inherently sensitive to shipping and storage conditions and could be subject to risk of loss or damage.

Our product candidates are sensitive to temperature, storage and handling conditions. Loss in product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product and is not fully quantified and is expected to be variable, and it is possible that our product candidates could be lost due to expiration prior to use. This has in the past led and could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or otherwise.

We are subject to significant regulatory oversight with respect to identification and manufacturing our product candidates. We do not have our own manufacturing facilities and relay on third party manufacturers to manufacturer our product candidates. The manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the FDA, the EMA, the TGA and other comparable regulatory authorities could result in significant delays in and costs of our products.

The manufacturing of immunotherapies for clinical trials or commercial sale is subject to extensive regulation. cGMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. We do not have our own manufacturing facilities and rely on third party CMOs to manufacturer our product candidates. The manufacturing facilities of our third-party CMOs or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the FDA, the EMA, the TGA and other comparable regulatory authorities could result in significant delays in and costs of our product candidates.

Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- ineffective process, equipment or analytical change management, resulting in failed lot release criteria;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- failed lot release or facility and utility quality control testing;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

All necessary documentation in support of clinical trials as well as a BLA or other marketing authorization application must be provided on a timely basis and must adhere to the FDA's, the EMA's, the TGA's and other countries' cGMP or other quality assurance requirements which are enforced, in the case of the FDA, in part through its facility inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMPs and manufacturing controls as described in the filing. If one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, approval to initiate clinical trials or to commercialize our product candidates may not be granted. Inspections by

regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product-specific or facility-specific for broader cGMP inspections or as a follow up to development or market issues that the regulatory agency may identify. Deficient inspection outcomes may negatively affect the ability of our third-party CMOs or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying the development of one or more of our product candidates.

The manufacturing process for any products that we may develop is subject to the FDA's, the EMA's, the TGA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who we believe can meet applicable regulatory authority requirements on an ongoing basis. If our third-party CMOs are not able to reliably produce product candidates to specifications acceptable to the FDA, the EMA, the TGA's or other regulatory authorities, we or our future partners may not obtain or maintain the approvals we or they need for our clinical trials or to commercialize such product candidates. Even if our future partners obtain regulatory approval for any of our immunotherapies, there is no assurance that either our CMOs or our future partners will be able to manufacture our product candidates to specifications acceptable to the FDA, EMA, TGA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we may not have direct control over the ability of our CMOs or our future partners to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, our CMOs may be engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities. Our future partners' failure, or the failure of our third-party CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our future partners) and our overall business operations. Our future dependence upon others for the manufacture of our product candidates and raw materials may adversely affect our future profit margins and our ability to conduct our clinical trials and the ability of our future partners to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, EMA, TGA and other regulatory authorities may require our future partners to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, the TGA or other regulatory authorities may require that our future partners do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our third-party CMOs may have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures or product recalls with respect to product produced by either our future partners' own facilities or those of our third-party CMOs could cause us and our future partners to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

Our future partners and our third-party CMOs also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our product candidates and materials, we may not be able to control for or ultimately detect intentional sabotage or negligence by any of our employees, the employees of our future partners or any contractor.

Risks Related to the Commercialization of our Pipeline

We will rely on our future partners to further develop our product candidates in late-stage clinical trials and to commercialize our product candidates if regulatory approval is obtained. The successful commercialization of our product candidates by our future partners will depend in part 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. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our partners' ability to market those products and thereby decrease our ability to generate revenue.

We will rely on our future partners to develop our product candidates in late-stage clinical trials and to commercialize our product candidates if regulatory approval is obtained. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the medicines that we and our future partners hope to develop and sell. In addition, because several of our product candidates represent new approaches to the treatment of cancer, we and/or our future partners cannot accurately estimate how these products would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and in other countries, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, our future partners may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow our future partners to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including genetic medicines. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

Outside the United States, certain countries, including a number of member states of the European Union and Australia, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our partners. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for our future partners, our revenues from sales by our future partners, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union. In the European Union, changes to pricing and reimbursement are almost exclusively a matter for national, and not European Union, law and policy. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, our future partners might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of such product or be subject to price regulations that would delay our partners' commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and in other countries, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the United States government recently released a "blueprint," which is a plan to reduce the cost of drugs. The blueprint contains certain measures that the HHS is already working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that our future partners will experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace.

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 market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling drug products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Our product candidates may face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which drugs developed from our product candidates are designed to be address. We also expect that our product candidates will face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of conditions for which we and our future partners are trying, or may in the future try, to develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products developed using our technologies.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are all currently conducting research in the fields of immuno-oncology and infectious diseases. These companies have significantly greater financial and human resources than we currently have. In addition to these large pharmaceutical companies, we may directly compete with fully integrated biopharmaceutical companies and other immunotherapy-focused oncology companies, as well as a number of companies focused on immunotherapies, some of which have entered into collaboration and funding agreements with larger pharmaceutical or biotechnology companies.

If we successfully develop product candidates, and our future partners obtain approval for them, we and our future partners will face competition based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of any approved immunotherapy;

- reimbursement coverage; and
- intellectual property position.

Our and our partners' competitors may develop or commercialize products with significant advantages over any products we or our future partners develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may therefore be more successful in commercializing their products than our future partners are, which could adversely affect our competitive position and business. Competitive products may make any products our future partners develop using our technologies obsolete or noncompetitive before we and our future partners can recover the expenses of developing and commercializing our products, if approved.

The 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. As the target patient populations for some of our programs are small, 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, for those product candidates that prove to be sufficiently beneficial, if any, 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, and, prior to any such approvals, we and/or 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 projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if for our product candidate, if approved, obtain significant market share, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We do not intend to establish marketing and sales organization and as a company, we have no experience in marketing pharmaceutical products. We will rely on the marketing and sales capabilities of our future partners and other third parties, which may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.

Given our stage of development, we have no sales, distribution or marketing capabilities, and we have not designed our pre-clinical studies and clinical trials with specific commercialization or marketing considerations in mind. We do not intend to establish marketing and sales organization and as a company, we have no experience in marketing pharmaceutical products. We will rely on the marketing and sales capabilities of our future partners and other third parties to commercialize any products that may result from our development programs in the United States, Europe and other regions. We intend to enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into such collaboration agreements on favorable terms, if at all. If our future partners do not commit sufficient resources to commercialize products developed using our technologies, if any, product sales revenue may not be generated in amounts sufficient to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our future profitability, if any, depends in part on our partners' ability to penetrate global markets, where they may be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.

Our future profitability, if any, will depend in part on the ability of our future partners to commercialize any products that our future partners may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our future partners pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability in particular non-United States economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities in other countries;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers;
- foreign currency exchange rate fluctuations;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

Our future partners may have limited experience in these areas. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that our future partners may develop using our technologies, which would limit their commercial potential and our revenues.

Even if our future partners obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community necessary for commercial success.

Even with the requisite approvals, the commercial success of products using our technologies will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and such products in particular, as medically useful, cost-effective and safe. Any product developed using our technologies that our future partners bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical community. Additionally, ethical, social and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, our future partners may not generate significant product sales revenue and may not become profitable, which could adversely affect our business operations and financial condition. The degree of market acceptance of products derived from our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer such products, if approved, at competitive prices;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- relative convenience and ease of administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in pre-clinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our and our partners' efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our and our partners' efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our programs.

Commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of products derived from our product candidates once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of products derived from our product candidates are approved for marketing, we and/or our future partners will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with cGMP and current good clinical practices, or GCP, for any clinical trials that we or our future partners conduct post-approval. In addition, there is always the risk that we or a partner or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with products derived from our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for our future partners to sell products derived from our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which regulatory approval is obtained. In addition, because our product candidates represent new approaches to the treatment of cancer and prevention of infectious diseases, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of products derived from our product candidates. Even if coverage for a given product is obtained, if the resulting reimbursement rates are insufficient, hospitals may not approve the product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use products derived from our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of such products. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which the product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We expect that our future partners will seek approval to market products derived from our product candidates in the United States, the European Union, Australia and other selected jurisdictions. If approval for a product in any particular jurisdiction, our future partners will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe and Australia, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product derived from our product candidates which receives regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products which receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Enacted and future legislation may increase the difficulty and cost for us or our future partners to obtain marketing approval of and commercialize any products derived from our product candidates and affect the prices we may charge for such products.

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 or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the ACA was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the United States pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Since its enactment, there have been and there remain executive, judicial and congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, former President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, former President Trump signed the first Executive Order, directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, former President Trump signed the second Executive Order terminating the cost-sharing subsidies (CSRs), that reimburse insurers under the ACA. On August 14, 2020, the United States Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Payments are expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the United States Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than $12 billion in ACA risk corridor payments that they argued were owed to them. This decision was appealed to the United States Supreme Court, which on April 27, 2020, reversed the decision, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is not clear what effect this result will have on our business, but we will continue to monitor any developments. While Congress has not passed comprehensive repeal legislation to date, it has enacted laws that modify certain provisions of the ACA such as the Tax Cuts and Jobs Act of 2017 (TCJA), which decreased the “individual mandate” to $0. On December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed. On June 17, 2021, the United States Supreme Court dismissed this case. It is unclear how the Supreme Court’s decision will impact the ACA and our business. There is significant uncertainty regarding the future of the ACA and its impact on our business and operations. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless Congress takes additional action. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent United States congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the United States Presidential administration's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the final rule now allows Medicare Advantage plans the option to use step therapy, a type of pre-authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain healthcare facilities. Some of these changes are undergoing legal challenges, and their status is currently in question. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Additionally, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, CMS issued an interim final rule implementing Former President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against the implementation of the interim final rule. Although a number of these executive orders and other proposed measures will require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, we expect that Congress will continue to seek new legislative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs of pharmaceutical and biological products. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug or biologic candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug or biologic candidates for which we obtain marketing approval, if any. Further, increased scrutiny by the United States Congress of the FDA's approval process for drugs and biological products may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. There also are a number of state and local legislative and regulatory efforts related to drug or biologic pricing, including drug or biologic price transparency laws that apply to pharmaceutical manufacturers, that may have an impact on our business.

In addition, the Drug Supply Chain Security Act enacted in 2013 imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and that law is expected to be fully implemented over a ten-year period. Most recently, on December 20, 2019, former 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. 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. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical or biological products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug or biologic candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

We expect that the healthcare reform measures that have been adopted, and that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize products derived from our product candidates. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union member state level may result in significant additional requirements or obstacles that may increase our operating costs.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products derived from our product candidates, this could prevent or delay marketing approval of products derived from our product candidates, restrict or regulate post-approval activities, and affect our or our future partners' ability to commercialize any products derived from our product candidates for which we or they obtain marketing approval.

We expect that additional healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for products derived from our product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates we are developing, change materially and limit payments for such product candidates, our business will be adversely impacted as any products derived from our product candidates may no longer be commercially viable based on their expected net present value; we may have invested significant resources in product candidates that cannot be commercially developed; or we may determine that assets that have reached an early phase of development cannot or will not be taken into further development, notwithstanding their clinical viability. In addition, development assets or clinical programs that are part of our collaborations may no longer be deemed commercially viable to pursue based on our partners' assessments of the impact of any proposed, announced, or legislated pricing reforms

We cannot predict what healthcare reform initiatives may be adopted in the future. Our product candidates from PIONEER may be issued with PD-1 or PD-L1 inhibitors and as a result become too expensive for government, or commercial payors coverage and as a result may reduce our potential market. Further legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from products derived from our product candidates that we may successfully develop and for which we or our future partners may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

European Union drug marketing and reimbursement regulations may materially affect our partners' ability to market and receive coverage for products derived from our product candidates in the European Union member states.

We expect that our future partners will have to seek approval to market products derived from our product candidates in the United States and in other selected jurisdictions. If our future partners obtain approval for products derived from our product candidates in a particular jurisdiction, they will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of products derived from our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of products derived from our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any such product and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. 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. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. 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. In some countries, we and/or our future partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. 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, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our future partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to our Reliance on Third Parties

We will rely on third parties in the conduct of significant aspects of our pre-clinical studies and clinical trials and 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 or fail to meet expected deadlines, regulatory approval for our product candidates may not be obtained.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, future partners, medical institutions and clinical investigators, to conduct various and significant elements of our clinical trials. We currently rely and expect to continue to rely on third parties to conduct certain research and pre-clinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it would delay our discovery or product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our pre-clinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.

Moreover, the FDA requires us to comply with Good Clinical Practice, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our pre-clinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of pre-clinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We also are responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the competent authorities of the member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of cGMP regulations. Our failure or the failure of our CROs or CMOs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design the clinical trials for certain of our product candidates, our future partners may design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will conduct all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future pre-clinical studies and clinical trials will also result in less direct control over the management of data developed through pre-clinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors;
- have human errors; or
- be subject to cyberattacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our pre-clinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform pre-clinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, our future partners may not be able to obtain regulatory approval and commercialize products derived from our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on pre-clinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay the development of our product candidates and/or commercialization of any products derived from our product candidates and could require significantly greater expenditures.

We also expect to rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product sales revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

Our existing collaboration, or any future collaboration arrangements or agreements with future partners, if any, that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop our product candidates and the commercialization of any products derived from our product candidates.

We have entered into a collaboration under which our collaborator may in the future provide funding and other resources for developing our product candidates and potentially commercializing any products derived from our product candidates. We intend to enter into additional collaborations and agreements with future partners, if any, to access additional funding, capabilities and expertise in the future. Our existing collaboration, and any future collaborations or agreements with future partners, if any, we enter into, may pose a number of risks, including the following:

- future partners may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- future partners may not pursue development and commercialization of any products derived from our product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the partners' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- future partners may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- future partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the future partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our future partners as competitive with their own product candidates or products, which may cause future partners to cease to devote resources to the development or commercialization of products derived from our product candidates;
- a partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with future partners, including disagreements over proprietary rights, contract interpretation, or the preferred course of development of any product candidates, may cause delays or termination of the research, development of such product candidates or commercialization of products derived from our product candidates, may lead to additional responsibilities for us with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- future partners may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

- future partners may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the partner and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development of the applicable product candidates or commercialization of products derived from such product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate future partners, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States.

If our collaborations do not result in the successful development of our product candidates or commercialization of products derived from such product candidates, or if one or more of our future partners terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty, or other contingent payments under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop our product candidates. In addition, in general our future partners have the right to terminate their agreements with us for convenience. If one or more of our future partners terminates its agreement with us, we may find it more difficult to attract new future partners and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Form 20-F apply to the activities of our partners.

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our AI platform technologies. If our future partners, if any, are unable to obtain approval for, and effectively commercialize, our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

We believe that the cost and expense of late-stage clinical testing, regulatory approval and commercialization of products for disease indications targeted by our product candidates are beyond the resources of all but the large biopharmaceutical and pharmaceutical companies. Therefore, we intend to develop our product candidates through Phase 2b clinical trials and then enter into partnership arrangements with these large biopharmaceutical and pharmaceutical companies to conduct late-stage clinical trials, regulatory and marketing approval and commercialization of our product candidates. We have not yet entered into any such partnerships and may be unable to do so on economically viable terms, if at all. As a result, late-stage clinical trials as well as pivotal clinical trials for our product candidates have not been commenced and even if such processes are commenced in the near future, it will be several years, if ever, before we or our future partners have a product candidate ready for commercialization. Even if we complete the necessary pre-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and our future partners may not be able to obtain approvals for the commercialization of any product candidates we may develop. Any immunotherapy we may develop, and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, the EMA, the TGA and by comparable global health authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our future partners must demonstrate through extensive pre-clinical studies and clinical trials that our products are safe and effective, including in the target populations. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a NDA to the FDA, a Marketing Authorization Application, or EMAA, to the EMA, a Marketing Authorization Application to the TGA, or AMAA and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent our future partners from commercializing the product candidate in a given jurisdiction. Neither we nor our future partners have received approval to market any of our product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and intend to rely on our future partners to conduct this process. To our knowledge, there is no current precedent for an immunotherapy such as the type we are developing being approved for sale by the FDA, the EMA, the TGA or any other regulatory agency elsewhere in the world. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we or our future partners develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union, Australia and elsewhere, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, the EMA, the TGA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional pre-clinical, clinical or other trials. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or our future partners, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays, or non-approval if an FDA panel of experts, referred to as an Advisory Committee, or the EMA, the TGA or other regulatory authority recommends non-approval or restrictions on approval. In addition, we and our future partners may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process.

Regulatory agencies also may approve an immunotherapy for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

The FDA, the EMA, the TGA and other regulatory agencies review the Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization.

In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, NDA, EMAA, AMAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential product candidate.

If our future partners experience delays in obtaining, or if they fail to obtain, approval of any product candidates we may develop, the commercial prospects for those product candidates will be harmed, and our ability to generate revenues from our collaboration agreements will be materially impaired. Additionally, even if our future partners are successful in obtaining marketing approval for product candidates, because our pre-clinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and our ability to generate revenues could be materially impaired.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research and development plans.

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with future partners will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate partners. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA, the EMA, the TGA or similar regulatory authorities outside the United States, Europe and Australia, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future partners may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential partners. Similarly, our collaboration agreements may contain non-competition provisions that could limit our ability to enter into collaborations with future partners.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

We have entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and we may not realize the benefits of such licensing arrangements.

We may obtain licenses that give us rights to third-party intellectual property, including patents and patent applications that are necessary or useful for our business. In particular, we have entered into license agreements with Statens Serum Institut, or SSI, and PharmaJet, Inc. or PharmaJet to obtain licenses for intellectual property useful in pharmaceutical formulations and delivery devices. We may enter into additional licenses to third-party intellectual property in the future.

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute any patent applications we may license. Even if patents were issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we may sublicense our rights under various third-party licenses to our partners. Any impairment of these sublicensed rights could result in reduced revenues under our collaboration agreements or result in termination of an agreement by one or more of our partners.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- our diligence obligations with respect to the use of the licensed intellectual property and technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions, trade secrets, know-how and other intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have in-licensed or other related contractual rights prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop our product candidates and the commercialization of any products derived from such product candidates may be adversely affected.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, our co-owners or our licensors fail to adequately protect, defend, maintain or enforce this intellectual property, our ability to commercialize products could suffer.

We rely on third parties to manufacture certain of our clinical product supplies, and we will rely on third parties to produce and process our product candidates, if approved.

We rely on outside vendors to manufacture supplies and process our product candidates. None of our product candidates have been manufactured or processed on a late-stage clinical trial or commercial scale and our third party CMOs and our future partners may not be able to achieve late-stage clinical trial or commercial-scale manufacturing and processing and may be unable to create an inventory of mass-produced product to satisfy demands for our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the availability of our product candidates in sufficient quantities to conduct our clinical trials or the commercial viability of any products derived from our product candidates. As a result, we and/or our future partners may never be able to develop a commercially viable product.

In addition, our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, the EMA, the TGA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates or any products derived from our product candidates after receipt of regulatory authority questions, if any;
- our third-party CMOs might not be able to timely formulate and manufacture our product candidates or any products derived from our product candidates or produce the quantity and quality required to meet our and our partners' clinical and commercial needs, if any;
- CMOs may not be able to execute our manufacturing procedures appropriately;
- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates or any products derived from our product candidates;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the United States Drug Enforcement Administration, or the DEA, and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over third-party CMOs or our future partners compliance with these regulations and standards;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party CMOs in the manufacturing process for our products;

- our third-party CMOs could breach or terminate their agreement with us; and

- our third-party CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates or any products derived from our product candidates by the FDA, the EMA, the TGA or regulatory authorities in other jurisdictions or the commercialization of our product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our product candidates or any products derived from our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We and/or our future partners may, in the future, be dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our product candidates.

We and/or our future partners may, in the future, be dependent on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our product candidates. We cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our or our future partners use of single-source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or our future partners commercial sale of any products derived from our product candidates. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we intend to maintain adequate inventory of the single source components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

In addition, as part of the FDA's approval of our product candidates, FDA review of the individual components of our process, which include the manufacturing processes and facilities of our single-source suppliers will also be required.

Our reliance on these suppliers, service providers and manufacturers may subject us to a number of risks that could harm our reputation, business and financial condition, including, among other things:

- delays to the development timelines for our product candidates;

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;

- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;

- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers' prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our and/or our partners' ability to meet demand for our product candidates or any products derived from our product candidates could be adversely affected.

Risks Related to Our Intellectual Property

If our 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.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our product candidates, proprietary technologies and their uses, as well as our and our partners' ability to operate, develop, manufacture and commercialize our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States, and Europe as well as in other countries related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. 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 such applications unless, and until, patents issue from such applications, and then only 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 United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in Europe and in other jurisdictions, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our product candidates or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to obtain patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings before various patent offices or in courts in the United States, Europe or other jurisdictions. The degree of future protection for our intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our technologies or permit us to gain or keep any competitive advantage. 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 have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or future partners will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our product candidates, proprietary technologies (including methods of manufacture) and their uses. These risks and uncertainties include, from time to time, the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, sell, import or otherwise exploit our product candidates or other technologies;

- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;

- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the economically feasible development and exploitation of our product candidates and other technologies or the economically successful commercialization of any product candidates and other technologies that we may develop;

- because patent applications in the United States, Europe and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and 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 partes 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;

- there may be significant pressure on the United States government, European government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States and Europe for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- United States government, European government and other international governments, may receive compulsory licensing wherein patents are required to be made available to third parties at reduce rates; and

- 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.

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 standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the Congress of the United States and in international jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as United States laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights. However, while certain incentives such as natural occurring products are not patentable in the United States, such inventions may be patentable in other jurisdictions, including Europe.

Furthermore, the patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. 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 output, such as our employees, corporate future partners, outside scientific future partners, CROs, CMOs, consultants, advisors and other third parties, 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. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. 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. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned 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. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. 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 degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own product candidates or any products derived from our product candidates, but that are not covered by the claims of the patents that we own or license;
- our future partners will be able to successfully commercialize products derived from our product candidates on a substantial scale, if approved, before the relevant patents that we own, or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the patents we own, or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own, or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or

- our development and commercialization activities of our future partners, including manufacturing processes, or products derived from our product candidates will not infringe upon the patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing our product candidates and other technologies, and may prevent our future partners from commercializing any products derived from our product candidates.

Our business involves new and evolving scientific fields, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the fields. We own and in-license patent applications and issued patents that describe and/or claim certain technologies, including products, reagents, formulations and methods including uses and manufacturing methods, or features or aspects of any of these. These issued patents and pending patent applications claim certain compositions of matter and methods relating to the discovery, development, manufacture and commercialization of therapeutic modalities and our delivery technologies, including LNPs. If we, our co-owners, our licensors, including our future partners, are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our product candidates and other technology and any product candidates and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

As the scientific fields mature, our known competitors and other third parties have filed, and will continue to file, patent applications claiming inventions in the field in the United States and in other countries. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

We, our co-owners or our licensors, including our future partners, may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. The Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, included a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. We expect that our competitors and other third parties may institute litigation and other proceedings, such as interference, reexamination and opposition proceedings, as well as *inter partes* and post-grant review proceedings against us and the patents and patent applications that we own and in-license. We expect that we may be subject to similar proceedings or priority disputes, including oppositions, in Europe or other foreign jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners or our licensors, including our future partners, are unsuccessful in any interference proceedings or other priority or validity disputes, including any derivations, post-grant review, *inter partes* review or oppositions, to which we or they are subject, we may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or our owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material adverse impact on our business and our ability to successfully compete against our current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that we or our future partners may need for our product candidates or any products derived from our product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, there may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we or our future partners may need such patents for the development, manufacturing and commercialization of our product candidates or any products derived from our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant us a license to such patent rights on reasonable terms or a court rules that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we or our future partners may need to cease the development, manufacture and commercialization of one or more of the product candidates or any products derived from our product candidates we or our future partners may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

We may not be successful in obtaining, maintaining, protecting or defending the necessary intellectual property rights to allow us to identify and develop product candidates, product components and manufacturing processes for our development pipeline.

We currently have rights to certain intellectual property, through our owned and in-licensed patents and other intellectual property rights, relating to identification and development of our product candidates or other technologies. As our pipeline may involve additional product candidates that could require the use of intellectual property and other proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. We may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, on reasonable terms, or at all, for product candidates and other technologies that we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we have in the past and may continue to collaborate with academic institutions in certain aspects of our pre-clinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain, or continue to maintain, exclusive rights to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or enforce the existing intellectual property rights we have, we may have to abandon the development of the relevant program or product candidate and our future partners may have to abandon the commercialization of any products derived from our product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most foreign jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patient's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may be reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product candidates, and we expect to enter into similar license agreements in the future. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Our licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of our licenses.

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution of our in-licensed intellectual property is controlled solely by the licensor. We may also require the cooperation of our licensors and future partners to enforce or defend any in-licensed patent rights, and such cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our partners. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual property could give the licensor the right to terminate the license. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize the product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this section. If we, our co-owners or our licensors, including our future partners, fail to adequately protect this intellectual property, our and our future partners ability to develop our product candidates, as well as the economic feasibility and our partners' ability to develop, market and commercialize any products derived from our product candidates, could suffer. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop our product candidates, and our future partners may not be able to successfully market and commercialize any products derived from our product candidates, which could have a material adverse effect on our business, financial condition, results of operations 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.

Composition of matter patent protection is generally considered to be desirable because it provides protection without regard to any particular method of use or manufacture or formulation. While we have obtained patent protection covering components of certain product candidates, manufacturing-related methods, formulations and/or methods of use and claims issued that are directed to a vaccine formulation containing a broadly defined protein antigen, we do not currently have any claims in our owned or in-licensed issued United States or European patents that cover the overall construct used in our product candidates, and we cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition of matter of our current or future product candidates.

Method of use patents protect the use of a product for the specified method and formulation patents cover formulations to deliver therapeutics. These types of patents do not prevent a competitor or other third party from developing, marketing or commercializing a similar or identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method of use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and this type of infringement is difficult to prevent or enforce. Consequently, we may not be able to prevent third parties from practicing our inventions in the United States or other countries.

Moreover, competitors or other third parties may in their commercial activities rely on secret know-how, including reliance on secret technologies. Such secret technologies may include manufacturing processes, intermediary products, manufacturing tools etc., the existence and utility of which is by nature not known to the public and for which we at a later stage may therefore seek patent protection and obtain valid patents. Such competitors and third parties could, if they can document their prior secret use of the patented technologies, have acquired prior user rights under applicable national laws, including in the United States the defense to patent infringement defined in 35 U.S.C. §273, that protect such competitors and third parties from claims of patent infringement raised by us. Under such circumstances, we might not be able to adequately prevent such a competitor or third party from commercially exploiting our patented technology in the United States or in other countries.

Intellectual property rights of third parties could adversely affect our partners' ability to commercialize any products derive from our product candidates, and we and/or our future partners might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Because our product candidates are still in early developmental stages, and one or more features of the product candidates or related technologies such as their manufacture, formulation or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while United States patent laws provide a "safe harbor" to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when a BLA or NDA is submitted. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit a BLA or NDA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued patent claims that cover our products or critical features of their production or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

It is also possible that we have failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of our platforms or product candidates. Given that, in most jurisdictions, a patent application is confidential when initially filed, and typically remains so until it is published about 18 months after the initial filing, it may not be possible for us to identify certain relevant filings in time to avoid using the technology that they claim. Additionally, the claims of pending patent applications and divisional continuation applications filed at a late stage can, subject to certain limitations, be amended over time, so that even patent applications whose claims did not cover our products or activities when published could be amended to cover one or more aspects of our platforms or product candidates over time, and we might not be aware that such amendment had been made.

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, each of which could be expensive, time consuming and unsuccessful.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding European and other non-United States patent offices. Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we may institute *inter partes* review proceedings against issued United States patents and opposition proceedings against European patents owned by third parties in the field of immunotherapy. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned, or in-licensed patents may be challenged and a court may decide that a patent we own, or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future partners were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-United States patent offices and may result in the revocation, cancellation or amendment of any ex-United States patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, ranging from our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use, development, manufacture or commercialization of our product candidates. As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same intellectual property and technology. Our defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing collaborations that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborations provide, and we expect additional collaborations to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our future partners to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, we have agreed, and may in the future agree, to indemnify certain third parties for certain costs incurred in connection with litigation relating to intellectual property rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any litigation or other intellectual property proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the ADSs.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees and we may employ outside firms and rely on our outside counsel to pay these fees due to non-United States patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-United States governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts and the USPTO, and their equivalents in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to obtain, maintain, protect, defend or enforce our intellectual property in the future.

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

In addition to seeking patent protection for some of our technology and product candidates, we also seek to rely on trade secret protection and confidentiality agreements to maintain our competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets and know-how may be difficult to protect.

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate future partners, outside scientific future partners, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our best efforts, any of these parties may breach the agreements and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Claims that we, our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may, in the future, be subject to claims that current or former employees, consultants, independent contractors, future partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, future partners and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants, independent contractors, future partners or other third parties who are involved in developing and commercializing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Furthermore, the laws of some countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the laws of the United States. A majority of our employees work in Denmark and are subject to Danish employment law. Employees' inventions that are either patentable or registrable as Danish utility models are subject to the provisions of the Danish Act on Employee Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act. Such disputes may be costly to defend and may take up our management's time and efforts regardless of whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who have assigned the rights to inventions to us may be deemed to be insufficient and we may under Danish law be required to increase the compensation due to such employees for the assignment of rights to such inventions. In those cases where rights to employees' inventions have not been assigned to us, we may need to agree with the respective employees on the assignment of such inventions, including i.e. by paying a suitable compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the Danish Act on Employee Inventions, our business, results of operations and financial condition could be adversely affected.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in Denmark and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and to the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, marketing and commercialization of competing products in violation of our intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names, as well as any trademarks or service marks that we may register, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential future partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 our competitive advantage. For example:

- others may be able to make patient-specific cancer immunotherapies and infectious disease products or product candidates that are similar to any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future partners might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We and our future partners or other contractors or consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Our internal computer systems and those of our current and any future partners, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, pandemics, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of pre-clinical data and/or clinical trial data from one or more ongoing or completed pre-clinical projects or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach to running multiple projects in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the GDPR and relevant member state law in the European Union, and the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and other relevant state and federal privacy laws in the United States. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, however, 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 adversely affect our business, results of operations and financial condition.

Risks Related to Government Regulation

Even if our future partners obtain regulatory approval for a product derived from one of our product candidates, such products will remain subject to regulatory scrutiny.

If a product derived from one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

BLA and NDA holders, as well as manufacturers of drug and biologics facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we, our partner and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Our future partners will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, our future partners may not promote our products "off-label" for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. Our future partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us and/or our future partners to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our partners' ability to commercialize and generate revenue from any products derived from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA, the EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any products derived from our product candidates. 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, Europe or other countries. For example, certain policies of the current United States administration may impact our business and industry. Namely, the current United States administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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 may have obtained and we may not achieve or sustain profitability.

We and our future partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If we and/or our future partners are unable to comply, or have not fully complied, with such laws, we and/or our future partners could face substantial penalties.

We and/or our future partners may be subject to additional healthcare regulation and enforcement by the United States federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business. If our future partners obtain FDA approval for any products derived from our product candidates and begin commercializing those products in the United States, our operations may be indirectly through our future partners and their prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- The federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;

- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;

- The United States Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- The United States Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- State law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances;

- The U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, United States companies and their employees and agents, as well as non-United States companies registered with the SEC from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and

- Similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Due to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as "trade laws", prohibit companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other future partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or future partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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 receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data. We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, storage, retention, protection, disclosure, transfer and other processing of personal data, collectively referred to as "data processing", in the different jurisdictions in which we operate, including comprehensive regulatory systems in the United States and Europe. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with United States and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with United States, European and other international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

Various states in the United States, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of patient health information and other personal information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA, which became effective on January 1, 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation (described below). The CCPA establishes a new privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. An initiative called the California Privacy Rights Act, or CCPA 2.0, passed in November 2020 and builds upon and amends the original CCPA aligning it more closely with the GDPR. CCPA 2.0 expands the privacy rights of California residents and could impact our operations or that of our partners. Other states have been considering legislation similar to the CCPA, and several federal privacy proposals are under consideration in the current session of Congress.

The collection and use of personal health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the European Union General Data Protection Regulation, or GDPR. While the Data Protection Directive did not apply to organizations based outside the European Union, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, some of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks. Additionally, on July 16, 2020, the Court of Justice of the European Union, or the CJEU, issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision calls into question certain data transfer mechanisms as between the European Union member states and the United States. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on the data exporters (transferring the data out of the European Union) as well as the data importers (the recipient of the data in the United States) to assess United States national security laws on their business and future actions of European Union data protection authorities are difficult to predict at the early date. Consequently, there is some risk of any such data transfers from the European Union being halted. Any contractual arrangements requiring the transfer of personal data from the European Union to us in the United States will require greater scrutiny and assessments as required under *Schrems II* and may have an adverse impact on cross-border transfers of personal data, or increase costs of compliance.

Since we are located in the European Union, we are subject to the GDPR. GDPR regulations have imposed additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, depending on the jurisdiction, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with the GDPR, especially with regard to clinical trial conduct. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects. If we fail to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which in a worst-case scenario can result in monetary penalties of up to $20,000,000 or up to 4% of the total worldwide annual revenue of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In the United States, notice of breaches must be made to affected individuals and the United States Secretary of HHS, and for extensive breaches, notice may need to be made to the media or state Attorneys General. Such a notice could harm our reputation and our ability to compete. HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, state Attorneys General are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

If we, our future partners or our third-party suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our future partners 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 and the operations of our future partners will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations and the operations of our future partners also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and the operations of our future partners and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If any of the physicians or other providers or entities with whom we expect to do business were found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

General Risks Related to our Business

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified executive management and scientific personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with capabilities and expertise in immuno-oncology and infectious diseases. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in pre-clinical studies or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our current or future product candidates.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if any products derived from our product candidates are commercialized. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to patients, healthy volunteers or their children;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of the status of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when any products derived from our product candidates obtain regulatory approval, we intend to expand our insurance coverage; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADSs to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our products become subject to a product recall it could harm our reputation, business and financial results.

The FDA, the EMA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot of other quantity of the biologic product presents an imminent or substantial hazard to the public health. For products developed using our AI platform technologies, a product recall may prevent other products derived from one or more of our product candidates using our AI platform technologies that target the same disease indication until we can demonstrate that the reason for any such product recall did not involve our technology. In addition, some governmental bodies outside the United States have the authority to require the recall of any product derived from one or more of our product candidates in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

If we engage in future acquisitions, joint ventures, partnerships or collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may not realize the benefits of these acquisitions, joint ventures or collaborations.

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition, joint venture, partnerships or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We may be adversely affected by global climate change or by legal, regulatory or market responses to such change.

Increasing stakeholder environmental, social and governance, or ESG, expectations, physical and transition risks associated with climate change, and emerging ESG regulation and policy requirements may pose risk to our market outlook, brand and reputation, financial outlook, cost of capital, global supply chain and production continuity, which may impact our ability to achieve our business objectives. Changes in environmental and climate change laws or regulations could lead to additional operational restrictions and compliance requirements upon us or our third -party providers or otherwise could negatively impact our business Physical impacts of climate change may drive increased costs to us and our suppliers and impact our continuity and data facilities.

Risks Related to Ownership of the ADSs

The price of the ADSs has been and may continue to be highly volatile and fluctuate substantially, which could result in substantial losses for purchasers of the ADSs who may not be able to resell the ADSs at or above the price they paid.

Since the closing of our IPO in February 2021 and our follow-on offering in November 2021, the market price of the ADSs has been and may continue to be highly volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, ADS holders may not be able to resell the ADSs at or above the price they paid for our ADSs. The market price for the ADSs may be influenced by many factors, including, but not limited to:

- results of our pre-clinical development and clinical trials of our product candidates or those of our competitors;

- the success of existing competitive products or technologies or new competitive products or technologies that may emerge;
- announcements by us or our competitors of commencement or termination of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- issuances or sales of our ordinary shares or ADSs by us, our insiders or our other shareholders or holders of the ADSs;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial condition, operating results, development timelines or issuance of new or updated research, reports or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcement or expectation of additional debt or equity financing efforts;
- currency fluctuations;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including the disruption in the financial markets caused by the COVID-19 pandemic; and
- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of the ADSs could decline substantially. Furthermore, any such fluctuations in our results may, in turn, cause the price of the ADSs to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm 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 shareholder 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 have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has been and will continue to be required to devote substantial time to compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act, which could result in sanctions or other penalties that would harm the business.

As a public company, and particularly after we are no longer an "emerging growth company" as defined in the JOBS Act, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, since becoming a public company as a result of our IPO in February 2021, the federal securities laws, including the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on our company, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report in connection with issuing our annual financial statements as of and for the year ending December 31, 2021 by our management on our internal control over financial reporting, and may be required to provide the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our annual filings with the SEC. To achieve compliance with Section 404 within the prescribed period, we have been and will continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the last day of the fiscal year following the fifth anniversary of the closing of our IPO in February 2021 (December 31, 2026). We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives.

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 earlier of:

- the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion;
- the date on which we have issued more than $1 billion in nonconvertible debt securities during the previous three years;

- the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity held by non-affiliates exceeds $700 million; and

- the last day of the fiscal year following the fifth anniversary of the closing of our IPO (December 31, 2026).

- For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Form 20-F. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find the ADSs less attractive if we rely on certain or all of these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price per ADS may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Such provisions are only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

As a "foreign private issuer," we are exempt from a number of rules under the United States securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than are domestic United States issuers. This 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. As a result, in accordance with the listing requirements of The Nasdaq Capital Market, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of The Nasdaq Capital Market. For instance, the Listing Rules for The Nasdaq Stock Market, or The Nasdaq Listing Rules, for domestic United States issuers require listed companies to have, among other things, a majority of their board members be independent, and to have independent director oversight of executive compensation, nomination of board members and corporate governance matters. As a foreign private issuer, however, while we intend to comply with these requirements, we are permitted to follow home country practice in lieu of the above requirements. Danish law does not require that a majority of our board consist of independent directors or the implementation of a remuneration committee or nominating and corporate governance committee, and our board may thus in the future not include, or include fewer, independent directors than would be required if we were subject to The Nasdaq Listing Rules, or they may decide that it is in our interest not to have a remuneration committee or nominating and corporate governance committee, or have such committees governed by practices that would not comply with Nasdaq Listing Rules. Since a majority of our board of directors may not consist of independent directors if we decide to rely on the foreign private issuer exemption to The Nasdaq Listing Rules, our board's approach may, therefore, be different from that of a board with a majority of independent directors, and as a result, the management oversight of our company could, in the future, be more limited than if we were subject to the Nasdaq Listing Rules. We intend to follow home country practice with regard to, among other things, quorum requirements generally applicable to general meetings of shareholders.

Furthermore, Danish law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in Denmark, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b).

Due to the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States, some investors may find the ADSs less attractive as a result, and there may be a less active trading market for the ADSs.

We qualify as a foreign private issuer and, as a result, we will not be subject to United States proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a United States domestic public company.

We report under the Exchange Act, as a non-United States company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Danish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to United States domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while United States domestic issuers depending on their size are required to file their annual report on Form 10-K within 60 or 90 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our shareholders and the holders of the ADSs may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

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

We have adopted and presented our financial statements in accordance with IFRS as issued by the IASB. IFRS is an internationally recognized body of accounting principles that are used by many companies outside of the United States to prepare their financial statements; and the SEC recently permitted foreign private issuers such as our company to prepare and file their financial statements in accordance with IFRS rather than U.S. GAAP. IFRS accounting principles are different from those of U.S. GAAP, and SEC rules do not require us to provide a reconciliation of IFRS accounting principles to those of U.S. GAAP. Persons who are not familiar with IFRS may misunderstand certain information presented in our financial statements. Accordingly, we suggest that readers of our financial statements familiarize themselves with the provisions of IFRS accounting principles in order to better understand the differences between these two sets of principles.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We qualify as a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to United States domestic issuers. If we cease to be a foreign private issuer, which is measured as of the end of our second fiscal quarter in each fiscal year after the completion of our IPO, we will be required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to United States domestic issuers as of January 1 of the following year. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive management or directors may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to United States domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under United States securities laws if we are required to comply with the reporting requirements applicable to a United States domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to United States domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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, or ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of the ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to a holder's right to cancel the ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of the ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, holders of ADSs may not be able to cancel the ADSs and withdraw the underlying ordinary shares when such holder owes 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 ordinary shares or other deposited securities. See "Item 12D. Description of Securities Other than Equity Securities."

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 23,203,828 ordinary shares outstanding as of December 31, 2021.

On April 6, 2021, we filed a registration statement on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, to register a total of 4,808,076 ordinary shares, representing all ordinary shares issued or issuable under our equity incentive scheme pursuant to the Appendices to our Articles of Association. Such Form S-8 registration statement automatically became effective upon filing. Accordingly, shares registered under such registration statement are available for sale in the open market following the expiration of the applicable lock-up period.

As of December 31 2021, there were 2,732,618 warrants outstanding. If these warrants are exercised then an additional 2,732,618 ordinary shares 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. In addition, as of December 31, 2021, there were 351,036 warrants issued to EIB under the loan agreement with EIB, which are expected to be cash settled. For a more detailed description of the EIB warrants see the section herein entitled “Our EIB warrants.”

Additionally, on November 28, 2021, we entered into a Share Sale and Restriction Agreement with, Dr. Lars Staal Wegner, our Chief Executive Officer, Dr. Niels Iversen Møller our Co-Founder, Chief Business Officer and interim Chief Financial Officer and Andreas Mattsson, our Co-Founder and Chief Innovation Officer, pursuant to which Dr. Wegner agreed to exercise 211,849 warrants in each of the two week exercise windows established under our Articles of Association that are expected to open two trading days following publication of our annual report and interim quarterly financial reports in March 2022, May 2022, August 2022 and November 2022, respectively.

Under the terms of this agreement, Dr. Wegner, Dr. Møller and Mr. Mattson further agreed with us that in the corresponding open trading window related to each such exercise consisting of the four-week period commencing on the third full trading day after the date of publication of our annual report or interim financial reports in March 2022, May 2022, August 2022 and November 2022, each a Trading Window, Dr. Wegner would sell such Ordinary Shares and Dr. Møller and Mr. Mattson will purchase such ordinary shares, with each of Dr. Møller and Mr. Mattson purchasing fifty per cent (50%) of such shares, at a purchase price per share equal to the Volume Weighted Average Price, or VWAP, of our ADSs at the close of the market on the date of exercise as reported on Nasdaq.

Under the terms of the agreement, Dr. Møller and Mr. Mattson agreed that during each Trading Window each of them will sell 328,731 ADSs representing Ordinary Shares at a price equal to the prevailing market price thereof on the date of such sale as reported on Nasdaq. Furthermore, pursuant the terms of the agreement, Dr. Møller and Mr. Mattson are required to sell such shares and are prohibited from exercising any subsequent influence over how, when, or whether to effect the trade(s).

Sales of ADSs or our ordinary shares as restrictions end or pursuant to the above described agreement 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.

Holders of the ADSs are not treated as shareholders of our company and will not have the same voting rights as our shareholders, which may affect the value of the ADSs.

Holders of ADSs are not treated as our shareholders unless they withdraw the ordinary shares underlying the ADSs from the depositary, which is the holder of the ordinary shares underlying the ADSs. Holders of ADSs, therefore, do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement. As such, holders of ADSs will not be able to directly vote underlying ordinary shares. Holders of ADSs may instruct the depositary how to vote the ordinary shares underlying their ADSs. If we ask it to, the depositary will send out information about shareholder meetings and solicit voting instructions and will try to carry out voting instructions it receives. However, we are not required to instruct the depositary to take

action with respect to shareholder meetings. If we do not do so, holders of the ADSs can still send voting instructions to the depositary and the depositary may try to carry out those instructions, but it is not required to do so. Holders of the ADSs may not become aware of shareholder meetings if the depositary does not send out information. Even if the depositary does solicit voting instructions, holders of ADSs may not receive the information in time. As a result of these factors, holders of ADSs may not be able to effectively exercise voting rights that they would have if they held our ordinary shares directly.

If we issue new ordinary shares or sell ADSs in future financings, holders of ADSs may experience immediate dilution and, as a result, the price of the ADSs may decline.

We may from time-to-time issue additional ordinary shares or sell ADSs at a discount from the current trading price of our ordinary shares or ADSs. As a result, holders of ADSs could experience further immediate dilution upon the issuance of any ordinary shares or ADSs sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, ordinary shares or ADSs. If we issue ordinary shares or securities convertible or exchangeable into ordinary shares, such as ADSs, holders of the ADSs could experience additional dilution and, as a result, the price of the ADSs may decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, our existing shareholders' ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect our existing shareholders' rights as a holder of ADSs. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as imitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Investors should be aware that the rights provided to our shareholders under Danish corporate law and our articles of association differ in certain respects from the rights that you would typically enjoy as a shareholder of a United States company under applicable United States federal and state laws.

Under Danish corporate law, except in certain limited circumstances (which require as a minimum that a proposal for inspection has been supported by a minimum of 25% of the shareholders voting and being present at a general meeting), our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of such shareholder's shareholdings, may do so. Shareholders of a Danish limited liability company are also unable to initiate a derivative action, a remedy typically available to shareholders of United States companies, in order to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of director/management liability under limited circumstances. In addition, a majority of our shareholders may release a director or manager from any claim of liability we may have, including if such director or manager has acted in bad faith, negligently or fraudulently. However, a shareholder may bring a derivative action on behalf of our company against, among other persons, a director or manager, provided that the circumstances of the act or omission giving rise to the claim of liability was not known to the shareholder at the time of such shareholder resolution, or if shareholders representing at least 10% of the share capital represented at the relevant general meeting have opposed such shareholder resolution. In contrast, most United States federal and state laws prohibit a company or its shareholders from releasing a director from liability altogether if such director has acted in bad faith or has breached such director's duty of loyalty to our company. Additionally, distribution of dividends from Danish companies to foreign companies and individuals can be eligible for non-refundable withholding tax, and not all receiving countries allow for deduction. Also, the rights as a creditor may not be as strong under Danish insolvency law, as under United States law or other insolvency law, and consequently creditors may recover less in the event our company is subject to insolvency compared to a similar case including a United States debtor. In addition, the use of the tax asset consisting of the accumulated tax deficit requires that we are able to generate positive taxable income and can be restricted by future amendments to Danish tax law. Finally, Danish corporate law may not provide appraisal rights in the case of a business combination equivalent to those generally afforded a shareholder of a United States company under applicable United States laws. As a result of these differences between Danish corporate law and our articles of association, on the one hand, and United States federal and state laws, on the other hand, in certain instances, holders of the ADSs could receive less protection as an shareholder of our company than such holders would as a shareholder of a United States company.

Holders of our ordinary shares or ADSs may not be able to exercise their pre-emptive subscription rights and may suffer dilution of their shareholding in the event of future issuances of our ordinary shares.

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 disapplied 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 at market value as well as by way of incorporation of available reserves (including premium). 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 bonds 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 depositary 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 on our ordinary shares represented by the ADSs or any value for them.

If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case ADS holders will receive no value for these rights.

United States holders of ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

A non-United States corporation will be classified as a passive foreign investment company, or PFIC, for United States 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 or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-United States corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, more than 25% (by value) of the stock. We do not believe we were a PFIC for United States federal income tax purposes for the taxable year ended December 31, 2021. PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, and therefore, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the applicable taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status for the taxable year ending December 31, 2022 and in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year. If we were to be or become a PFIC for any taxable year during which a United States holder (defined below in "Taxation – Certain Material United States Federal Income Tax Considerations") holds ADSs, certain adverse United States federal income tax consequences could apply to such United States holder. 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 ordinary unlisted shares for Danish tax purposes. However, recent communications from the Danish tax authorities indicate that a holder of ADSs may not be treated as holding unlisted shares in the company for Danish tax purposes. In the event that the holders of ADSs are not treated as holding unlisted shares in the company, it is likely that they will be treated as either holding listed 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 from the Danish tax authorities indicate if the holders of ADS are not treated 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. Substantially all of our assets are located outside the United States. A number of our directors and the majority of our officers and employees reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States.

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 the lack of a treaty as described above, United States investors may not be able to enforce against us or members of our board of directors, our executive board, our executive management or certain experts named herein who are residents of Denmark or countries other than the United States any judgments obtained in United States courts in civil and commercial matters, including judgments under the United States federal securities laws.

We may fail to meet our publicly announced guidance or other expectations about our business, which could cause the market value of our ADSs to decline significantly.

We may provide from time to time guidance regarding our expected financial and business performance. Correctly identifying key factors affecting business conditions and predicting future events is inherently an uncertain process, and our guidance may not ultimately be accurate in all respects. Our guidance is based on certain assumptions, such as those relating to anticipated production and sales volumes, average sales prices, supplier and commodity costs, and planned cost reductions. If our guidance varies from actual results, the market value of the ADSs could decline significantly.

If securities 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 the ADSs will rely, in part, on the research and reports that securities or industry analysts publish about us or our business. If no or only limited securities or industry analysts cover our company, the trading price for the ADSs would be negatively impacted. If any of the analysts who cover us downgrades our equity securities or issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, the market price of the ADSs would likely decline. If one or more of these analysts cease to cover the ADSs, or downgrades our securities, we could lose visibility in the market for the ADSs, which in turn could cause the market price of the ADSs to decline or their trading volume to decline.

Our principal shareholders and executive management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

As of December 31, 2021, our executive management, directors, holders of 5% or more of our ordinary shares and their respective affiliates beneficially own 42% of our outstanding voting securities. As a result, these security holders will have the ability either alone or voting together as a group to determine and/or significantly influence the outcome of matters submitted to our shareholders for approval, including the election and removal of directors, payment of dividends, amendments to our articles of association, including changes to our share capital or any mergers, demergers, liquidations and similar transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares or ADSs that holders of ADSs may feel are in their best interest as a holder of ADSs. In addition, this group of shareholders may have the ability to control our management and affairs. Such control and concentration of ownership may affect the market price of the ADSs and may discourage certain types of transactions, including those involving actual or potential change of control of us (whether through merger, consolidation, take-over or other business combination), which might otherwise have a positive effect on the market price of the ADSs.

We have broad discretion in the use of our cash, cash equivalents and investments, including the funds raised from our follow-on offering and our IPO, and we may not use them effectively.

Our management will have broad discretion in the application of our cash, cash equivalents and investments, including the funds raised from our follow-on offering and our IPO, and could spend these funds in ways that do not improve our results of operations or enhance the value of our ordinary shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the market price of the ADSs to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and investments, including the funds raised from our follow-on offering and our IPO, in a manner that does not produce income or that loses value.

We may not have sufficient funds available to pay amounts due and owing European Investment Bank upon the exercise of certain warrants and may be required to use a portion of the proceeds from funds raised from the follow-on offering or our IPO to make such payments.

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 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, or the 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, or the 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 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.

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. 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. In the first six months following the completion of our IPO that occurred in February 2021, the VWAP price to be paid by us is calculated for the entire period from the completion of our IPO until the exercise of the 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 the funds raised from our follow-on offering and/or our IPO 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 on our ordinary shares and do not anticipate doing so in the foreseeable future, capital appreciation, if any, will be the sole source of gain on investments in the ADSs.

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.

You may be subject to limitations on surrenders of the ADSs and the withdrawal of the underlying shares.

Temporary delays in the cancellation of the ADSs and withdrawal of the underlying shares may arise because the depositary 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.

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 depositary 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 depositary 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 depositary 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 depositary. If a lawsuit is brought against us or the depositary 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 depositary of compliance with any substantive provision of the United States federal securities laws and the rules and regulations promulgated thereunder.

Item 4. Information on the Company

4.A. Business Overview

General

We are a clinical-stage AI-immunology™ platform company using our proprietary artificial intelligence, or AI, technology, engineering expertise and drug development know-how to simulate the human immune system and generate predictive models to identify and develop novel immunotherapies for the treatment of various cancers, bacterial diseases and viral infections. Drug discovery and clinical development using historically prevailing techniques is a long, costly process with a high attrition rate. We believe our proprietary AI-immunology platforms, trained to translate vast amounts of data into a deep understanding of biological processes in the human body, can be harnessed to rapidly and cost effectively design and develop unique immunotherapies, thereby potentially revolutionizing the process of drug discovery and development. In an effort to validate the predictive power and scalability of our AI platforms, we have identified and are developing a pipeline of clinical product candidates initially focused in the areas of immuno-oncology and infectious disease. We are currently in the clinic with our two lead product candidates, EVX-01 and EVX-02, for the treatment of various cancers.

Our AI Platforms

Our four proprietary AI platforms include (i) PIONEER™, our immuno-oncology platform, (ii) EDEN™, our bacterial disease platform, (iii) RAVEN™, our viral disease platform, and (iv) AI-DeeP™, our newly developed immuno-oncology platform for prediction of drug response. Currently, we are focused on using PIONEER for the development of patient-specific immunotherapies for various cancers and using EDEN to develop vaccines against bacterial diseases. We plan to use our RAVEN platform to discover and develop vaccines against future coronaviruses as well as other viral infections. We intend to use AI-DeeP to determine which patients may benefit from cancer immunotherapies. We may, in the future, develop additional platforms to address other conditions known to have a large immunological component, examples of which could include autoimmune diseases, microbiome dysbiosis, allergies and parasites.

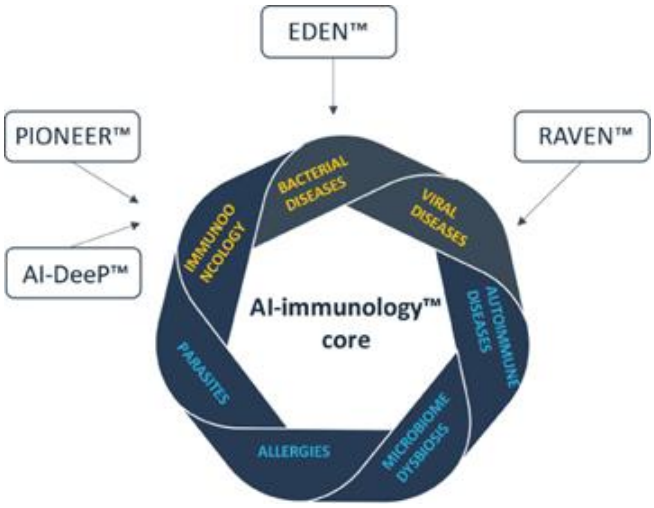

Figure 1. Present (orange) and potential future (blue) AI platforms based on Evaxion's AI-Immunology core.

Using the powerful AI technology of our PIONEER and EDEN platforms, we are currently developing four product candidates: EVX-01, for the treatment of advanced or metastatic unresectable melanoma; EVX-02, for adjuvant treatment of resectable melanoma; EVX-03, for multiple cancer indications; and EVX-B1, a vaccine for the prevention of *S. aureus* (including methicillin-resistant *S. aureus*, or MRSA, induced skin and soft tissue infections, or SSTI. Upon completion of successful Phase 2b, proof-of-concept, or PoC, trials, we plan to monetize our product candidates via out-licensing arrangements with pharmaceutical partners. We believe this scalable strategy will allow us to capture value from both the predictive power of our proprietary AI technology platforms and their ability to accelerate drug development.

The immune system is generally considered nature's strongest weapon to fight disease. When the immune system is engaged, people are often able to entirely eliminate a disease or infection from the body. Using our deep understanding of the human immune system and our proprietary AI technology, we are able to mimic the human immune system *in silico* and predict whether the body will have an immune response to certain stimuli. Our predictive power relies on our ability to process and interpret vast amounts of data, a process known as computational immunology. Using our *in silico* AI models, we are able to transform such data into advanced algorithms that we believe can accurately predict cellular interactions within the immune system and identify the right targets that will stimulate a relevant response. To translate the identified targets into product candidates, we test multiple delivery modalities and move the most promising forward. We believe this process allows us to discover new product candidates and move them into the clinic without expending time and resources on clinical development of product candidates that may ultimately fail to produce a therapeutic or prophylactic response.

Our Proprietary Platforms and Product Pipeline

In order to validate the predictive ability of our platforms, combined with our multiple delivery modality approach, we are developing the following pipeline of drug candidates:

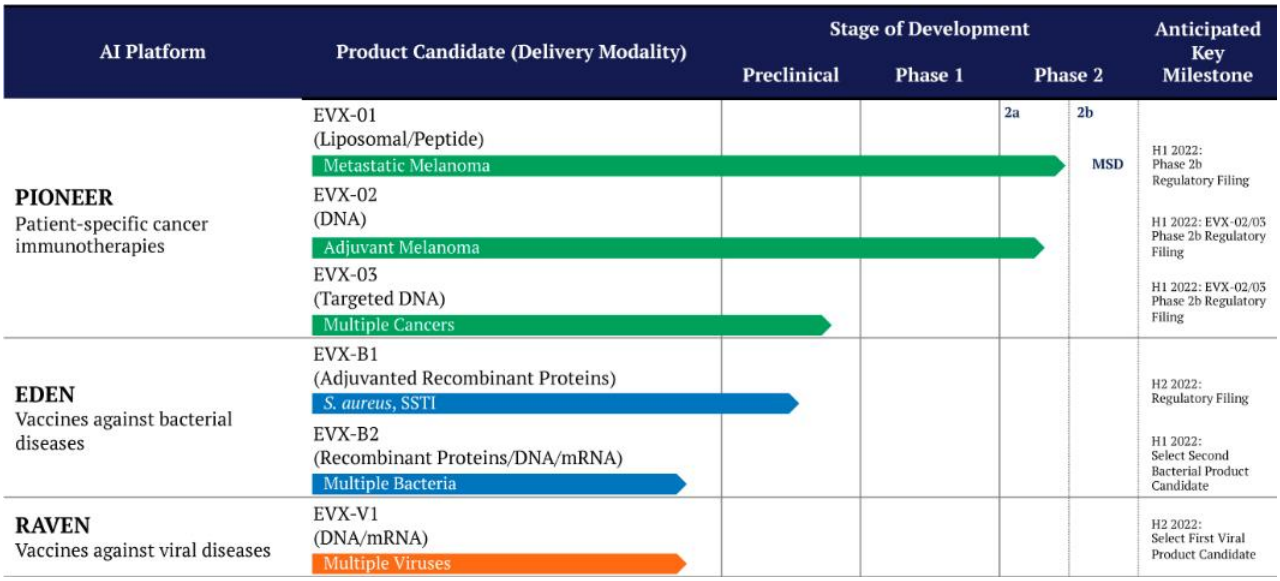

Figure 2: Our current product development pipeline.

Our first lead product candidate developed using our PIONEER platform, EVX-01, is a novel liposomal, peptide-based cancer immunotherapy designed to engage a patient's own immune system to fight various cancers by mounting a targeted response against tumors. EVX-01 is administered in combination with PD1/ PD-L1 checkpoint inhibitor, or CPI. In July 2021, we announced initial data readout from our Phase 1/2a clinical trial of EVX-01 in advanced or metastatic unresectable melanoma demonstrating an overall response rate, or ORR, of 67% across all nine patients compared with a historical ORR of 40% with anti-PD-1 treatment alone. The study also demonstrated a complete response, or CR, of 22%, compared with a historical CR of 7% with anti-PD-1 treatment alone. Among the four patients on the highest two doses, there was an ORR of 75%. Three patients with stable disease, or SD, for 10, eight and nine months on anti-PD-1 treatment alone, achieved CR, CR and partial response, or PR, respectively, following EVX-01 administration. In addition, the data showed induction of neoepitope-specific T cells in 100% of patients. 76.2% of the administered neoepitopes induced reactive T cells in patients, of which 83.3% were *de novo* responses.

The results also demonstrated that our recently introduced, novel proprietary AI-Immunogenetic Drug Response Platform, or AI-DeeP, which seeks to infer which patients benefit from our cancer immunotherapies based on immunogenetic expression signatures in the tumor microenvironment, is able to identify patients responding to therapy with high precision.

Based on our Phase 1/2a clinical trial initial data readout,on October 21, 2021, we entered into Clinical Trial Collaboration and Supply Agreement, or the Merck CTCSA, with MSD International GmbH and MSD International Business GmbH, subsidiaries of Merck & Co., Inc., (known collectively as MSD outside the United States and Canada), or MSD, to evaluate in a new Phase 2b clinical trial, the combination of our patient-specific neoepitope cancer immunotherapy compound, EVX- 01,with MSD's anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) compound, a humanized anti-human PD-1 monoclonal antibody.

We will act as the sponsor of the clinical trial under our own IND with the right of reference to the IND of MSD's compound. The planned multi-center Phase 2b clinical trial will enroll patients with Stage III and IV advanced or metastatic unresectable melanoma and will investigate EVX-01 in combination with KEYTRUDA®. Under terms of the Merck CTCSA, we will be responsible for the conduct of the study. MSD will be responsible for the supply of all of the necessary KEYTRUDA® and we will continue to collaborate with MSD as the data mature.

We will own all data (including raw data) and results generated from the clinical trial other than data related to Sample Testing Results, Joint Clinical Data or MSD Clinical Data, as those terms are defined in the Merck CTCSA, a copy of which is filed as Exhibit 99.2 to Form 6-K filed with the SEC on October 25, 2021.

Under the terms of the Merck CTCSA, MSD may terminate the agreement in the event it believes that its compound is being used unsafely. Either we or MSD may terminate the agreement if either of us determines (i) that there has been a material breach thereof by the other party, (ii) that the clinical trial may adversely affect patient safety or (iii) to withdraw the development of its compound for medical, scientific or legal reasons. In addition, either we or MSD may terminate the agreement if any regulatory authority takes any action or raises any objection that prevents the terminating party from supplying its compound.

In January 2022, we received regulatory clearance from the Australia Therapeutic Goods Administration, or the TGA, to initiate a Phase 2b clinical trial of our lead product candidate EVX-01 in combination with KEYTRUDA® for the treatment of melanoma. We expect to initiate our Phase 2b clinical trial in the first half of 2022.

Our second lead product candidate developed using our PIONEER platform, EVX-02, is a novel, DNA-based cancer immunotherapy designed to induce a therapeutic immune response in the adjuvant setting in patients with resected melanoma, administered in combination with PD-1 CPI.

In July 2021, we announced preliminary data readout from our Phase 1/2a adjuvant clinical trial of EVX-02 in resectable melanoma demonstrating activation of neoepitope-specific T cells with tumor killing potential. In addition, EVX-02 appeared to be well-tolerated. As of December 31, 2021, 16 patients were recruited to the trial. In March 2022, we reported completion of recruitment of Part 1 of the EVX-02 Phase 1/2a clinical trial.

We believe that the preliminary clinical immune and safety data from the Phase 1/2a clinical trial together with pre-clinical data from both our DNA-based patient-specific cancer immunotherapies, EVX-02 and EVX-03, support moving this candidate into a combined EVX-02/EVX-03 Phase 2b clinical trial. We intend to submit a regulatory filing in the first half of 2022.

Our third lead product candidate developed using our PIONEER platform, EVX-03, is a novel, DNA-based cancer immunotherapy with an antigen presenting cell, or APC, targeting, proprietary unit intended for the treatment of multiple cancers. EVX-03 is in late pre-clinical development. Data from ongoing pre-clinical studies has shown high levels of neoepitope-reactive T cells. We intend to submit a regulatory filing for initiation of a combined Phase 2b clinical trial of our DNA-based cancer immunotherapies, EVX-02 and EVX-03, in the first half of 2022.

For each cancer immunotherapy derived from our PIONEER platform, we have selected the optimal delivery modality to maximize its potential antitumor effect. We are screening and testing a variety of modalities including but not limited to peptides, DNA and mRNA for their ability to elicit an active antitumor effect and T-cell response. Data readouts from our standardized pre-clinical models allow us to select those modalities which we believe will exert the most active antitumor effect in patients. In addition, we also screen and ultimately select different modalities for their speed and cost of manufacturing ensuring they allow for rapid development and large-scale production of our cancer immunotherapies. We believe utilizing this strategy, will provide an advantage as our success with patient-specific cancer immunotherapies does not depend on one single modality.

Additionally, using our EDEN platform, we are developing EVX-B1, a prophylactic multi-component subunit vaccine initially in development for the prevention of *S. aureus* induced SSTI in patients undergoing elective abdominal hernia surgery. EVX-B1 includes two proprietary and highly protective antigens identified by EDEN in combination with our proprietary chimeric toxin, formulated with a potent adjuvant system. We believe that the predictive power of EDEN and our unique approach to vaccine design may lead to a more effective and highly protective vaccine. EVX-B1 is in late pre-clinical development and we intend to submit a regulatory filing for initiation of our clinical trial in the second half of 2022. We also plan to select our second bacterial product candidate in the first half of 2022.

AI Platform	Product Candidate	Phase	2022	2023	2024	2025
PIONEER Immuno-oncology	EVX-01 (with MSD)	Phase 2b	H1 Regulatory filing H1 First-patient-first-visit	H2 Interim readout	1-year follow-up readout	2-year follow-up readout
PIONEER Immuno-oncology	EVX-02/03	Phase 2b	H1 Regulatory filing H2 First-patient-first-visit		Interim readout	Full readout
PIONEER Immuno-oncology	EVX-02	Phase 1/2a	H1 Recruitment completed	H1 Clinical readout		
EDEN Infectious diseases	EVX-B1	Phase 1	H2 Regulatory filing			
EDEN Infectious diseases	EVX-B2	Pre-clinical	H1 Selection of second bacterial target			
RAVEN Infectious diseases	EVX-V1	Pre-clinical	H2 Selection of commercial target			

Figure 3: Anticipated key milestones 2022-2025.

Our Strengths

- Our fully AI-based approach enables us to discover and develop immunotherapies with unique targets, which we believe may translate into a higher likelihood of clinical success.
- Our fully AI-based approach enables us to discover and develop immunotherapies more rapidly when compared to other standard approaches.
- Our unique ability to generate and leverage biologically relevant data that enables the continuous development of our AI-immunology platforms with enhanced predictive power, which we believe may translate into a higher likelihood of clinical success.
- Our model for iterative training provides continuous improvement of our AI platforms as data is generated throughout the development stages.
- Our model for screening and testing different delivery modalities that we believe will allow us to potentially develop a broad portfolio of product candidates.
- Our ability to rapidly move from target identification to clinical development. We expect that we will be able to speed up the time from target identification to clinical development. For our EVX-02 program, we demonstrated our ability to do so in just 18 months. However, there is no guarantee that we will be able to identify potential product candidates in this time frame in the future.
- Our portfolio of product candidates that target large patient populations.
- Our AI-immunology technology that enables a high level of scalability, offering the potential to expand our portfolio of product candidates as well as our proprietary AI-immunology platforms.

Our Strategy

- **Validate the predictive ability of our four proprietary AI-immunology platforms by developing our current pipeline of product candidates through successful Phase 2b PoC.** To demonstrate that our AI platform derived product

candidates translate into clinical effect, we plan to take at least one product candidate from each platform through clinical PoC. Upon receipt of platform validation, we plan to expand our product portfolio within each platform.

- **Rapidly advance our three lead product candidates, EVX-01, EVX-02 and EVX-03, derived from our PIONEER platform through completion of Phase 2b PoC trials.** In July 2021, we announced data from our EVX-01 Phase 1/2a clinical trial and interim data from our EVX-02 Phase 1/2a clinical trial. We intend to initiate a Phase 2b clinical trial for EVX-01 in the first half of 2022 and a Phase 2b clinical trial for EVX-02 in combination with EVX-03 in the first half of 2022. We believe a positive readout in these planned Phase 2b trials will provide us with validation of our lead product candidates as well as our PIONEER platform technology and overall AI-immunology platform approaches.

- **Leverage our clinical collaboration with MSD to advance our EVX-01 lead product candidate into Phase 2b clinical trials in combination with KEYTRUDA.** We recently entered into the Merck CTCSA and are planning to conduct a multicenter Phase 2b clinical trial in patients with Stage III and IV advanced or metastatic unresectable melanoma to investigate EVX-01 in combination with KEYTRUDA, MSD's anti-PD-1 therapy in the first half of 2022. Under terms of the Merck CTCSA, we will be responsible for the conduct of the study, and MSD will supply all of the necessary KEYTRUDA® and will continue to collaborate as the data mature.

- **Pursue out-licensing arrangements for late-stage clinical development with pharmaceutical partners for our lead product candidates to advance them toward regulatory approvals and allow us to monetize the development of our product candidates.** We plan to out-license on a non-exclusive basis the PIONEER platform, while specific delivery modalities will carry exclusivity for one or more cancer indications. The PIONEER platform will remain in our full control. We also plan to out-license our EDEN derived product candidates. We retain all rights to our core AI-immunology technology and platforms for future product candidate development and platform enhancements.

- **Progress additional pipeline candidates developed with our PIONEER, EDEN and RAVEN platforms into the clinic and through Phase 2b trials, and then pursue out-licensing arrangements.** After progressing our lead product candidates through Phase 2b, we plan to move EVX-B1 from our EDEN platform, into the clinic and through Phase 2b PoC trials. We will then focus our attention on our earlier stage programs, including selection of our next bacterial and viral targets.

- **Become a world leader in AI-immunology, translating our platforms into products.**

    - **With our PIONEER platform, we plan to develop our pipeline with the use of new delivery modalities**. To create our patient-specific cancer immunotherapies, we develop or in-license delivery modalities we believe have the ability to induce antitumor effect of PIONEER predicted neoepitopes. We progress the most promising modality candidates tested in the pre-clinical setting into our clinical pipeline. In addition, this enables us to mitigate the uncertainty of the antitumor effect of different delivery modalities.

    - **With our EDEN platform, we plan to progress additional bacterial product candidates through pre-clinical and clinical development**. We have already demonstrated *in vivo* protection and filed patent applications for vaccine antigens identified by EDEN for seven different bacterial pathogens, of which the majority have been classified as public health threats by the United States Centers for Disease Control and Prevention, or CDC. We believe EDEN can be applied for the development of multiple bacterial product candidates in the future.

    - **With our RAVEN platform, we plan to develop vaccine product candidates for the use against future coronaviruses as well as other viruses**. Initially, we intend to develop our RAVEN platform as a response platform with the ability to rapidly develop and produce a vaccine candidate against the next coronavirus. We also plan to expand the platform to target other viruses such as human respiratory syncytial virus, cytomegalovirus and influenza.

- **Continue to invest in our PIONEER, EDEN, RAVEN and AI-DeeP platforms.**

    - **Further refine and strengthen the predictive performance of our existing AI platforms.** Through machine learning and new immunological data generation, we are continuously working to improve the predictive power of

our *in silico* AI models incorporated in our AI-immunology technology. With each major iteration of our PIONEER platform, we have demonstrated significant improvement in its predictive power which has led to stronger antitumor effect in pre-clinical models. We believe this speed with which we are able to train and improve our platforms provides us with a clear advantage over our competition.

  - **Generate and utilize new data to improve our platform performance**. We generate new, proprietary data to support the continuous development and increase the performance of our platforms. We also develop new methodologies for data generation such as unique mass spectrometry methodologies. Furthermore, we are utilizing and will continue to use our clinical data from our ongoing trials to improve our platforms.

  - **Develop new AI platforms to allow us to target indications beyond cancer, bacterial disease and viral infections**. We are continuously exploring new frontiers in AI-immunology, including evaluating new therapeutic areas where our know-how and technologies can make a difference such as autoimmune diseases, allergies, microbiome dysbiosis and parasites. We are continuously monitoring the technologies and medical development in such therapeutic areas for timely launch of new AI platforms applicable to such areas.

- **Continue to grow and develop the best talent within AI-immunology**. By bringing together leading experts within AI and immunology, our goal is to invest in our team to realize their full potential and maximize their expertise. We intend to further strengthen our leadership position by collaborating closely with leading academic institutions and advisors to share and develop new capabilities that are critical to our ability to develop and maintain proprietary AI platforms.

- **Secure and maintain a strong IP portfolio**. We have developed a strong IP portfolio, pursuing different strategies for our immuno-oncology and infectious diseases products, to ensure the exclusive rights to all our lead product candidates and protect our proprietary AI technology as well as to support best the possible commercialization outcomes. We intend to keep all IP rights with respect to a product candidate until end of Phase 2b and out-licensing of the product candidate. We will retain all IP rights to our AI platforms. We currently have 14 issued patents, one allowed and 45 pending patent applications.

Our Management Team

We believe that our fully AI-driven approach and our portfolio of AI platforms places us at the forefront of effectively translating the immune system into novel drug candidates that trigger the immune system to treat a variety of diseases. To deliver on our objectives, we have built an experienced and broadly skilled management team. Our Chief Executive Officer, Lars Staal Wegner, M.D., joined us in August 2017. He served as part of the Senior Management team, leading all commercial and medical affairs efforts at Bavarian Nordic A/S, a NASDAQ Copenhagen listed biotech company, for 10 years prior to joining our company. Prior to that, Dr. Wegner worked in oncology at Pfizer Inc. and served as a clinician at public institutions. On October 15, 2021, our then Chief Financial Officer, Glenn S. Vraniak, informed us that he would be leaving to pursue opportunities outside the biopharmaceutical industry effective on November 1, 2021. Prior to joining us, Mr. Vraniak had served as Chief Financial Officer of electroCore, Inc., a US publicly traded company, from August 2016 until April 2019. As of November 1, 2021, our Co-Founder and Chief Business Officer, Niels Iversen Møller, M.D., replaced Mr. Vraniak, and since that time has acted as our Interim Chief Financial Officer. Prior to founding our company, from our inception in 2008 until August 2017, Dr. Møller was our Chief Executive Officer. Dr. Møller received his M.D. from the University of Copenhagen and his BA in Economics from Copenhagen Business School. Dr. Møller has also held positions as Medical Director at Medical Prognosis, a bioinformatic company, and as Medical Advisor on new oncology product development at AstraZeneca PLC. Erik Deichmann Heegaard, Ph.D., DMSc, joined us in April 2021 as our Chief Medical Officer. Dr. Heegaard has more than 25 years of experience within oncology and infectious diseases. Prior to joining us, Dr. Heegaard served as Head of Medical at Novartis Oncology, Nordics, and as Chief Medical Officer of the oral GLP-1 project at Novo Nordisk where he successfully completed Phase 1 and 2 clinical trials for the project and served as chief architect of the global Phase 3 clinical development program for the project. Prior to that, Dr. Heegaard held numerous research and clinical positions in companies such as Sandia National Laboratories, Bavarian Nordic and Statens Serum Institut. Our other Co-Founder and Chief Innovation Officer, Andreas Holm Mattsson, is a pioneer within *in silico* development, having already initiated the framework of our proprietary AI platforms while enrolled in academic studies, and eventually inventing the EDEN platform. Our Chief Scientific Officer, Birgitte Rønø, Ph.D., joined us in September 2017. Dr Rønø has more than 15 years' experience in biopharmaceutical drug discovery from academia and industry. Prior to joining Evaxion, Dr. Rønø served as a specialist, team leader and project manager at Novo Nordisk, from 2013-2017, where she was leading early drug discovery projects, evaluating in-licensing opportunities, and supporting drug development projects with pre-clinical and biomarker expertise.

Jesper Nyegaard Nissen, MSc joined us in March 2022 as our Chief Operating Officer pursuant to the terms of his Service Agreement entered into on January 16, 2022. Mr. Nissen has more than 25 years of experience in the pharmaceutical industry across finance, investments, research and development. Mr. Nissen began his career in Novo Nordisk Corporate Finance being responsible for development of controlling and performance management processes followed by the role as finance responsible for different corporate business areas. In 2020, Mr. Nissen moved into senior leadership roles as Vice President / and later as Corporate Vice President within for Global Research Operations with the focus on research and development and strategic and operational development, which included the responsibilities for clinical sourcing, development IT strategies, establishment of development shared service center in India, application of real world evidence, orRWE and health economics related to clinical trials, development of research strategies, research portfolio governance, operation of global research sites, design and operation of external research engagement models among others. Since January 2021 until joining us, Mr. Nissen has worked for Fujifilm Diosynth Biotechnologies in the program management team for large scale capital projects driving Fujifilm Diosynth Biotechnologies mission to become a global leader within contract development and manufacturing orgsanizations, or CDMOs. Mr. Nissen received his MSc Business Economics (Cand. Oecon.) from the University of Aarhus, Denmark.

On March 14, 2022, we announced that Bo Karmark would join us as our Chief Financial Officer. Mr. Karmark is an experienced financial executive with a career spanning more than 25 years working for several multinational listed companies, primarily in the biotech, pharma, and bioscience industries. Before joining us, he served as the Chief Financial Officer for Aquaporin A/S, a water technology company, for the past seven years. Aquaporin is listed on the Nasdaq Copenhagen stock exchange. Before that, Mr. Karmark held numerous financial management positions at various companies including Chr Hansen Holding A/S, H. Lundbeck A/S, and NsGene A/S. Mr. Karmark received his M.Sc. in Business Administration and Auditing form the Copenhagen Business School, Denmark.

Background on Cancer Immunotherapy and the Role of Neoepitopes

The immune system is our body's natural defense system that protects us against infection and diseases. It keeps track of all of the substances normally found in the body and raises an alarm if an unfamiliar substance is found, launching an attack against it. However, cancer cells can present a more challenging target for the immune system. Cancer cells are altered normal cells and therefore the immune system doesn't always recognize them as foreign. In fact, cancer cells possess several mechanisms through which they escape immune surveillance as they:

- Harbor genetic changes that make them less visible to the immune system
- Express proteins on their cell surface that inhibit immune cell effector functions
- Induce changes in the normal cells around the tumor thus interfering with how the immune system responds to the cancer cells

To overcome this, immunotherapies use different ways to seek the power of the patient's own immune system to fight cancerous cells. The regulatory approval of immune CPIs has been a major breakthrough in treatment of patients suffering from advanced solid tumor cancers by demonstrating beneficial clinical responses, durable disease control and improved survival in subsets of patients. Detailed mapping of the underlying mechanisms has revealed that the CPI-induced antitumor effect is associated with the patient's ability to mount a tumor-specific T-cell response. To further improve clinical efficacy, different co-targeting strategies are currently being explored, including the combination of CPI and T-cell immunotherapies capable of directing and improving the patients' immune response specifically towards essential functions in the cancer cells.

The Role of T Cells in Cancer Immunotherapy

T cells are a type of white blood cell that play a central role in the immune system. T cells are involved in both detecting and killing infected or abnormal cells, such as cancer cells, as well as coordinating immune responses. T cells can be classified into two major subsets, CD4+ T cells and CD8+ T cells, each possessing different functionalities. CD8+ T cells are considered the main effectors in T-cell mediated tumor killing, however, several reports have highlighted the importance of inducing both CD4+ and CD8+ T cells as T helper 1, or Th1, CD4+ T cells support CD8+ T cells priming as well as promote the desired effects via secretion of effector cytokines.

T cells recognize cancer cells using T-cell receptors, or TCRs, that interact with specific immune targets, or epitopes, presented by a molecular structure on the surface of cells known as the major histocompatibility complex, or MHC. The MHC molecules bind to peptides from protein degradation inside the cell before being transported to the cell surface to present the peptide to TCRs. If a peptide bound to the MHC molecule is recognized by T cells, it is called an epitope. There are two classes of MHC molecules, class I and class II, that activate CD8+ and CD4+ T cells, respectively. In humans, MHC is encoded by the genes of the HLA locus. HLA genes show high allelic variation, resulting in MHC molecules that have different peptide binding preferences. Each person expresses a unique combination of molecularly distinct class I and class II MHC molecules that bind a specific set of peptides and epitopes.

Mutated genes in cancer cells lead to expression of altered proteins which are, like all proteins, processed by the cellular machinery into protein fragments known as peptides. When these mutated peptides are presented on MHC molecules, by either tumor cells or antigen presenting cells, and recognized by T cells, they are known as neoepitopes.

The immune system refrains from targeting the body's own healthy cells principally through processes known as central and peripheral tolerance, by which T cells are educated not to respond to MHCs displaying peptides from normal proteins and therefore avoid targeting normal cells for destruction. The TCR-peptide-MHC interaction is a vital immune mechanism that allows the body both to respond against threats, including cancer, as well as to avoid targeting the body's own healthy cells. Understanding the interactions between TCRs, peptides and specific MHC alleles is critical to directing and activating an immune response to cancer.

Neoepitope-Based Cancer Immunotherapies

The common feature of cancer is accumulation of mutations in the genes, which manifests as tumors with uncontrolled growth. Cancer is a complex, extremely heterogeneous condition. Despite this complexity and variability, patients with the same type and stage of cancer have historically been administered the same treatment. This approach has been altered in recent years with the introduction of precision medicine cancer immunotherapies, a tailored approach for selecting therapy at the individual patient level based on the genetic makeup of a patient's cancer. Discovery of molecular cancer biomarkers (i.e. cancer oncogenes) has paved the way for the first generation of personalized therapies. Genomic screening approaches have been commonly employed to identify tumor-specific, overexpressed proteins or genetic mutations that may confer targets for an effective cancer immunotherapy.

We believe a truly personalized, or patient-specific approach, incorporating the entirety of the tumor ecosystem, while taking a more unbiased approach to drug design, is required to advert the inherent complexities of the tumor microenvironment and heterogeneous cellular landscape, and to improve the clinical outcome of cancer immunotherapies. We believe such approach can be achieved by directing immunotherapies towards cancer-exclusive peptide sequences, so called neoepitopes, displayed on the surface of tumor cell originating from patient-specific mutations. Neoepitope-targeting immunotherapies have shown great promise in pre-clinical animal models as well as in early clinical trials.

Neoepitopes provide an avenue for tumor-specific immune cell recognition, a prerequisite for a beneficial clinical response of a neoepitope-based immunotherapy. Antigen presenting cells, or APCs, educate the immune system by presenting neoepitopes to T cells. Tumor cells can also present neoepitopes on their cell surface, providing accessible targets for T cells. T cells recognize and kill neoepitope-presenting cancer cells and effect a positive feedback loop to heighten and broaden the cancer specific immune response as more epitopes will be available for APC uptake upon T-cell mediated tumor cell lysis.

Once patient-specific neoepitopes are administered to the patient, APCs will process the neoepitopes by the MHC epitope presentation machinery, migrate to the lymph node and present neoepitopes to T cells. TCRs on circulating CD4+ and CD8+ T cells bind to the presented neoepitopes triggering initial T-cell activation. Once activated, the T cells will enter the circulation to reach distant organs, including the tumor. In the tumor, reactive T cells will encounter tumor cell surface displayed neoepitopes, resulting in T cell mediated tumor cell killing.

Cancer patients normally do not have a meaningful numbers of T cells that recognize their tumor. We believe a neoepitope-targeting approach will generate a strong, *de novo* tumor-specific T-cell response which will lead to killing of tumor cells and thereby an improved clinical response. Further, we believe such approach has great therapeutic potential because neoepitopes represent foreign elements to the immune system and are unique to each person's tumor cells which means neither self-tolerance nor adverse side effects are likely to limit the clinical application of a neoepitope-based immunotherapy.

We believe our truly patient-specific approach targeting neoepitopes will allow us to harness the natural power of a patient's own immune system to elicit a strong, cancer-specific immune response, potentially holding the key to long-lasting tumor control or even universal cure for many cancer patients.

PIONEER – Our AI Platform for the Discovery of Novel, Patient-Specific Immuno-Oncology Therapies

Overview

PIONEER is our proprietary AI platform for the rapid discovery and design of patient-specific neoepitopes used to derive immuno-oncology therapies. Our proprietary *in silico* AI models within PIONEER, for the prediction of T-cell activation, allow us to efficiently identify and select those neoepitopes that we believe are most likely to generate a strong, *de novo* T-cell response leading to significant antitumor effect in each patient. The goal of our PIONEER derived immunotherapies is to deliver therapeutic neoepitopes to patients in a way that trains the patients' own immune system to target and kill tumor cells with no or very limited adverse effects on healthy non-cancer cells. As shown in Figure 4 below, PIONEER simulates the key biological steps in presenting each neoepitope to the patient's immune system with our high-performance, AI-based *in silico* models.

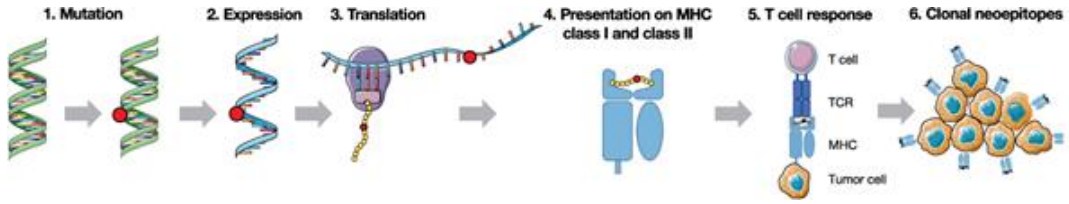

Figure 4: Illustration of mechanisms within the tumor cell that are required for a neoepitope to have a clinical effect in patients.

Key biological steps simulated by PIONEER Include:

Step 1 – Mutation: PIONEER identifies cancer-specific mutations by comparing DNA sequencing data from the tumor sample(s) and normal tissue sample using our proprietary AI-based somatic variant caller.

Step 2 – Expression: Only a subset of the cancer-specific mutations is found in genes that are expressed in the tumor cells. The expression levels of each gene are determined by analyzing tumor RNA sequencing data. In addition, PIONEER calculates the mutation-specific expression levels using an in-house developed computational model.

Step 3 – Translation: Not all cancer-specific mutations result in altered protein sequences. Some mutations may be found in regions that do not code for protein sequences or they may simply be synonymous mutations (where the DNA sequence is altered, but the encoded amino acid is the same). PIONEER determines the effects of each cancer-specific mutation. The coding regions around non-synonymous mutations are then translated into amino acid sequences, generating cancer-specific neopeptide sequences.

Step 4 – Presentation on MHC Class I and Class II: To induce an immune response, neopeptides must contain subsequences that are bound by MHC molecules and presented on the cell surface. The identified neopeptides are given as input to our proprietary AI-based tool suite, EvaxMHC, along with the patient's HLA type to identify neopeptides containing MHC ligands bound by the patient's MHC molecules specifically.

Step 5 – T-Cell Response: Neoepitopes presented by MHC class I and class II are recognized by T cells, triggering an immune response and tumor cell death. However, while being presented as MHC ligands is a prerequisite for generating an immune response, not all MHC ligands are recognized by T cells. PIONEER includes a tool that predicts the likelihood of a given mutated MHC ligand eliciting a T-cells response.

Step 6 – Clonal Neoepitopes: Tumors are extremely heterogeneous, meaning that not all tumor cells necessarily encode and express the same neoepitopes. Targeting clonal neoepitopes, defined as neoepitopes arising from clonal mutations that are present in all cancer cells, allows for systemic eradication of the whole tumor, as well as potential metastases in the patient. Multiple reports suggest that targeting clonal neoepitopes results in a more effective treatment. PIONEER determines the clonal status of a neoepitope by analyzing

the DNA sequencing data using *in silico* AI models. For patients where DNA sequencing data from multiple tumor biopsies is available, PIONEER seamlessly integrates the information from each biopsy to improve the clonality estimate.

Identifying those neoepitopes that will induce a strong antitumor immune response capable of eradicating all tumor cells in the patient requires sophisticated AI-based *in silico* models. Such models must be capable of accurately identifying tumor specific mutations along with all steps involved in neoepitope processing, presentation and TCR recognition. State-of-the-art, publicly available tools for neoepitope prediction return a vast number of candidates, of which only a handful are ever found to trigger bona fide antitumor responses in patients. We have benchmarked our proprietary tools from PIONEER against state-of-the-art public tools (Mutect2, MixMHCpred-v2.1/MixMHC2pred-v1.2, RSEM-v1.2.0 quantified expression) and we believe our platform produces superior results.

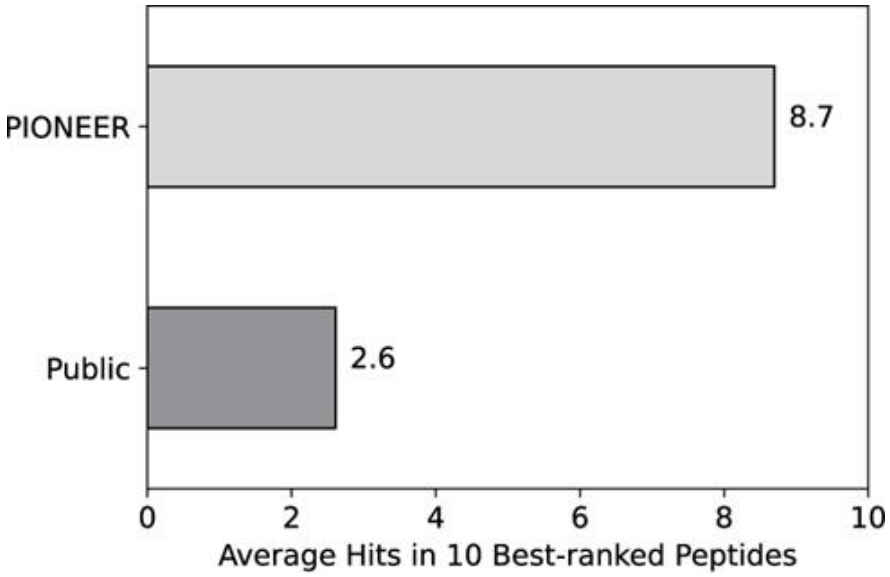

Figure 5: Benchmark study of PIONEER against state-of-the-art, public tools for number of hits identified in the top 10 best-ranked neoepitopes.

To compare PIONEER to a pipeline of state-of-the-art public tools, we designed a simulation study with 3,000 patients. Each patient was assigned 500 potential neoepitopes in a 1:5 positive to negative ratio. Both pipelines were tasked with selecting a set of 10 neoepitopes for each patient and the average number of positive neoepitopes was assessed. Results are depicted in Figure 5 above.

Our benchmark study demonstrates that the best publicly available tools are only capable of identifying 2.6 correct neoepitopes in the top 10, which, we believe, in a neoepitope-based cancer immunotherapy is not sufficient to reach a strong antitumor effect. In comparison, PIONEER was able to identify 8.7 correct neoepitopes in the top 10, which we anticipate is optimal to drive an enhanced antitumor immune response. PIONEER include several *in silico* tools, some of which are AI-based, corresponding to each biological step in neoepitope presentation to the immune system. We believe that our multi-parameter improvements incorporated across our *in silico* AI models will translate into better antitumor effect. In pre-clinical studies,we have already demonstrated that enhanced neoepitope prediction directly links to improved antitumor effect in mice (see Figure 6 below).

Improved Neoepitope Prediction Directly Translate into Better Antitumor Effect

Our proprietary *in silico* AI models within PIONEER have been trained on our proprietary data as well as other data, including, but not limited to, next generation sequencing data from tumor samples, mass spectrometry immunopeptidomics, peptide-MHC-binding affinity data, T-cell immunogenicity data, peptide-MHC-binding stability data. We have demonstrated that development and iterative training of our AI platform directly translates into improved antitumor effect in pre-clinical studies. In a pre-clinical tumor study, the efficacy of three versions of PIONEER, each with increasing number of new features were directly compared (see Figure 6 below). Mice treated with neoepitopes predicted by PIONEER 2.0 demonstrated statistically significant better antitumor effect than the groups

treated with neoepitopes predicted by earlier versions of PIONEER, thereby demonstrating that improved neoepitope prediction directly translates into improved antitumor effect.

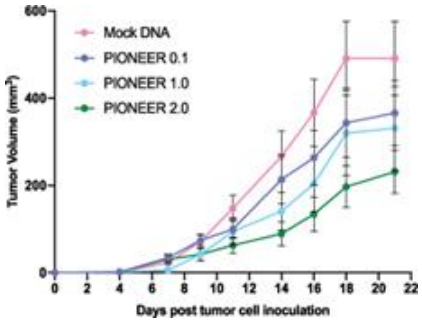

Figure 6: To explore the biological impact of different improvements, three versions of PIONEER were evaluated in the CT26 mouse tumor model. For each version, the top 10 ranked neoepitopes were encoded in separate DNA constructs, designated PIONEER 0.1, PIONEER 1.0, and PIONEER 2.0. Mice were intramuscularly treated twice with the various DNA constructs prior to CT26 cells inoculation. A "mock" plasmid without neoepitopes was included as control.

We believe we are uniquely positioned to develop a neoepitope-based immunotherapy and address the shortcomings from competing approaches through our proprietary algorithms and i*n silico* AI models contained in PIONEER.

Key Advantages of Our PIONEER Platform

- **Identification of Therapeutic Neoepitopes:** PIONEER is able to identify therapeutic neoepitopes that drive a T-cell response with higher accuracy compared to predictions done by state-of-the-art public tools. These neoepitopes have been shown to have an antitumor effect in mice. Clinical data from our ongoing EVX-01 clinical trial demonstrate that our immunotherapies induce specific and active T cells in 100% of all patients and 76.2% of the administered neoepitopes induced reactive T cells in patients, of which 83.3% were *de novo* responses.

- **Identification of Therapeutic Patient-Specific Neoepitopes:** PIONEER is able to identify truly patient-specific neoepitopes that are unique to a patient's cancer based on their HLA subtype.

- **Identification of Multiple Neoepitopes:** PIONEER identifies multiple neoepitopes that can be incorporated in the immunotherapy to increase therapeutic effect and overcome issues related to cancer clonal heterogenicity and tumor immune escape.

- **Speed:** PIONEER rapidly identifies neoepitopes in as little as 24 hours from receipt of patient biopsy sequencing data.

- **World Wide Clinical Applicability:** PIONEER is clinically applicable, automated and deployable anywhere in the world and has been through a process of validation according to the International Society for Pharmacoepidemiology, ISPE's, latest revised guide for Good Manufacturing Practice, or GAMP5, to ensure compliance with legislature and good practice regulations to maintain a high standard of quality in the system.

- **Potential for Repeat Use of PIONEER Over the Lifetime of a Patient's Cancer Treatment**: Multiple PIONEER designed therapies targeting different sets of neoepitopes can be applied. We believe that with this approach, even relapsing patients will benefit from additional, newly designed PIONEER immunotherapies that target emerging cancer clones specifically.

- **Safety Profile:** PIONEER has been configured to deselect potentially harmful neoepitopes, limiting off target effects.

- **Continuous Improvement:** PIONEER was developed in 2016 and has been updated and improved numerous times by incorporating additional unique data generated in-house and through strategic partnerships, and other available data sets. We

will continue this ongoing data incorporation as we generate more pre-clinical and clinical data from our ongoing trials to ensure that our *in silico* AI models remain state-of-the-art. In addition, we continue to include new features in the platform to increase its predictive power.

Example of Continuous Improvement: Proprietary, In-House MS Methodology Moves Prediction from 60% to 90% Accuracy

We take a unique approach to data generation to further improve the predictive power of PIONEER. One such example includes our novel mass spectrometry, or MS, -based assay for proprietary data generation of *in vivo* MHC ligand stability data, which we believe overcomes limitations of current stability assays that only explore the feature *in vitro*. The unique data generated from our assay was used to create an MHC ligand stability prediction tool. Figure 7 below shows data from our PoC study in which predictions were benchmarked on confirmed cancer neoepitopes demonstrating superior performance of our tool in predicting the top 10 neoepitopes compared to predictors created using traditional MS data. We have filed patent applications on both the experimental assay and the algorithmic approach for data interpretation. Our article describing these findings have been published in Nature Communication.

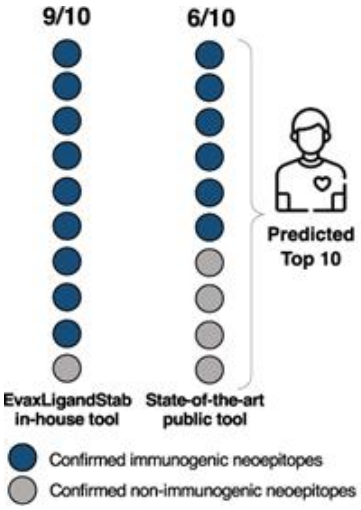

Figure 7: EvaxMHCIstab demonstrates improved performance when compared to the current state-of-the-art prediction tools (EvaxMHCI and NetMHCpan-4.0).

As shown in Figure 7 above, the AI model was trained using proprietary thermostability data from a mass spectrometry-based immunopeptidomics workflow and used to predict 26 immunogenic cancer neoepitopes and 20 confirmed negative cancer peptides curated from the Immune Epitope Database. Of the 10 peptides predicted to be the most stable by EvaxMHCIstab, nine were confirmed neoepitopes. In comparison, only six to eight of the neoepitopes were ranked as part of the top 10 predicted peptides by the other prediction tools.

Using PIONEER to Derive Our Immuno-Oncology Product Candidates

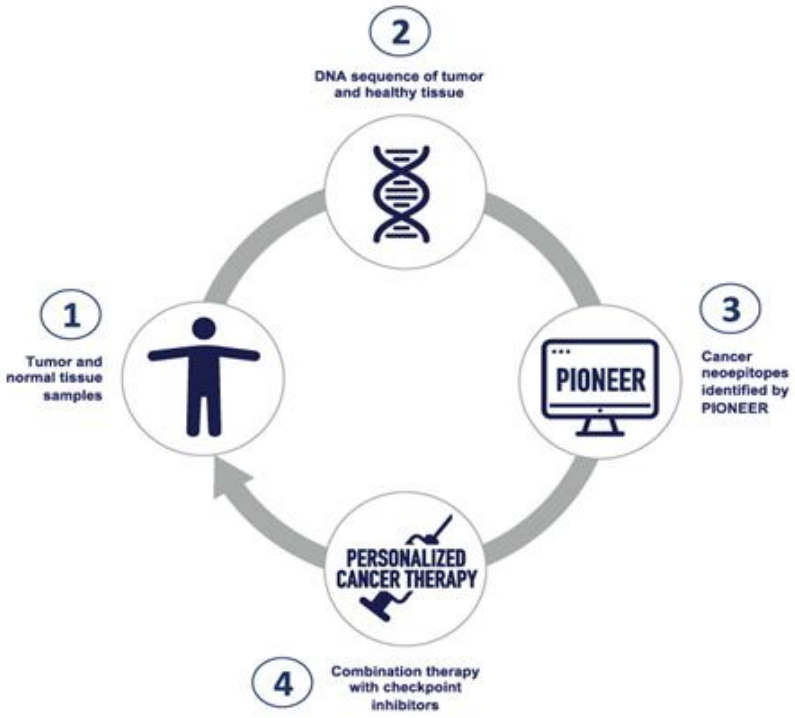

Figure 8: Our process for delivering a patient-specific cancer immunotherapy.

As shown in Figure 8 above, the following steps describe our process for delivering patient-specific cancer immunotherapy:

Step 1 – Tissue Biopsy: Tumor tissue sample(s) and a blood sample are collected from the patient;

Step 2 – DNA and RNA sequencing: We then apply deep-sequencing to the patient's tumor biopsy specimen and blood to derive high-quality DNA and RNA sequence information;

Step 3 – Identify Critical Neoepitopes: PIONEER uses this sequence information to identify tumor mutations. Next, PIONEER identifies potential neoepitopes from the tumor mutations and ranks such neoepitopes according to their likelihood of being (a) truly cancer-specific (b) present in all cancer cells (c) presented by MHC molecules on tumor cells and (d) able to interact with a TCR and (e) generating an immune response. PIONEER selects the top 10-20 neoepitope candidates and designs the final cancer immunotherapy; and

Step 4 – Administer Neoepitopes to Patient: The selected neoepitopes are manufactured and administered to the patient.

Initially, our patient-specific immunotherapies are intended for the use as a combination therapy with CPIs. Evidence suggests that in patients responding well to CPI treatment, the response is partly mediated by neoepitope-reactive T cells. Induction of *de novo* neoepitope-specific T cells in combination with CPIs represent a synergistic strategy to expand the number of patients responding to treatment as well as improving the clinical outcome. We intend to evaluate our patient-specific immunotherapies as monotherapies in the future.

Our PIONEER Derived Immuno-Oncology Programs

We are currently advancing a unique pipeline of patient-specific cancer immunotherapies derived from our PIONEER platform.

For each cancer immunotherapy derived from our PIONEER platform, we have selected the optimal delivery modality to maximize its potential antitumor effect. We are screening and testing a variety of modalities including peptides, mRNA and DNA for their ability to elicit a strong antitumor and T-cell response. Data readouts from our standardized pre-clinical models allow us to select those modalities which we believe will exert the strongest antitumor effect in patients and rapidly move them into the clinic.

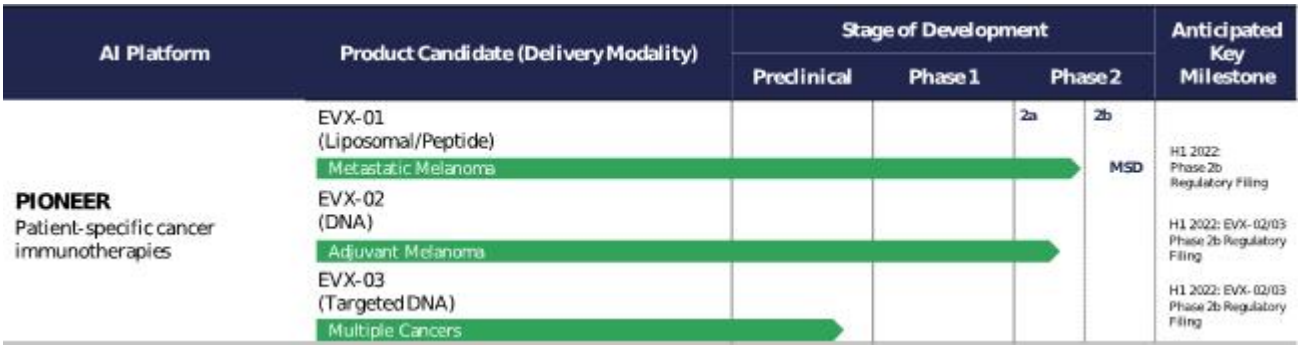

Figure 9: Our immuno-oncology product development pipeline derived from PIONEER.

Our Lead Product Candidate EVX-01

Overview

Our lead product candidate EVX-01, is a novel cancer immunotherapy designed to engage the patient's own immune system by mounting a targeted response against tumors. EVX-01, in combination with PD-1/-L1 CPIs, is intended for the first-line treatment of a variety of metastatic and unresectable cancers amenable to PD-1/-L1 inhibition. In July 2021, we announced initial data readout from our Phase 1/2a clinical trial of EVX-01. Based on the data readout, we entered into a collaboration with MSD and plan to advance EVX-01 into a Phase 2b clinical trial in combination with MSD's KEYTRUDA. We expect to initiate our Phase 2b clinical trial in the first half of 2022.

EVX-01 consists of five to 10 PIONEER-identified neoepitopes formulated as peptides (neopeptides) together with a strong CD8+ and CD4+ T-cell inducing adjuvant, CAF09, in-licensed from SSI. When administered to the patient, we believe EVX-01 will induce neoepitope -specific T cells that will migrate to the tumor site and induce tumor killing or target circulating tumor cells to eliminate these before becoming metastatic.

We have selected CAF09, a cationic liposomal adjuvant formulation, for its potent ability to induce neoepitope-specific T-cells and for its ability to induce significantly higher T cells compared to well-characterized adjuvants or similar liposomal systems in pre-clinical studies performed by SSI.

To investigate the ability of CAF09 to induce a tumor specific immune response and prevent tumor growth, we performed a pre-clinical study in mice engrafted with the mice cancer melanoma cell line B16F10. A mouse EVX-01, or mEVX-01, immunotherapy comprising three B16F10 tumor specific epitopes was produced and mixed with CAF09. In mice treated with mEVX-01 a reduced tumor burden was observed compared to untreated or CAF09 only treated mice (p-value <0.05, unpaired t test with Welch's correction, Figure 10A). In whole blood from the mEVX-01 group, high frequent epitope-specific CD8+ T cells were detected (p-value <0.05, unpaired t test with Welch's correction, Figure 10B). Collectively, these pre-clinical data underline the ability of EVX-01 to promote functional T cells with tumor killing potential.

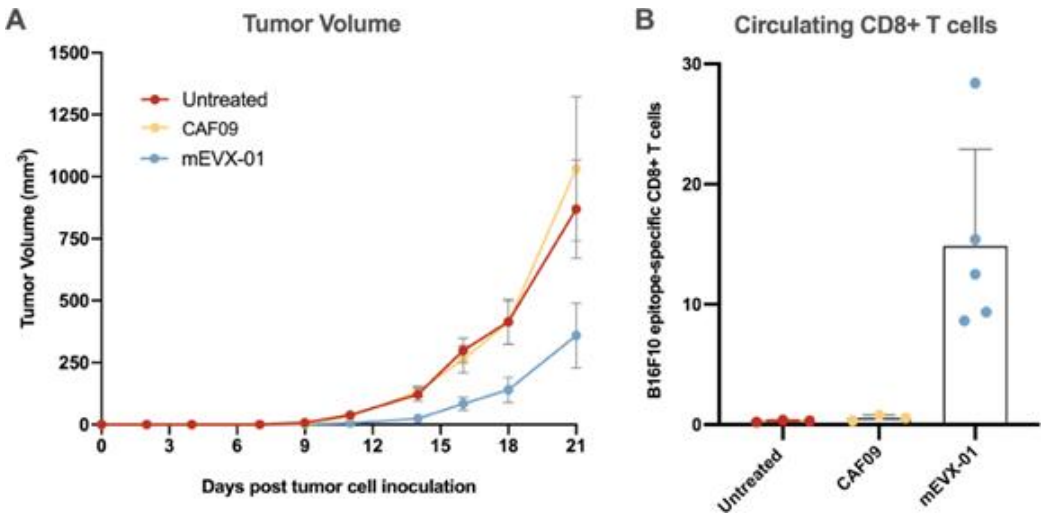

Figure 10: CAF09 was co-formulated with three well-described B16F10 specific CD8+ T cell epitopes, referred to as mEVX-01 in the graph. Mice were treated prophylactically with mEVX-01 starting two weeks prior to B16F10 tumor cell inoculation at day 0. P-values were calculated using unpaired t test with Welch's correction. 10A: P<0.05; 10B: P<0.05.

EVX-01 was developed in collaboration with a consortium consisting of Center for Cancer Immune Therapy at Herlev Hospital, Department of Health Technology at Danish Technical University, Center for Genomic Medicine at University Hospital Copenhagen and the Center for Vaccine Research at SSI. The development and Phase 1/2a clinical trial of EVX-01 was partly funded through a $3 million grant from the Innovation Fund Denmark. Evaxion retains all of the commercial development rights to EVX-01.

Addressable Market for EVX-01

We are currently developing EVX-01 for the treatment of advanced or metastatic unresectable melanoma with the potential to expand into other solid tumor types such as non-small cell lung cancer, or NSCLC, and bladder cancer. All indications we believe are large market opportunities with unmet medical need globally. According to the American Cancer Society, in 2021 there will be in the U.S.:

- 106,110 new melanoma cases and 7,180 deaths from melanoma;
- 235,760 new lung cancer cases and 131,880 deaths from lung cancer. NSCLC makes up on average 84% of all lung cancer cases; and
- 83,730 new cases of bladder cancer and 17,200 deaths from bladder cancer.

The treatment paradigm for metastatic and unresectable melanoma, NSCLC and bladder cancer has been revolutionized over the last few years with the approval of PD-1/PD-L1 CPIs across treatment lines, including first-line for metastatic and unresectable melanoma and in NSCLC as monotherapy or in combination with chemotherapy/other CPIs depending on a patient's status. In bladder cancer, PD-1/PD-L1 CPIs are approved in the first-line setting for cisplatin ineligible patients as well as later line treatments. Only a minority of patients in these three indications have durable responses to PD-1/PD-L1 CPIs with a majority of patients ultimately showing progressive disease. We believe that our therapeutic neoepitopes could change the treatment paradigm in combination with PD-1/PD-L1 CPIs across these three indications by expanding the patient population responding to PD-1/PD-L1 inhibitor treatment (CPI-resistant patients) and potentially increasing the effect in patients already responding to PD-1/PD-L1inhibitor treatment.

Our EVX-01 Phase 1/2a Clinical Trial

Our EVX-01 Phase 1/2a clinical trial was a first-in-human clinical trial of EVX-01 in combination with anti-PD-1 or anti-PD-L1 (NCT03715985). The trial commenced in January 2019 and was an open-label, single-arm trial. The objectives of the trial were to evaluate the safety/tolerability (primary endpoint) and immunogenicity and feasibility of manufacturing (secondary endpoint) and

establish a recommended Phase 2b dose, or RP2D. The trial was initially intended as a basket trial for three indications: metastatic melanoma, NSCLC and bladder cancer. The indications were subsequently changed to advanced or metastatic unresectable melanoma.

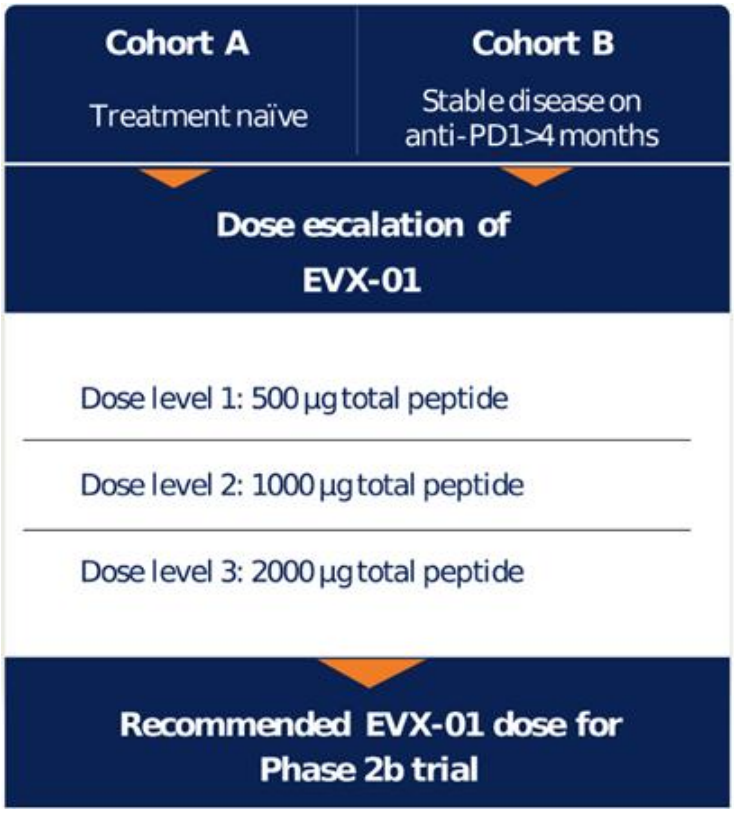

Figure 11: Clinical design of the first-in-human Phase 1/2a clinical trial in the EVX-01 program.

Initial Data Readout from Our EVX-01 Phase 1/2a Clinical Trial and MSD Collaboration

In July 2021, we announced initial data readout from our Phase 1/2a clinical trial of EVX-01 in advanced or metastatic unresectable melanoma demonstrating an ORR of 67% across all nine patients compared with a historical ORR of 40% with anti-PD-1 treatment alone. The study also demonstrated a CR of 22%, compared with a historical CR of 7% with anti-PD-1 treatment alone. Among the four patients on the highest two doses, there was an ORR of 75%. Three patients with stable disease, or SD, for 10, eight and nine months on anti-PD-1 treatment alone, achieved CR, CR and PR, respectively, following EVX-01 administration. In addition, the data showed induction of neoepitope-specific T cells in 100% of patients. 76.2% of the administered neoepitopes induced reactive T cells in patients, of which 83.3% were *de novo* responses. Data from the trial also showed that EVX-01 appeared to be well-tolerated with only Grade 1 and 2 adverse events such as fatigue and fever.

Based on our Phase 1/2a clinical trial initial data readout,on October 21,2021, we entered into the Merck CTCSA to evaluate in a new Phase 2b clinical trial, the combination of our patient-specific neoepitope cancer immunotherapy compound, EVX- 01, with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) compound, a humanized anti-human PD-1 monoclonal antibody.

In January 2022, we received regulatory clearance from the Australia Therapeutic Goods Administration, or the TGA, to initiate a Phase 2b clinical trial of our lead product candidate EVX-01 in combination with KEYTRUDA® for the treatment of melanoma. We expect to initiate our Phase 2b clinical trial in the first half of 2022.

Our EVX-01 Phase 1/2a Clinical Trial Data

As of December 31, 2021, 13 Stage IV (M1a-c) metastatic and unresectable melanoma patients were treated with EVX-01; five at dose level 1, three at dose level 2 and five at dose level 3.

Cohort	Months of SD on CPI prior to EVX-01 treatment	Best clinical response	% reduction of tumor target lesion	Dose level	Patient ID	CPI
B	10	CR	100%	2	D02_A	Pembrolizumab
B	8	CR	100%	1	D01_A	Pembrolizumab
B	9	PR	73%	2	D02_B	Pembrolizumab
B	8.5	SD	-	2	D02_C	Pembrolizumab
A	-	PR	56%	1	D01_B	Pembrolizumab
A	-	PR	77%	1	D01_C	Nivolumab
A	-	PR	45%	3	D03_A	Pembrolizumab
A	-	PD	11%	1	D01_E	Pembrolizumab
A	-	PD	-	1	D01_D	Pembrolizumab

Figure 12: Results on nine patients with metastatic melanoma treated with EVX-01 in the EVX-01 Phase 1/2a clinical trial.

Figure 13: % change in target lesion size for nine patients treated with EVX-01. Disease development determined according to RECIST criteria.

As shown in Figure 13 above, a benefit of the combination therapy was observed for six patients. Of these, two patients had a CR, four patients had a partial response, or PR, one patient had stable disease, or SD, and two patients had progressive disease, or PD as best outcome.

	EVX-01 ALL DOSE LEVELS	KEYTRUDA® LABEL[a]	KEYNOTE-006[b]
ORR	**67%**	33%	40%
CR	**22%**	6%	7%
PR	**44%**	27%	33%

	EVX-01 HIGH DOSE[c]	KEYTRUDA® LABEL[a]	KEYNOTE-006[b]
ORR	**75%**	33%	40%
CR	**25%**	6%	7%
PR	**50%**	27%	33%

Figure 14: Overview of RECIST disease assessment of EVX-01 compared to KEYTRUDA label (Keynote-006 study) and KEYNOTE-006 (Robert et al. 2015. Pembrolizumab versus Ipilimumab in Advanced Melanoma. N. Engl. J. Med. 372: 2521–32, Keynote 006 responses after 2 months corresponding to time from biopsy to first dose of EVX-01). High dose level refers to dose level 1 and 2.

As shown in Figure 14 above, ORR, CR and PR Achieved by EVX-01 in combination with anti-PD-1 compares favorably to anti-PD-1 treatment alone.

Immunogenicity Data From our EVX-01 Phase 1/2a

Immune monitoring data from the nine patients treated with EVX-01 demonstrated that 100% of patients had reactive T cells and 76.2% of the administered neoepitopes induced reactive T cells in patients, of which 83.3% were *de novo* responses (see Figure 15).

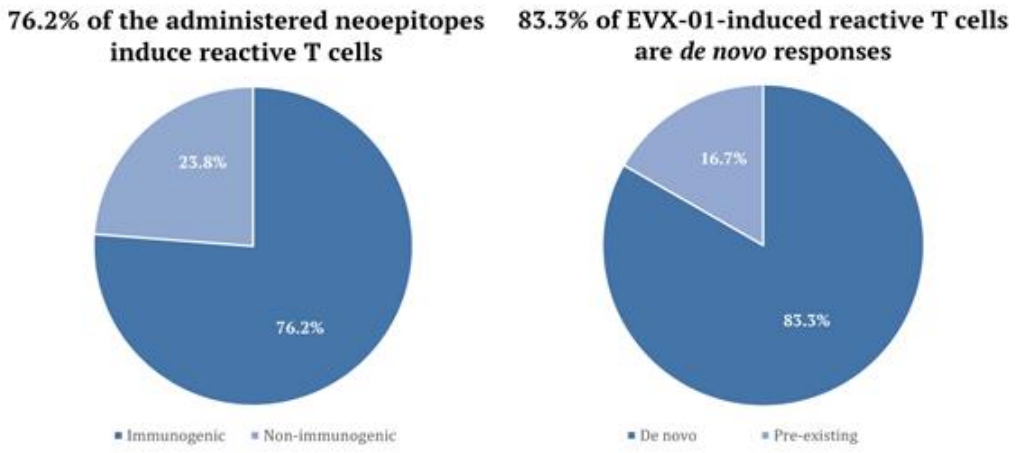

Figure 15: Immune readout for the nine patients treated with EVX-01 in combination with PD-1 inhibitor treatment.

Neoepitope and Clinical Response Correlations

As shown in Figure 16 below, we observe a correlation between broadness of immune response and clinical benefit when investigated if responding patients had a higher frequency of neoepitopes resulting in a tumor specific immune response as measured in blood by ELISpot. As seen in Figure 16, responding patients in general had a higher frequency of immunogenic neoepitopes after three EVX-01 doses. Furthermore, *de novo* induced neoepitopes were also more frequently induced in responding patients. We also observed a correlation between PIONEER predictions and clinical benefit when investigating the PIONEER score and the number of identified, high quality neoepitopes against clinical outcome in the nine patients. As seen in Figure 17 below, responding patients generally harbor more high scoring neoepitopes and more high quality neoepitopes.

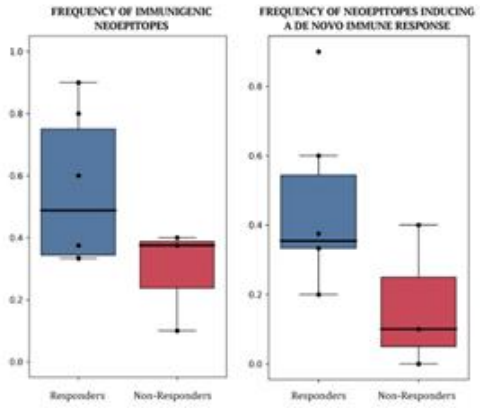

Figure 16: Frequency of immunogenic neoepitopes (left)and frequency of neoepitopes inducing a de novo immune response (right). Clinical response as defined by RECIST, immunogenic neoepitopes are defined as neoepitopes where the T-cell response (SFU) after three EVX-01 treatments is at least double the response induced by irrelevant peptides at the same timepoint, frequency of immunogenic neoepitopes is calculated per patient and de novo immunogenic neoepitopes are defined as neoepitopes where the T-cell response (SFU) is less than or equal to twice the response induced by irrelevant peptides at timepoints before EVX-01 treatment and at least double the response induced by irrelevant peptides after 3 EVX01 treatments.

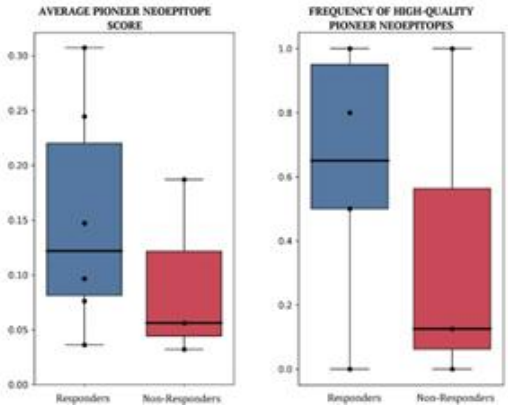

Figure 17: Average PIONEER neoepitope score (left) and frequency of high-quality PIONEER neoepitopes (right). Clinical response as defined by RECIST, mean PIONEER score is the mean PIONEER score of the 5-10 neoepitopes included in the treatment of individual patients, high quality neoepitopes are defined as neoepitopes with a PIONEER score above the median value of all neoepitopes included in the treatments in EVX-01 (5-10 neoepitopes per patient, 63 neoepitopes in total).

Patient Cases From our EVX-01 Phase 1/2a Trial

Patient D02_A is a 64-year-old female diagnosed with Stage IV (M1a) metastatic melanoma with a PD-L1 tumor expression of <1%. Lesion A (right arm sc, target lesion) and lesion B (abdominal sc) were identified at baseline. This patient had SD on CPI for 10 months prior to EVX-01 treatment (Cohort B) and achieved a complete response after treatment with EVX-01. The patient had a T-cell response to 100% of EVX-01 neoepitopes and the neoepitope-specific T-cell responses were observed to migrate to the neoepitope target. CT scan and PET-CT show complete elimination of the tumor following EVX-01 treatment.

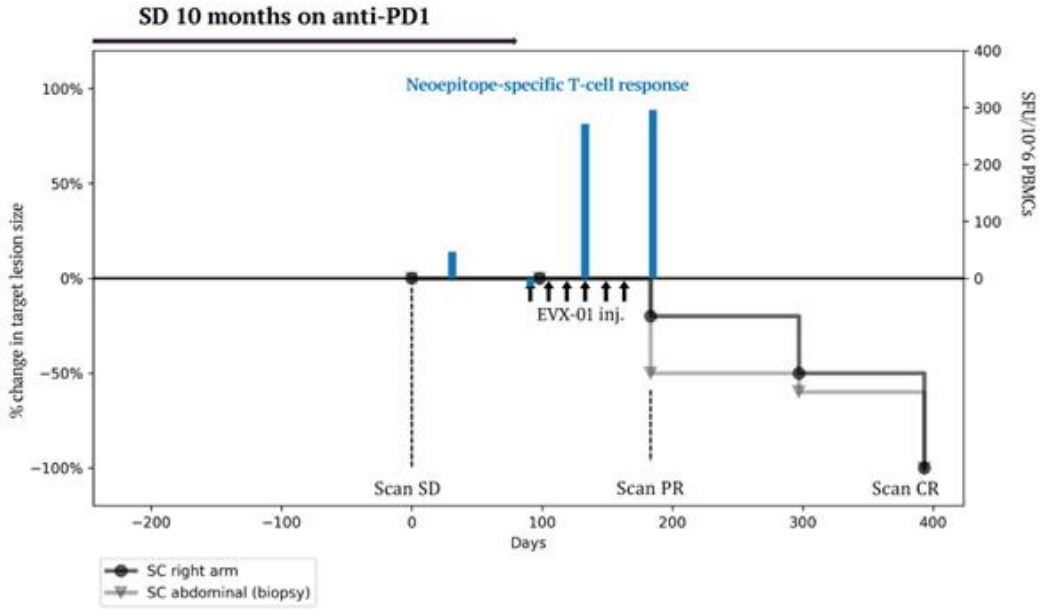

Figure 18: The change in lesion size measured for Patient D02_A. The % change in lesion size is plotted at each evaluation time point. The time point for each EVX-01 dose is indicated in the plots with black arrows. The strength of the neoepitope-specific immune response in patient PMBCs, as measured by IFNy ELISPOT, are also included in the spider plots, visualized with blue bars.

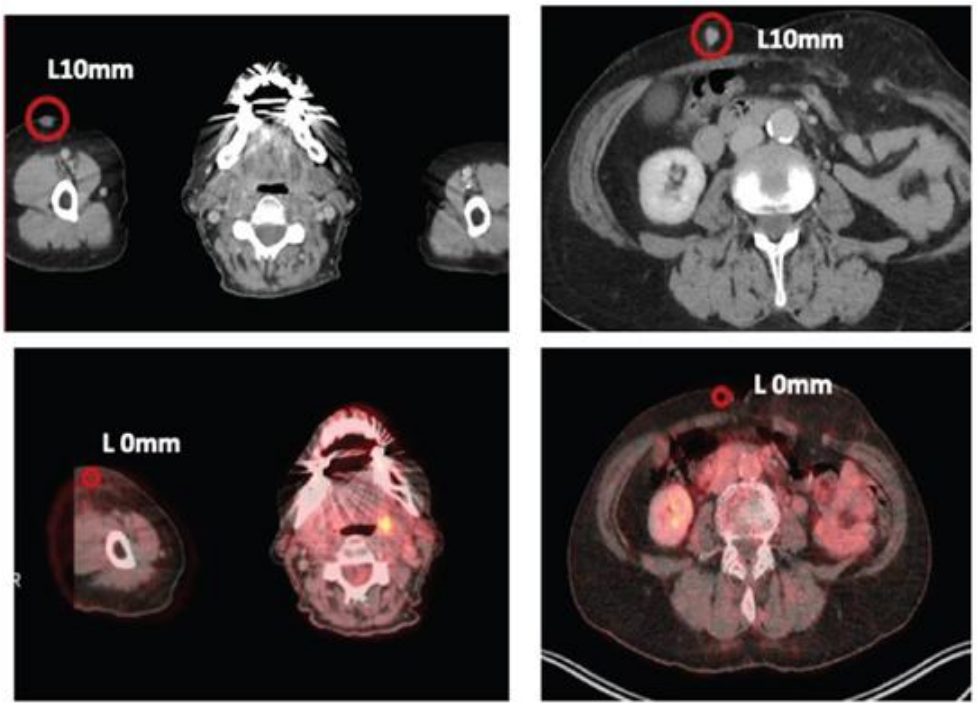

Figure 19: CT scan and PET-CT for Patient D02_A at enrollment (top) and following EVX-01 treatment (bottom).

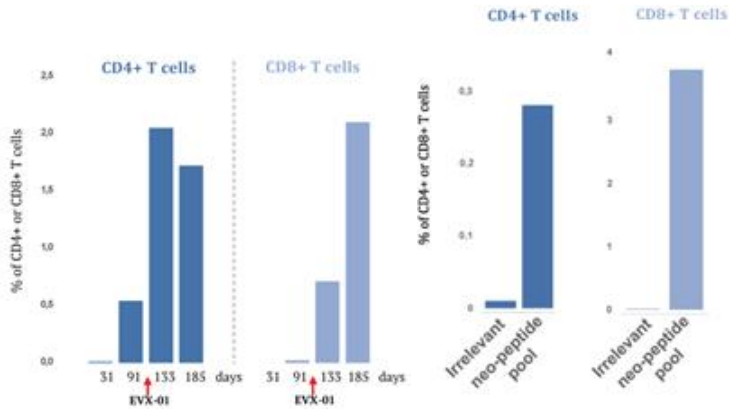

Figure 20 (left): EVX-01 induction of neoepitope-specific T cells in patient D02_A. T cells staining double positive for IFNg/TNFa/CD107a/CD137 upon stimulation with EVX-01 neopeptide pool. Figure 20 (right): EVX-01 induction of neoepitope-specific T cells that migrates to the neoepitope target, measured as Skin Infiltrating Lymphocytes (SKIL's) after 2 injections of EVX-01 for patient D02_A.

Patient D01_B is an 81-year-old male diagnosed with Stage IV (M1b) metastatic melanoma. Lesion A (left lung) and lesion B (left thorax wall) were identified at baseline. This patient was treatment näive upon enrollment (Cohort A) and achieved a partial response lasting more than 24.5 months after treatment with EVX-01. The patient had a T-cell response to 100% of EVX-01 neoepitopes, sustained EVX-01 specific T-cell levels and increased immune activation in the tumor microenvironment following EVX-01 treatment was observed. CT scan and PET-CT show clear reduction in tumor size following EVX-01 treatment.

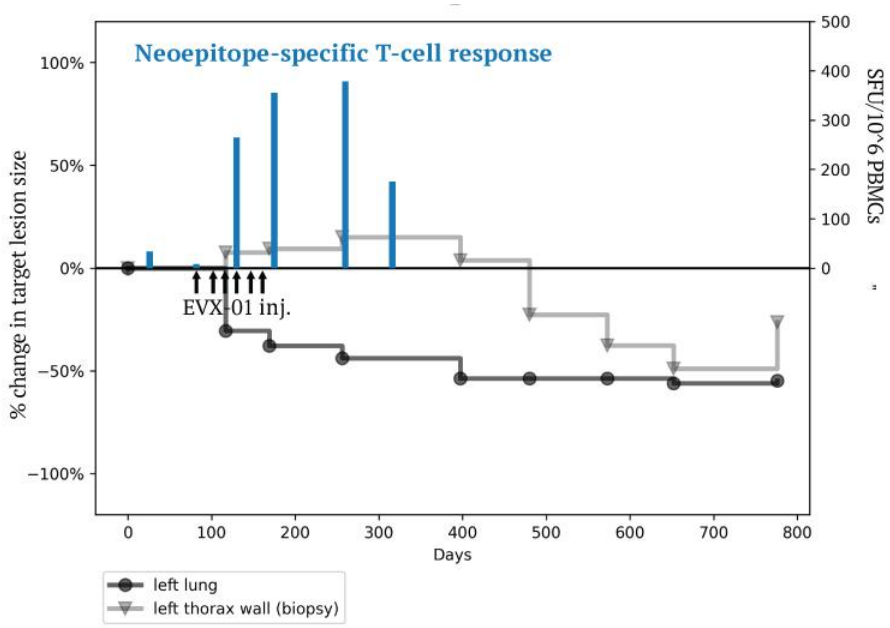

Figure 21: The change in lesion size measured for Patient D01_B. The % change in lesion size is plotted at each evaluation time point. The time point for each EVX-01 dose is indicated in the plots with black arrows. The strength of the neoepitope-specific immune response in patient PMBCs, as measured by IFNy ELISPOT, are also included in the spider plots, visualized with blue bars.

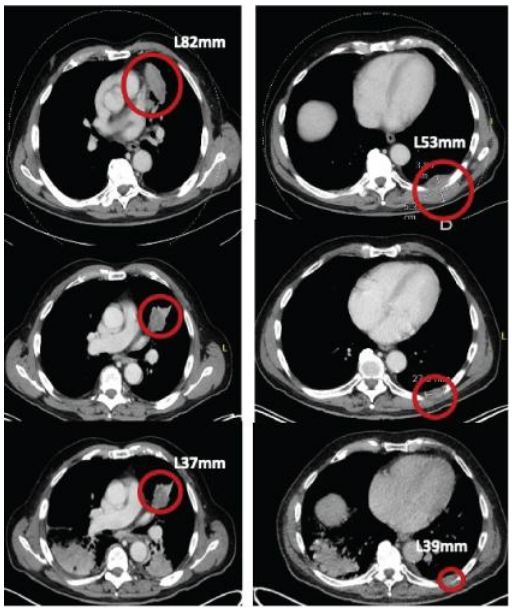

Figure 22: CT scan and PET-CT for Patient D01_B at enrollment (top) and following EVX-01 treatment (bottom).

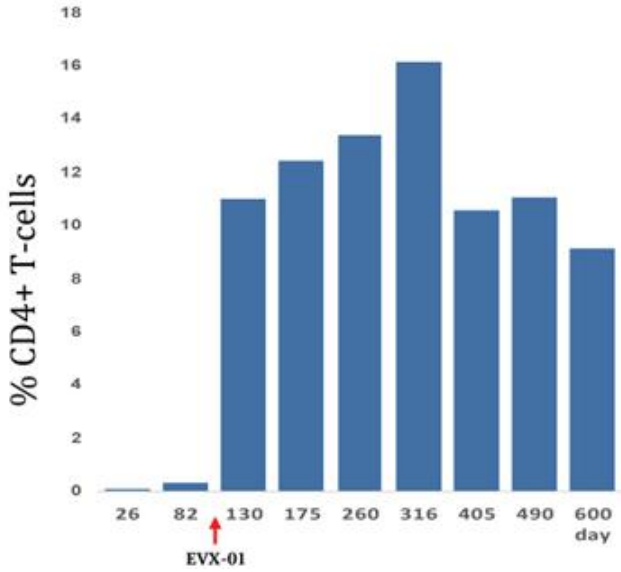

Figure 23: Sustained circulating CD4+ T-cell activation for patient D01_B. T cells staining double positive for IFNg/TNFa/CD107a/CD137 upon stimulation with EVX-01 neopeptide pool.

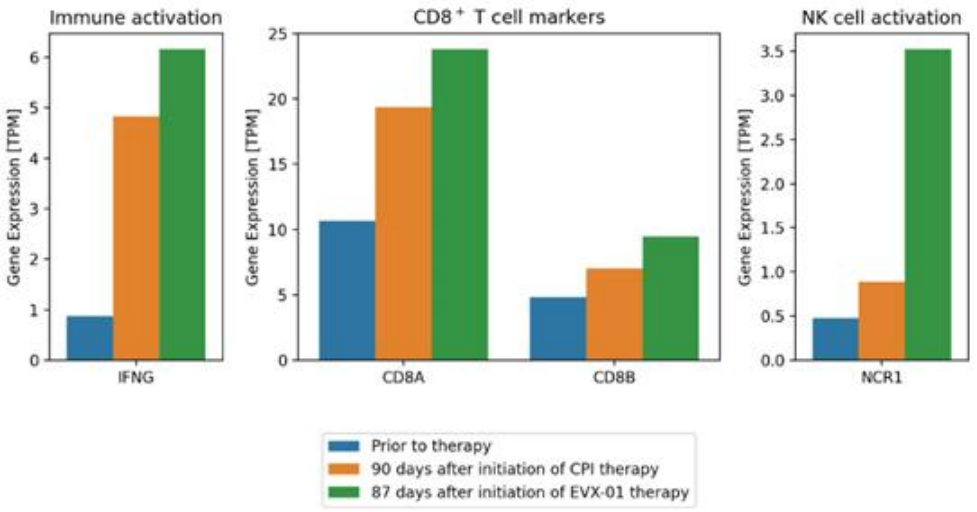

Figure 24: Genomic biomarker expression profiling of baseline and follow-up tumor biopsies of patient D01_B indicating that CD8+ T cells and NK cells are activated and infiltrating the tumor microenvironment. Induction is observed after CPI treatment and further induction is observed after EVX-01 treatment.

Our EVX-01 Phase 1/2a Clinical Trial Dose Escalation and Safety Reporting

Data from our clinical trial suggest that patients treated with higher dose levels of EVX-01 (dose level two and three) seem to have a better T-cell response. When investigating the effect of peptide dose on T-cell response in general, we find that higher dose levels increase ORR and T-cell activation, see Figure 25 below.

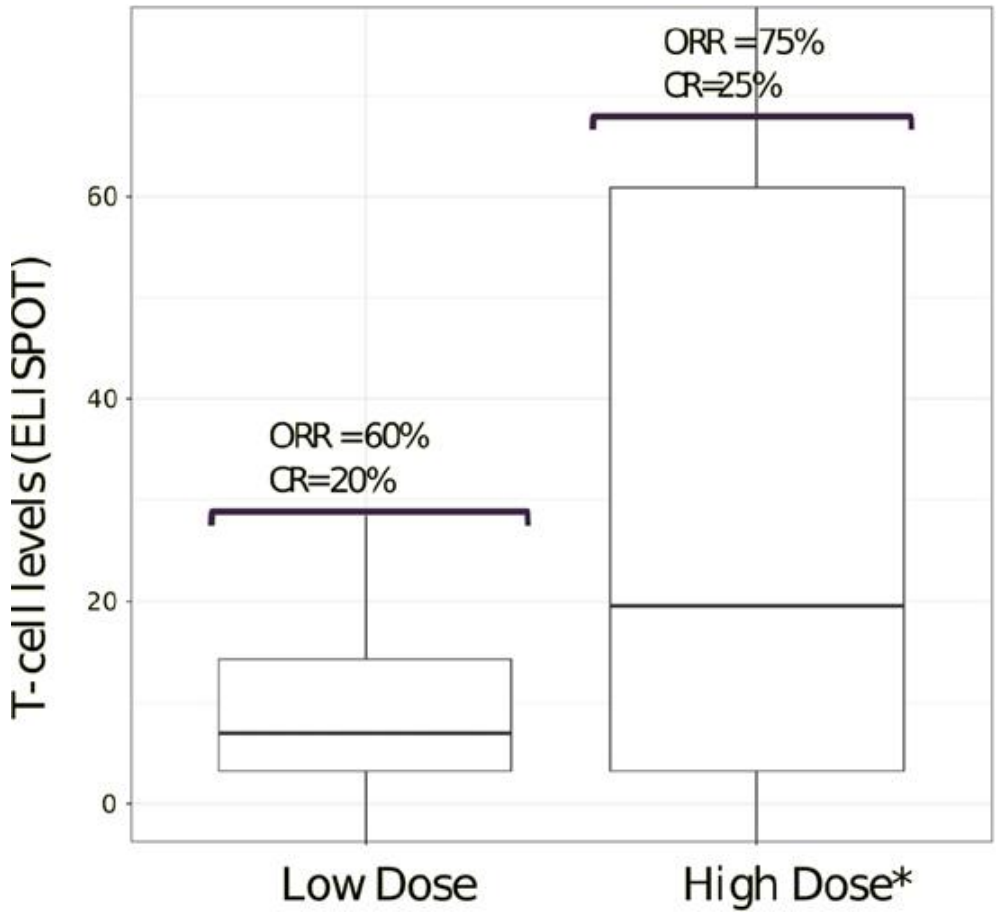

Figure 25: ELISpot count of each peptide plotted as a function of dose. * Dose levels 2 and 3.

Increasing the dose level of EVX-01 does not affect the safety profile. Only grade 1 and 2 treatment related adverse events, or TRAEs, were observed across the three dose levels. Most frequently observed TRAEs include fatigue, stomach pain and fever.

EVX-01 Treatment Related Adverse Events (TRAEs) 9 patients	
Grade 1	8 (88.8%)
Grade 2	4 (44.4%)
Grade 3	0 (0%)
Leading to drug discontinuation	0 (0%)
Leading to death	0 (0%)

Figure 26: Summary of safety data observed for the nine patients treated with EVX-01.

Our Phase 2b Clinical Trial Plans

Based on our Phase 1/2a clinical trial initial data readout,on October 21,2021, we entered into the Merck CTCSA to evaluate in a new Phase 2b clinical trial, the combination of our patient-specific neoepitope cancer immunotherapy compound, EVX- 01, with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) compound, a humanized anti-human PD-1 monoclonal antibody. We expect to initiate our Phase 2b clinical trial in the first half of 2022.

The proposed Phase 2b clinical trial will be an open-label, multi-center, single arm trial evaluating the efficacy (best objective response, overall response rate, progression free survival and overall survival) and safety of EVX-01 in adults with advanced or metastatic unresectable melanoma on pembrolizumab (anti-PD-1 antibody) treatment. The trial will be powered to show an improvement in the best overall response of patients with SD or PR after 12 weeks on pembrolizumab treatment. The trial design is guided by recently published KEYNOTE-001 and 006 data from MSD which demonstrates that advanced melanoma patients with SD at week 12 and subsequent progression had poor survival outcomes. We believe EVX-01 in combination with pembrolizumab has the potential to significantly improve patient outcomes. The trial design is developed in collaboration with world leading KOLs; Georgina Long (Melanoma Institute Australia, AU), Patrick Ott (Dana-Faber Cancer Institute, USA) and Inge-Marie Svane (Center for Cancer Immune Therapy, Denmark), and will be conducted in partnership with MSD.

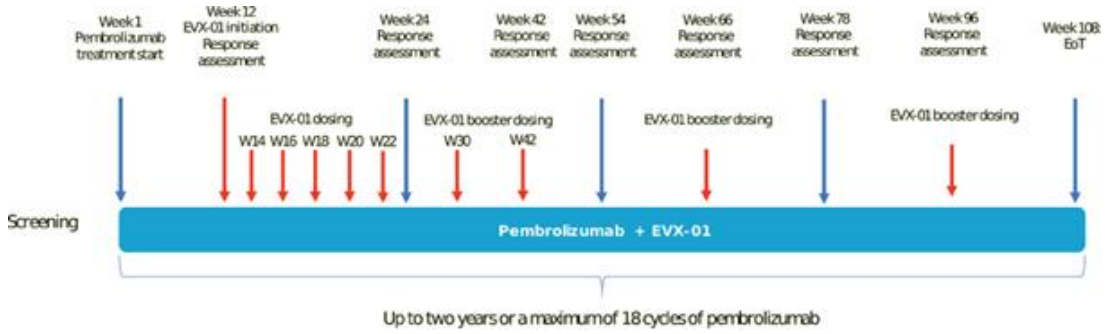

Figure 27: EVX-01 Phase 2b clinical trial design.

The trial design allows for fast readout, and we anticipate interim readout in the second half of 2023, 1-year readout in 2024 and 2-year readout in 2025. Each readout will serve as a decision point for out-licensing the program. First-patient-first-visit is planned for the first half of 2022.

Manufacturing of Our EVX-01 Drug Product

The peptide-based format used to deliver PIONEER-identified neoepitopes in EVX-01 is able to specifically stimulate neoepitope-specific T cells and has a turnaround time of approximately seven weeks from collection of patient-specific biopsies to administration of the therapy. We believe that this seven-week turnaround time is significantly shorter as compared to other current patient-specific, peptide-based, immunotherapies, which have been shown to have turnaround times of 20 or more weeks. Using the peptide-based format, we believe that we have successfully addressed a major bottleneck in the production of patient-specific immunotherapies and can significantly accelerate the manufacturing process for the treatment of patients with advanced cancer.

Our Second Lead Product Candidate EVX-02

Overview

Our second lead product candidate, EVX-02, for adjuvant treatment of resectable melanoma, was also developed using our PIONEER AI platform. EVX-02 is a novel, neoepitope-based immunotherapy administered using a DNA plasmid modality. We have chosen a DNA-based format due to its strong pre-clinical data, its self-adjuvating effects and because of its potential for delivery of a large number of neoepitopes simultaneously.

The goal of the cancer immunotherapy is to promote T-cell priming and expansion of effector T cells for direct and specific tumor killing. It is well-established that DNA vaccination harbors self-adjuvating effects via the innate DNA sensing machinery in mammalian cells. This directs the immune response towards Th1-like immunity which is generally considered to be preferable in cancer therapies. Further, the DNA plasmid allows for a large number of neoepitopes to be delivered simultaneously in one single drug molecule thus making it possible to include all top ranked PIONEER predicted neoepitopes in the therapy. When administered to the patient, we expect that EVX-02 DNA plasmid will be taken up by APCs and neoepitopes will be expressed, processed into smaller components and loaded onto the MHC molecules on the cell surface eliciting a neoepitope-specific immune response.

Addressable Market for EVX-02

Despite the recent significant advances with the use of CPIs for melanoma, there continues to be a significant unmet medical need for patients with Stage IIIB/IIIC/IIID and Stage IV melanoma that are completely surgically excised. With current standard of care, approximately 30.0% of patients relapse within one year and more than 40.0% within three years and eventually succumb to their disease. Thus, we believe well-tolerated and effective treatments are still needed in the adjuvant setting of melanomas to improve clinical outcomes.

Our EVX-02 Pre-Clinical Data

The pharmacological effect of EVX-02 mouse specific compounds was addressed in the well-established CT26 syngeneic tumor mouse model. As the EVX-02 immunotherapy is truly patient-specific and the plasmid design is based on each patient's individual tumor mutational profile, pre-clinical efficacy testing of patient-specific EVX-02 molecules is not feasible. Instead, mouse surrogate compounds were designed by PIONEER directed identification of CT26 tumor-specific neoepitopes.

In several *in vivo* pharmacology studies, treatment with a mouse specific EVX-02 immunotherapy, or mEVX-02, induced robust, dose-dependent antitumor immunity in the CT26 tumor model (see Figure 28A and Figure 29 below). Moreover, we have demonstrated enhanced antitumor effects by including both MHC class I and II epitopes in the mEVX-02 neoepitope-targeting immunotherapy (Figure 30) and by combining mEVX-02 immunizations with anti-mouse PD1 treatment (Figure 31). Further, detailed complementary *ex vivo* analyses, unravelling the mEVX-02 induced T-cell response, demonstrated neoepitope-recognizing circulating CD8+ T cells (see Figure 28B below) and neoepitope-reactive T cells in the spleens of EVX-02 treated mice as evidenced by cytokine positive CD4+ and CD8+ T cells (Figure 28C-D).

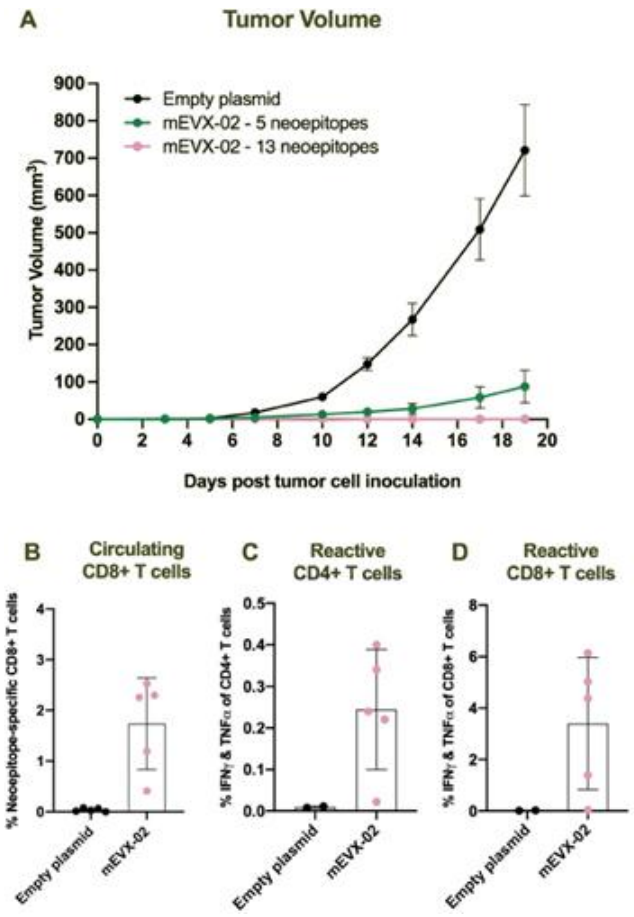

Figure 28: In vivo pharmacology study testing the antitumor effect of a mouse EVX-02 surrogate compound. P-values were calculated using unpaired t test with Welch's correction. 30A: P<0.001 (tumor volume AUC of Empty plasmid vs mEVX-02 - 5 neoepitopes) and P<0.001 (tumor volume AUC of Empty plasmid vs mEVX-02 - 13 neoepitopes); 29B: P<0.05 Empty plasmid vs mEVX-02 - 13 neoepitopes, 30C: P<0.05 Empty plasmid vs mEVX-02 - 13 neoepitopes, 28D: P<0.05 Empty plasmid vs mEVX-02 - 13 neoepitopes.

As shown in Figure 28 above, groups of BALB/c mice were intramuscular, or IM, administered with 100 µg empty plasmid or plasmids encoding either 5 or 13 top ranked PIONEER identified CT26 neoepitopes, co-formulated with poloxamer 188, designated Empty plasmid, mEVX-02 - 5 neoepitopes and mEVX-02 - 13 neoepitopes, respectively. Figure 28A shows that the mEVX-02 compound containing 13 neoepitopes completely prevented tumor establishment (n=13-14 in all groups). Whole blood neoepitope-MHC I tetramer staining revealed presence of circulating neoepitope-specific CD8+ T cells in the mEVX-02 groups as illustrated in Figure 28B. Complementary *ex vivo* analysis revealed intermediate and high levels of neoepitope-reactive CD4+ and CD8+ T cells, respectively, in the mEVX-02 -13 neoepitope group depicted in Figure 28C and 30D.

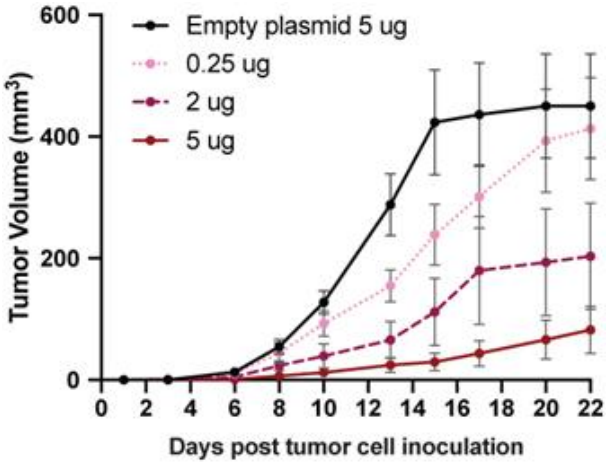

Figure 29: mEVX-02 dose-dependently inhibited the growth of subcutaneous CT26 tumors. In mice immunized with PIONEER-predicted neoepitopes encoded in a plasmid DNA at doses as low as 5 µg DNA, the growth of CT26 tumors was prevented.

As shown in Figure 29 above, in BALB/c mice IM administered with either 0.25, 2 or 5 ug of clinically grade mEVX-02 plasmid encoding 13 PIONEER identified CT26 neoepitopes, co-formulated with poloxamer 188, a clear dose-response effect was obtained (n=13-14 in all groups).

In further *in vivo* studies, we have demonstrated that the antitumor effect is enhanced by including both MHC class I and II neoepitopes in the mEVX-02 drug construct compared to either a mono MHC class I or II neoepitope-targeting immunotherapy (see Figure 30).

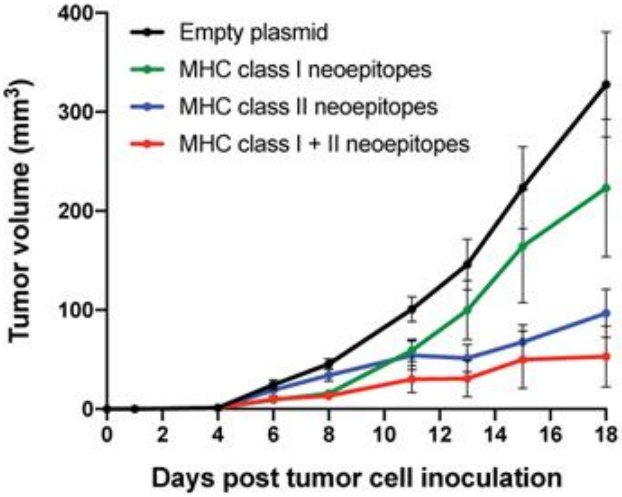

Figure 30: In vivo tumor study investigating the interplay of MHC class I and II neoepitopes in mEVX-02-mediated antitumor immunity. P-values were calculated using unpaired t test with Welch's correction. Not significant (tumor volume AUC of Empty plasmid vs MHC I neoepitopes), P<0.001 (tumor volume AUC of Empty plasmid vs MHC II neoepitopes) and P<0.001 (tumor volume AUC of Empty plasmid vs MHC I+II neoepitopes).

As depicted in Figure 30 the mean tumor volume observed in CT26 bearing BALB/c mice IM administered with 50 µg mEVX-02 containing two MHC class I and three class II neoepitopes was reduced compared to the tumor volumes in mice treated with either 50 µg mEVX-02 consisting of the two MHC class I or the three MHC class II PIONEER predicted neoepitopes. (n=13-14 in all groups.).

In an additional *in vivo* pharmacology study, co-treatment with a suboptimal mEVX-02 dose and an anti-mouse PD-1, or mPD-1, antibody led to a combinatorial antitumor effect in a syngeneic tumor model illustrated by an increase in time to reach humane endpoints in mEVX-02 + anti-mPD-1 administered mice compared to single compound treatment groups (see Figure 31 below).

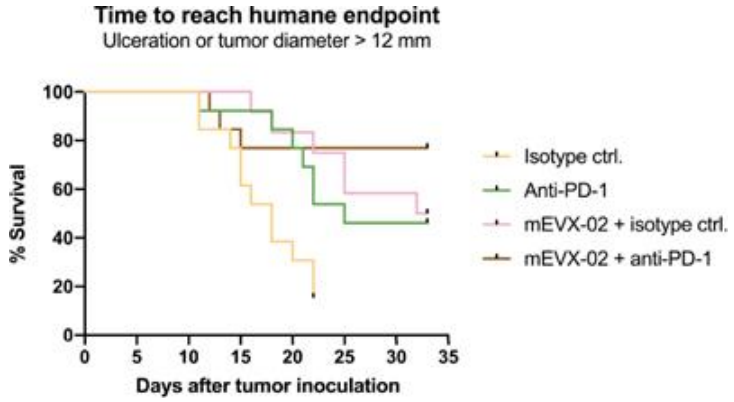

Figure 31: In vivo tumor study investigating the combinatorial effect of mEVX-02 and anti-mPD-1 antibody. P-values were calculated using log-rank (Mantel-Cox) test P<0.01.

In Figure 31, the time to reach humane endpoint, defined by tumor ulceration or a tumor diameter of more than 12 mm, was increased in CT26 tumor bearing BALB/c mice receiving IM injections of a sub-optimal mEVX-02 dose and intraperitoneal, or IP, injections of 200 µg anti-mPD-1 antibody compared to mEVX-02 and anti-PD-1 monotherapy. The anti-PD-1 antibody treatment was initiated when the tumors reached a mean volume 80-100 mm^3 in the groups receiving mEVX-02 treatment. As control for unspecific antibody mediated antitumor effect, parallel isotype control antibody groups were included (n=12-13 in all groups.).

The comprehensive *in vivo* pharmacology data package provides clear evidence of complete EVX-02 induced antitumor responses accompanied by induction of reactive CD4+ and CD8+ T cells and an effect of combining the EVX-02 therapy with standard of care, for example, CPI treatment. The pre-clinical data holds great promise for an efficient patient-specific neoepitope immunotherapy to the benefit of patients suffering from resectable melanoma.

Our EVX-02 Phase 1/2a Clinical Trial

The EVX-02-001 clinical trial is a first-in-human, open label, safety and pharmacodynamic multi-center trial in resectable Stage III/IV melanoma patients (NCT04455503), initiated in the third quarter of 2020. Each patient will, upon tumor resection, receive a unique EVX-02 immunotherapy designed based on their tumor genomic fingerprint in combination with PD-1 CPI. Each patient will receive eight doses of EVX-02 at a two-week interval. Antibodies targeting PD-1 will be administered before, during and after administration of EVX-02 to unleash the potential of the induced EVX-02-specific T cells as well as direct and specific tumor killing. Our goal for the clinical development of EVX-02 is to take it through completion of Phase 2b clinical trials.

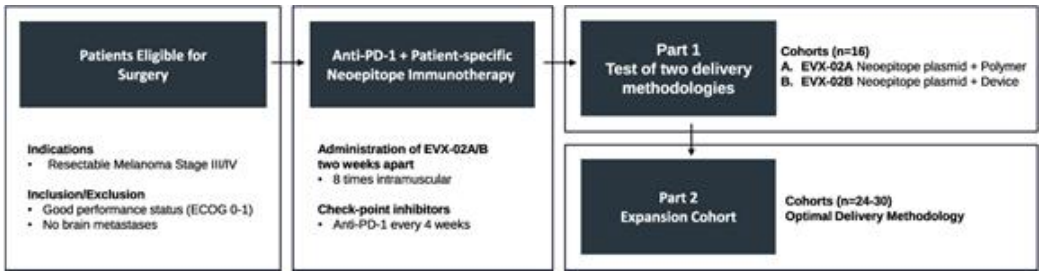

Figure 32: Clinical design of the first-in-human Phase 1/2a clinical trial of EVX-02.

As shown in Figure 32 above, the EVX-02-001 clinical trial was intended to consist of two parts. In the first part, two different methodologies for DNA plasmid delivery are being evaluated. The second part was intended to consist of an expansion cohort of the most effective DNA delivery modality, determined by assessment of safety and induced immune response. We believe data from the ongoing EVX-02-001 clinical trial supports progressing the development of EVX-02 from Part 1 into a subsequent Phase 2b trial. As of December 31, 2021, 16 patients were recruited in the EVX-02-001 trial. In March 2022, we reported completion of recruitment of Part 1 of the EVX-02 Phase 1/2a clinical trial.

Preliminary Data Readout from Our EVX-02 Phase 1/2a Clinical Trial

In July 2021 we announced preliminary data readout from our Phase 1/2a adjuvant clinical trial of EVX-02 in resectable melanoma demonstrating activation of neoepitope-specific T cells with tumor killing potential. In addition, EVX-02 appeared to be well-tolerated.

Patient ID	Administration methodology	Ex vivo ELISPOT	IVS[1] ELISPOT	ICS[2] CD4+ T cells	ICS[2] CD8+ T cells	Reactive neoepitopes
101-E01	Jet Injector	Yes	Yes	Yes	Yes	8/13
104-E01	Polymer	Yes	Yes	Yes	Yes	7/13

Figure 33: Preliminary clinical data from first two patients treated with EVX-02.

Our EVX-02/EVX-03 Phase 2b Clinical Trial Plans

We believe preliminary clinical immune and safety data from the Phase 1/2a clinical trial of EVX-02 together with pre-clinical data from both our DNA-based patient-specific cancer immunotherapies, EVX-02 and EVX-03, support moving into a combined Phase clinical 2b trial for which we intend to submit a regulatory filing in the first half of 2022. The proposed combined Phase 2b clinical trial will be a randomized, multi-center, three-arm adjuvant trial in 225 patients with Stage IIIB/IIIC/IIID and Stage IV resectable melanoma, studying our DNA-based patient-specific cancer immunotherapies, EVX-02 and EVX-03 in combination with anti-PD1 against anti-PD1 monotherapy. The objectives of the trial are to evaluate recurrence-free survival (primary) and the induction of relevant immunologic response (secondary). First-patient-first-visit is planned for the second half of 2022.

Manufacturing Our EVX-02 Drug Product

To produce patient-specific therapies, DNA plasmids are designed to encode 13 PIONEER identified neoepitopes. EVX-02 is manufactured in two investigational drug products: EVX-02A is patient-specific DNA plasmid formulated with Poloxamer 188 delivered by a standard syringe IM and EVX-02B is patient-specific DNA plasmid delivered via the PharmaJet Stratis® needle-free injection system for IM administration. We have established a manufacturing process with a number of different contract development and manufacturing organizations, or CDMOs, and the entire process from the time of patient biopsy to the time of treatment for these two drug products takes approximately 10 to 12 weeks.

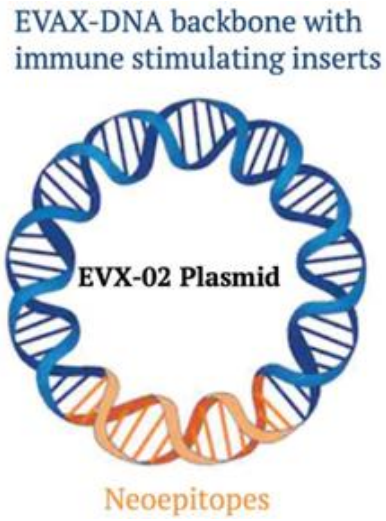

Figure 34: Illustration of our EVX-02 DNA plasmid containing a backbone vector with immune stimulating inserts and PIONEER-identified neoepitopes.

Our Third Lead Product Candidate EVX-03

Overview

Our third lead product candidate based on our PIONEER AI-platform, is a next generation neoepitope-based immunotherapy using a DNA modality with a proprietary APC targeting unit for the treatment of a variety of cancers. EVX-03 is in late pre-clinical development. Data from our pre-clinical studies demonstrates high levels of neoepitope-reactive T cells as well as antitumor effect as shown in Figures 37-39. We intend to submit a regulatory filing for a combined EVX-03 and EVX-02 Phase 2b clinical trial in the first half of 2022.

Directing neoepitopes to APCs is known to be an effective way to initiate an immune response by mediating maturation of the APCs. APC-targeting can be accomplished by introducing modules that selectively engage receptors on specific APC populations.

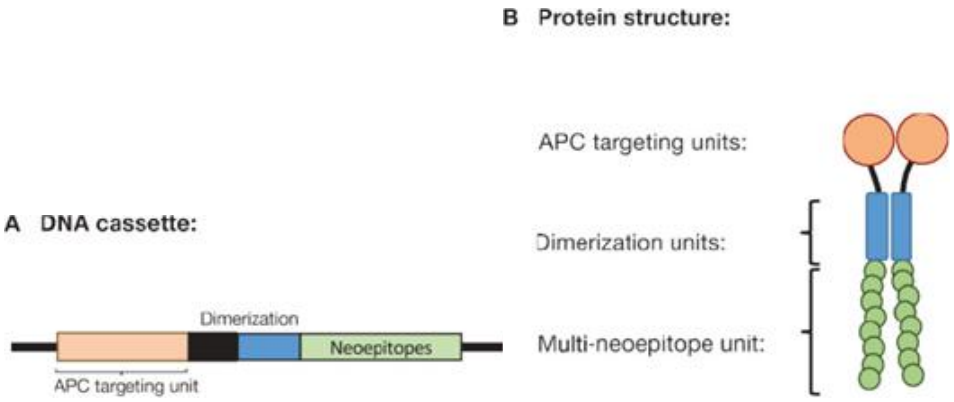

Figure 35: Design and protein structure of our proprietary APC targeting EVX-03 compound.

Figure 35A above shows that the EVX-03 plasmid contains a cassette encoding a fusion protein with an APC targeting unit, a dimerization domain and a multi-neoepitope unit. Figure 35B above shows that the translated protein product from the DNA cassette will form a homo-dimeric structure through the dimerization domain, which improves stability of the protein and APC internalization.

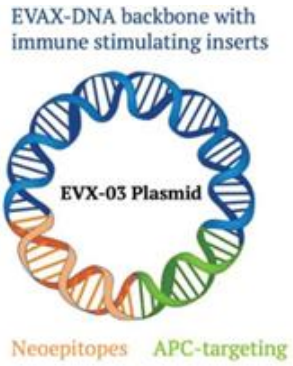

Figure 36: Illustration of our EVX-03 DNA plasmid containing a backbone plasmid with immune stimulating inserts, PIONEER-identified neoepitopes and an APC-targeting unit.

Our EVX-03 Pre-Clinical Data

The pharmacological effect of EVX-03 mouse specific compounds was addressed in the well-established CT26 syngeneic mouse tumor model. As the EVX-03 immunotherapy is truly patient-specific and the plasmid design is based on each patient's individual tumor mutational profile, pre-clinical efficacy testing of patient-specific EVX-03 molecules is not feasible. Instead, mouse surrogate compounds were designed by PIONEER directed identification of CT26 tumor-specific neoepitopes.

Figure 37A and 37B below show that the majority of mice treated with mouse EVX-03, or mEVX-03, had complete tumor eradication compared to mice treated without an APC targeting unit. Figure 37C below shows that two weeks after tumor inoculation, whole blood neoepitope-MHC I tetramer staining revealed higher levels of neoepitope-specific CD8+ T cells in the group treated with mEVX-03 compared to mEVX-03 without a targeting unit. Figure 37D below shows that complementary *ex vivo* analysis revealed higher levels of neoepitope-reactive T cells in the mEVX-03 group as compared to mEVX-03 without a targeted unit.

Figure 38 below shows that EVX-03 induces both a CD4+ and CD8+ neoepitope-specific T-cell response cells detected by intracellular cytokine staining.

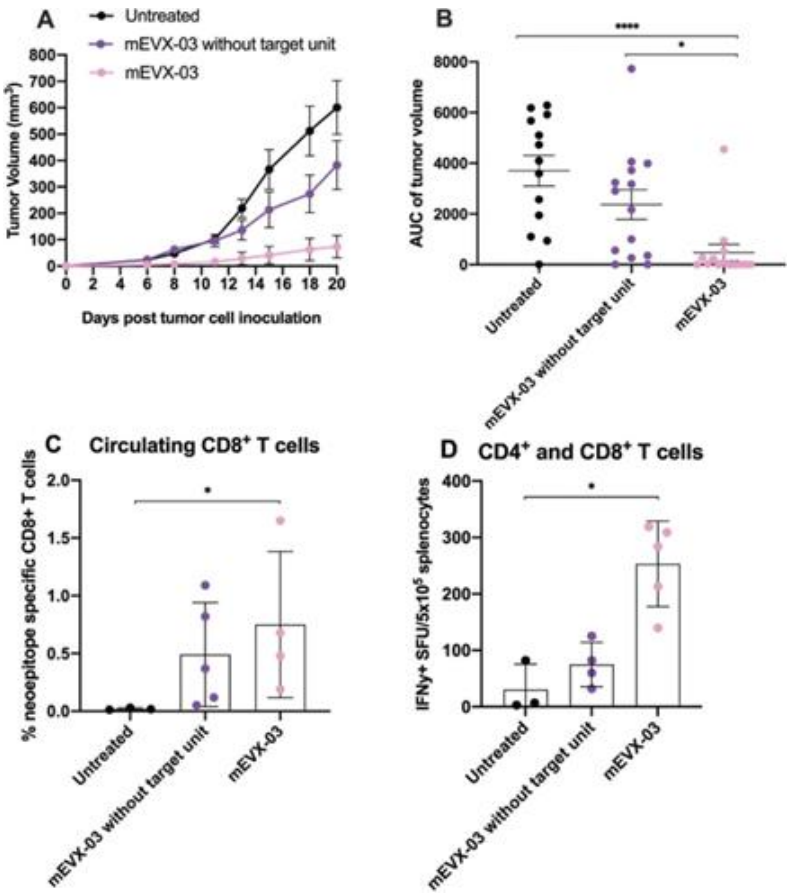

Figure 37: In vivo pre-clinical data for EVX-03. AUC = Area under the curve. Statistical analysis was performed using non-parametric Kruskal-Wallis with Dunn's multiple comparison corrections (*p<0.05, ****p<0.0001).

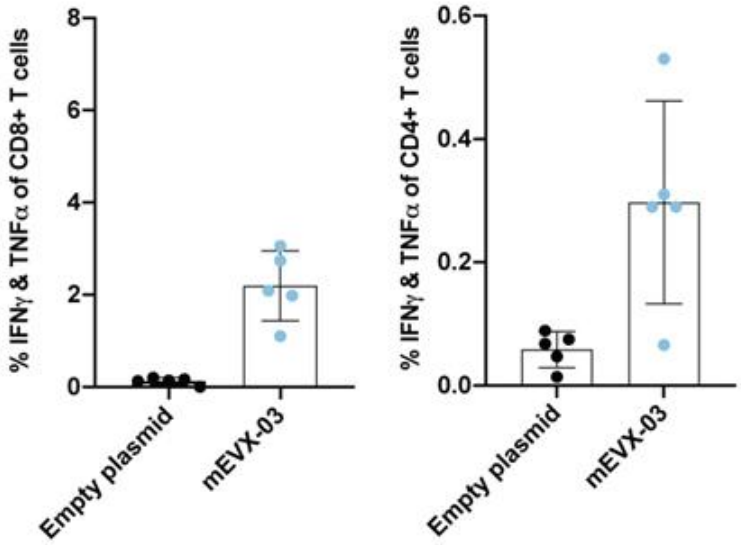

Figure 38: In vivo pre-clinical data for EVX-03 showing mEVX-03 induces neoepitope-reactive CD4+ and CD8+ T cells detected by intracellular cytokine staining.

In Figure 39 below, BALB/c mice were prophylactically treated once a week starting two weeks prior to CT26 tumor cell inoculation. mEVX-03 DNA doses ranging from 5-0.25 µg plasmid encoding the thirteen top ranked PIONEER identified CT26 neoepitopes, co-formulated with poloxamer 188, were IM administered to the mice. mEVX-03 doses as low as 0.25 µg elicited a significant antitumor effect.

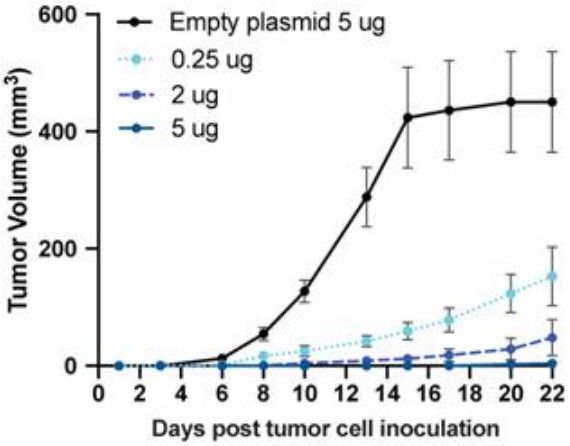

Figure 39: In vivo pre-clinical data for EVX-03. Establishment of subcutaneous CT26 tumors is prevented in mice immunized with PIONEER-predicted neoepitopes encoded in a plasmid DNA. Antitumor efficacy at DNA doses as low as 0.25 µg is observed.

Our EVX-03 Clinical Development Plans

Our EVX-03 product candidate is currently in pre-clinical development. We believe preliminary clinical immune and safety data from the Phase 1/2a clinical trial of EVX-02 together with pre-clinical data from both our DNA-based patient-specific cancer immunotherapies, EVX-02 and EVX-03, support moving into a combined Phase 2b clinical trial for which we intend to submit a regulatory filing in the first half of 2022.

The proposed combined Phase 2b clinical trial will be a randomized, multi-center, three-arm adjuvant trial in 225 patients with Stage IIIB/IIIC/IIID and Stage IV resectable melanoma , studying our DNA-based patient-specific cancer immunotherapies, EVX-02 and EVX-03 in combination with anti-PD1 against anti-PD1 monotherapy. The objectives of the trial are to evaluate recurrence-free survival (primary) and the induction of relevant immunologic response (secondary). First-patient-first-visit is planned for the first half of 2022.

AI-DeeP, Our Proprietary Immuno-Oncology Platform for Prediction of Drug Response

We recently developed AI-DeeP, an AI-immunogenetic drug response prediction platform, that is based on immunogenetic expression signatures in the tumor microenvironment and seeks to identify patients who may benefit from cancer immunotherapies.

As shown in Figure 40 below, AI-DeeP identifies patients responding to therapy with high precision. When applied to EVX-01, we see an increase in ORR to 100% versus 67% without the predictions of AI-DeeP. We believe this platform may decrease clinical development risk and increase patient and payer benefit through patient stratification based on predicted likelihood of response to immunotherapy. We continue to generate data to further validate and increase sensitivity and precision of AI-DeeP.

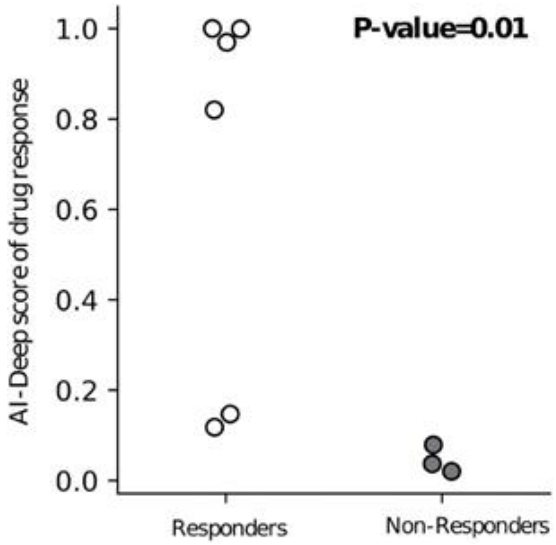

Figure 40: Prediction of patient response to immunotherapy from immunogenetic expression profiles in baseline tumor biopsy. At enrollment to the EVX-01clinical trials, tumor biopsies were collected from malignant melanoma patients. Immunogenetic profiling was performed on the tumor biopsies using RNA sequencing. Leave-one-patient- out analysis demonstrate that patient outcomes can be successfully predicted on the 9 patients in the EVX-01 clinical trial. The prediction of patient outcome was found statistically significant (p=0.01) using the permutation test.

Bacterial Diseases

Drug-resistant bacteria pose a major medical and societal issue as bacteria are rapidly becoming resistant to many of the antibiotics that are currently used as standard of care. According to the World Health Organization, or the WHO, antibiotic resistance is one of the biggest threats to global health and it is rising to dangerously high levels in all parts of the world. New resistance mechanisms are emerging and spreading globally, threatening our ability to treat common bacterial diseases. A misuse of antibiotics is accelerating this process.

We believe the development of prophylactic vaccines is the sustainable solution to address and counteract drug-resistant bacterial infections for several reasons, including:

- Vaccines can be used for decades without generating significant resistance

- Vaccines reduce antimicrobial use to further diminish pressure toward resistance
- Vaccines are cost-effective

The market for combatting drug-resistant bacteria is projected to increase significantly. According to The World Bank, drug-resistant infections could by 2050 cause global economic damage on par with the 2008 financial crisis. The Global Bacterial Vaccines Market was valued at $16.27 billion in 2018 and is projected to reach $29.85 billion by 2026, growing at a CAGR of 7.9% from 2019 to 2026.

Bacterial Vaccinology

Vaccines work by training the immune system to recognize and combat pathogens, either bacteria or viruses. To do this, certain molecules, called antigens, from the pathogen must be introduced into the body to trigger a protective immune response. By injecting vaccines containing antigens, the immune system will safely recognize them and trigger an immune response that leads to protective immunity. If the antigen-harboring bacteria or virus appears in the body during an early infection, the immune system will recognize the antigens displayed and immediately attack the pathogen before it can invade and establish a persistent infection and cause disease. The antigens can be secreted toxins or specific virulence factors and by targeting them, the pathogen can more easily be neutralized.

The adaptive immune response following vaccination protects the body from infections by mounting a specific antibody-mediated immune response (B-cell response) and/or a T-cell response. Antibodies can have different functions, but in general they either lead to neutralization of the pathogen (blocking function of important surface molecules or toxins), opsonization (antibodies bind to pathogen surface and flag them for phagocytosis and killing by immune cells), or complement activation (bound antibodies trigger a cascade of proteins that bind to the pathogen and form a pore that eventually lyses the bacteria or enhances opsonization further). On the other hand, the cellular immune response involves cell-mediated cytotoxicity (killing of infected cells), release of cytokines and chemokines as well as phagocytosis (pathogens are taken up and neutralized by macrophages).

In order to provoke the correct type of immunity as well as receive long-lasting and high protection, many vaccines include adjuvants as part of the formulation. Different adjuvants systems trigger different parts of the immune system. Even though adjuvants are critical components of the vaccines, they typically do not have protective properties by themselves in the absence of the specific antigens. The use of correct adjuvants in combination with the selected vaccine antigen(s) is important for the vaccine design.

A typical bacterial pathogen consists of thousands of unique proteins. Only few of them elicit a protective immune response in a vaccine setting. Modern sequencing technology has enabled detailed insight into the entire genome of several clinical isolates of the same pathogen. This in turn has paved the way for computational antigen selection tools that can select a limited number of vaccine antigen candidates from whole bacterial genomes as a starting point for vaccine development. A challenge in computational, or bioinformatic, predictions, however, is to correctly identify posttranslational modifications and other molecular mechanisms that can change the structure and potential antigenic properties of bacterial antigens and optimize antigens in terms of stability, epitope presentation, ease of production and safety.

EDEN – Our AI Platform for the Discovery and Design of Novel Prophylactic Vaccines for Bacterial Diseases

Overview

EDEN is our second AI-driven platform that rapidly identifies novel, highly protective antigens for the use in pathogen-specific prophylactic vaccines against drug-resistant bacteria. Within EDEN, our proprietary algorithms allow us to predict and identify those antigens that we believe will trigger a robust, protective immune response against almost any bacterial infectious disease. EDEN has also been constructed to redesign vaccine antigens, i.e. engineer such antigens into soluble vaccine constructs for large scale production which potentially allow us to move antigen candidates into the clinic far faster than traditional vaccine discovery and development approaches.

The core of our EDEN technology is a proprietary machine learning ensemble of AI models used to interpret immunological-relevant information in relation to bacterial antigens that incur protection in a vaccine setting. EDEN has been trained on our own curated data set derived by trawling through publicly available patents and publications reported to identify truly protective and non-protective antigens tested in clinical and pre-clinical settings. The input to the AI models is a feature transformation of the protein data set, in which several global and sequence-resolved properties are extracted. These structural and functional features have been selected for their relevance in protein chemistry, immunology and protein structure and ability to guide the network in discriminating protective versus non-protective antigens.

Figure 41: EDEN is a self-taught AI model that provides important insight into what makes antigens elicit a protective immune response. EDEN identifies novel protective proteins by recognizing abstract features shared with known highly protective proteins.

We believe our approach can be used to target almost any bacterial infection and rapidly enables the discovery and development of vaccine product candidates. We have applied EDEN in seven pathogens to test its predictive power. For each pathogen, EDEN identified novel vaccine antigens which were subsequently expressed as proteins and tested in pre-clinical, mouse infection models, demonstrating protection against all seven pathogens. We intend to develop a pipeline of vaccine product candidates using this platform. We are currently focused on the development of EVX-B1, our novel vaccine product candidate for the prevention of *S. aureus*, specifically MRSA, infections. We expect to submit a regulatory filing for a clinical Phase 1 trial in the second half of 2022.

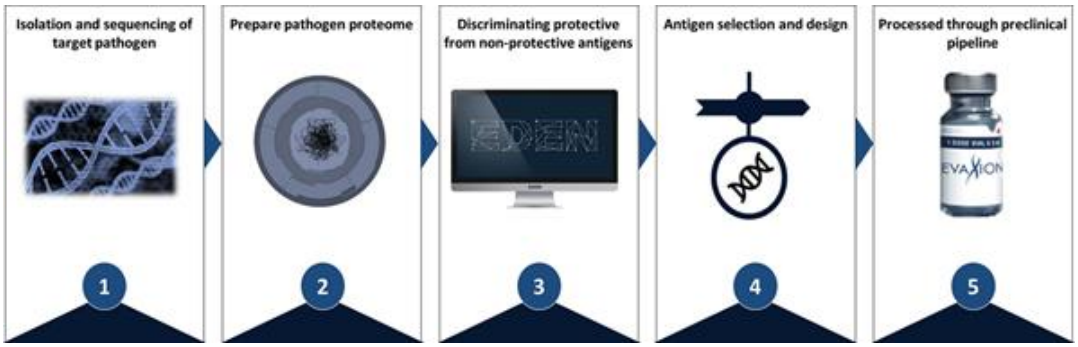

Figure 42: Evaxion's approach to bacterial vaccine discovery and design.

Key Steps in the EDEN AI Platform Include:

Step 1 – Isolation and Sequencing of the Target Pathogen: To identify novel, broadly protective vaccine antigens for a bacterial infection, EDEN utilizes proteomes from clinically relevant bacterial strains as input;

Step 2 – Prepare Pathogen Proteome: The protein coding regions of such strains are translated into amino acid sequences;

Step 3 – Discriminate Protective from Non-Protective Antigens: EDEN identifies unique feature combinations. 23 features are built into EDEN, one such example is an abstract MHC epitope feature along with antibody recognition features that attribute to protective antigens. EDEN predicts previously untested proteins, scoring each of them from 0 to 1 for their probability of eliciting a protective immune response.

Step 4 – Select and Design Antigen: Using EDEN, only a few dozen candidate antigens identified from a whole bacterial proteome are left to be tested experientially. AI-based antigen optimization strategies incorporated in EDEN are used to optimize the design of identified vaccine antigens in term of antigenic and structural properties as well as ease of production; and

Step 5 – Process Antigen Through Pre-Clinical Development Pipeline: Once designed, the antigen candidates are produced in high quality and processed through a pre-clinical development pipeline for *in vivo* confirmation. As part of each vaccine product candidate project, we evaluate different adjuvants and delivery modalities to optimize the immune response and the potency of our developed vaccines. We believe that the correct composition of antigens and adjuvants generates highly potent vaccines.

We have demonstrated that within as little as 48 hours, EDEN is able to identify novel and highly protective vaccine antigens, although there is no guarantee that we will be able to identify product candidates within this time frame in the future. Following discovery of such antigens, within a matter of weeks, new product candidates can be produced to be tested in pre-clinical studies. We believe that if such performance is reproducible, it will accelerate the speed of antigen identification and design, resulting in reduced costs associated with drug discovery and pre-clinical development.

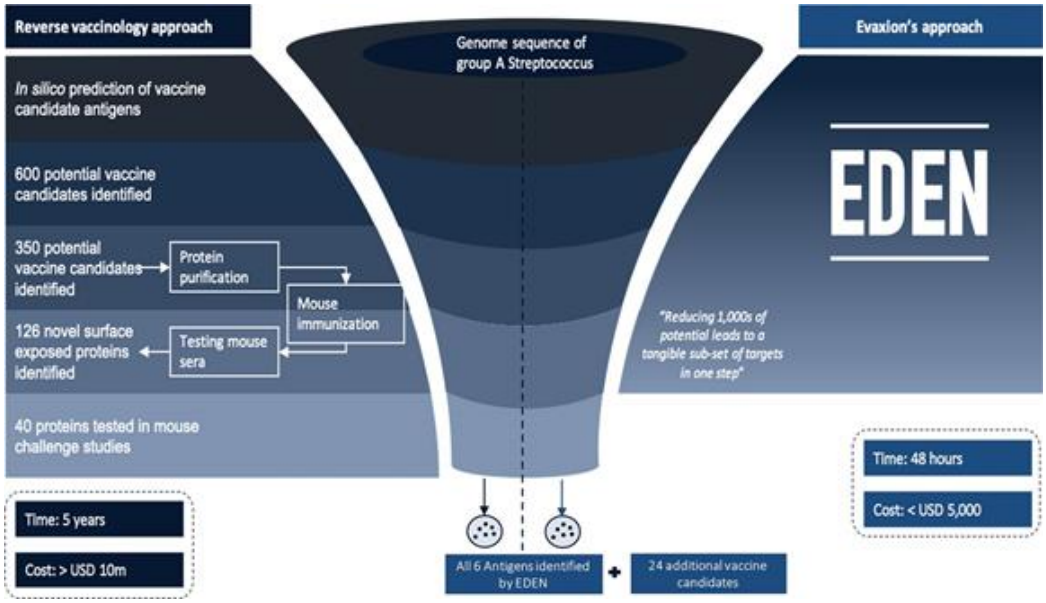

Figure 43: To demonstrate the power of EDEN, Evaxion has performed a retrospective validation on Group A Streptococcus M1 strain comparing reverse vaccinology (RV) with the EDEN platform. EDEN was able to identify the same six vaccine product candidates as identified using RV within only 48 hours at a cost of approximately $5,000 compared to five years and more than $10 million spent applying the RV approach. In addition, EDEN identified 24 vaccine product candidates not identified by the RV approach.

Key Advantages of our EDEN Platform

We believe that our AI-based vaccine discovery and design approach has several advantages over more traditional approaches, including:

- **Ability to Predict Protective Vaccine Antigens:** The ability of EDEN to predict protective vaccine antigens has been shown in pre-clinical models. Once clinically validated, we believe our approach may have the ability to improve on the attrition rates for new vaccine product candidates.

- **Identification of Novel and Unbiased Targets**: EDEN has been trained to identify the underlying feature patterns (e.g. structural or immunological elements) that are important for protection to enable discovery of novel and unbiased targets that are not necessarily homologous to existing products. Traditional reverse vaccinology, or RV, relies heavily on sequence homology (proteins identical to previously tested antigens) in antigen identification.

- **Data Driven Precision**: With carefully curated data, EDEN has learned to filter away irrelevant proteins, narrowing the field of candidates substantially from thousands to a few dozen proteins, reducing the burden on pre-clinical development.

- **Extraordinary Sensitivity**: EDEN has been retrospectively benchmarked against marketed vaccines and shows extraordinary sensitivity in finding antigens included in the vaccines as well as novel, protective antigens.

- **Ability to Provide Broad Protection**: The rapid "evolution" of the genome that can occur in some bacterial pathogens makes it difficult to capture all pathogen strains by a single vaccine. EDEN is capable of leveraging genomic sequencing data to find important targets or domains that are present in the majority of clinical strains. By combining the correct antigens, most, if not all, relevant strains can be covered.

- **Speed**: Traditionally, developing and verifying the safety and efficacy of a novel vaccine takes between 10 to 15 years, often resulting in a new vaccine arriving too late on the market to influence the spread of infections to the general population. We believe that EDEN is capable of identifying vaccine product candidates in a matter of weeks instead of years thus potentially lowering the overall development time.

- **Scalability:** EDEN is highly scalable due to its ability to rapidly produce a broad range of antigens, or vaccine candidates, against almost any bacteria, including drug-resistant bacteria, such as MRSA.

The EDEN platform is continuously improved to ensure it remains state-of-the-art and incorporates multiple aspects of vaccine development from discovery to clinical testing. We explore among other improvements, incorporation of new translational features and data into EDEN, novel machine learning architectures such as deep learning and probabilistic programming to enhance protein structure and function prediction, generation of novel high-throughput data to be incorporated into our AI technology for assessment of solubility and CMC-readiness and methods for determining broadness of protection across strains. By continuous improvement in all aspects of vaccine development, we believe the EDEN platform will continue to produce potent vaccine product candidates with minimal testing before entering clinical development.

EDEN in Vivo PoC

To obtain initial *in vivo* PoC, EDEN was applied to seven pathogens reported to exhibit resistance to standard antibiotics, identifying both novel and known antigens. For each pathogen, EDEN-identified vaccine antigens were expressed as proteins and their protective ability tested in pre-clinical infection models. Intellectual property, or IP, rights have been filed for all identified targets conferring significant protection.

Bacterial species	*In vivo* PoC	*In vivo* model (mouse challenge models)	IP filed
Staphylococcus aureus	✓	Lethal peritonitis and skin abscess model	✓
Pseudomonas aeruginosa	✓	Lethal peritonitis and lethal acute pneumonia model	✓
Non-typeable Haemophilus influenzae	✓	Lung colonization model	✓
Moraxella catarrhalis	✓	Lethal peritonitis and lung colonization model	✓
Neisseria gonorrhoeae	✓	Vaginal colonization model	✓
Acinetobacter baumannii	✓	Lethal acute pneumonia model	✓
Klebsiella pneumoniae	✓	Lethal peritonitis and lethal acute pneumonia model	✓

In Vivo PoC Data Example

For *Pseudomonas aeruginosa*, or PA, we employed EDEN and identified 35 vaccine antigens which were expressed as recombinant protein constructs. These antigens were tested for induction of protective immunity in mouse models. 16 antigens confirmed protection in peritonitis and acute pneumonia models. These lead antigens are involved in numerous different biological functionalities including; adhesion, iron uptake, secretion of toxins and thus targeting different virulence factors.

Data from four of the 16 candidates are shown in the figure below, demonstrating protection in two different lethal challenge mouse models.

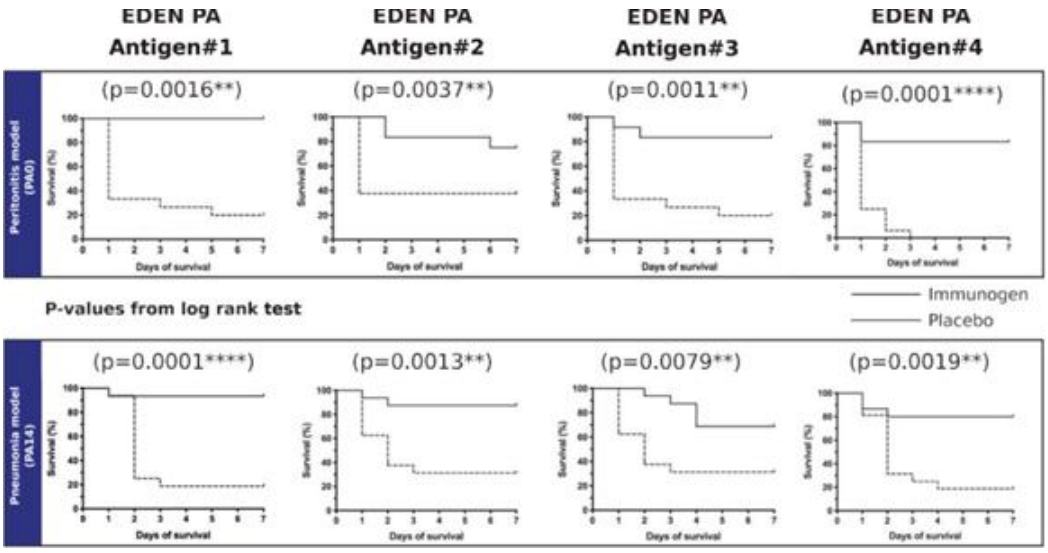

Figure 44: Pseudomonas aeruginosa antigens identified by EDEN show high level of protection in two challenge models.

The data demonstrate that our EDEN platform is capable of identifying highly protective antigens based on the bacterium proteome. A finding that holds true for multiple bacteria with diverse pathogenicity, emphasizing the broad usability of the platform.

Our EVX-B1 Product Candidate

Overview

Our EVX-B1 product candidate is a multi-component subunit prophylactic vaccine, initially being developed for the prevention of SSTI in patients undergoing elective hernia surgery. EVX-B1 includes two proprietary and highly protective antigens identified by EDEN in combination with two known toxins that play a key role in *S. aureus* pathogenesis formulated together with a potent adjuvant, CAF01. EVX-B1 is intended to be administered prior to surgery. Upon administration to the patient, we believe that EVX-B1 will significantly reduce *S. aureus* related SSTI.

EVX-B1 is currently in pre-clinical development. We intend to assess the final formulation of EVX-B1 for safety in a repeat dose toxicity trial for a regulatory filing in the second half of 2022.

Previous attempts to design vaccines to combat *S. aureus* have not been successful. We believe EVX-B1 is a highly competitive vaccine capable of out-performing other programs in clinical development as it has been designed to:

- **Include novel antigens with high protection abilities**. Our proprietary AI platform EDEN has identified several novel vaccine antigens and of these, two have been selected based on protection levels observed in different pre-clinical animal models such as sepsis and skin abscess, and when using multiple challenge strains.

- **Induce broad and effective protection**: By including antigens widely present and highly conserved among multiple clinically relevant strains, the vaccine will have a broad coverage and effectively address the medical need.

- **Include multiple antigens**: By including multiple antigens with conserved B- and T-cell epitopes, the infecting bacteria is attacked from several angles and critical functions needed for bacterial pathogenicity, persistence and growth are targeted.

- **Target critical toxins**: To increase protection even further, EVX-B1 includes a proprietary designed toxoid fusion protein targeting two critical toxins released by the bacteria during infection.

- **Include a potent adjuvant**: By including the liposomal adjuvant CAF01, driving a balanced Th1 and Th17 type of immune response, we believe the vaccine induces the most optimal response needed to combat the pathogen.

Addressable Market for EVX-B1

S. aureus is responsible for significant morbidity and mortality worldwide and antibiotic-resistant *S. aureus*, and in particular MRSA infections, are, according to the CDC, of critical concern and remain a prevention priority. In the United States, *S. aureus* is estimated to cause 20,000 deaths and amount to a total bill of $15 billion on the health service annually. The global MRSA drugs market is expected to reach over US$ 3.9 billion by 2025.

We are initially developing EVX-B1 for the prevention of *S. aureus* induced SSTI in patients undergoing hernia surgery. To date, no prophylactic vaccine for the prevention of *S. aureus* infections has received marketing authorization. With the development of EVX-B1, we are addressing this unmet medical need and believe our candidate has the potential to be the first vaccine to receive approval for the prevention of *S. aureus* infections.

Upon successful completion of a Phase 2b clinical trial, we intend to expand development of EVX-B1 for the prevention of *S. aureus* in surgical infections beyond abdominal hernia surgery, such as orthopedic surgical infections, and may explore other indications such as recurrent skin infection indications including, acne, diabetic foot ulcers and impetigo.

Our EVX-B1 Pre-Clinical Data

EVX-B1 is a multicomponent vaccine, consisting of three components to derive a strong vaccine product candidate:

- Novel, EDEN-identified vaccine antigens evaluated in pre-clinical protection and challenge studies and with critical functions.
- Uniquely designed toxins selected from a long list of relevant toxins and pre-clinically evaluated as single proteins and fusion protein constructs.
- Adjuvant selected based on pre-clinical tests and optimal profile for clinical indication.

Each component has been carefully tested and evaluated pre-clinically as outlined in Figure 45 below.

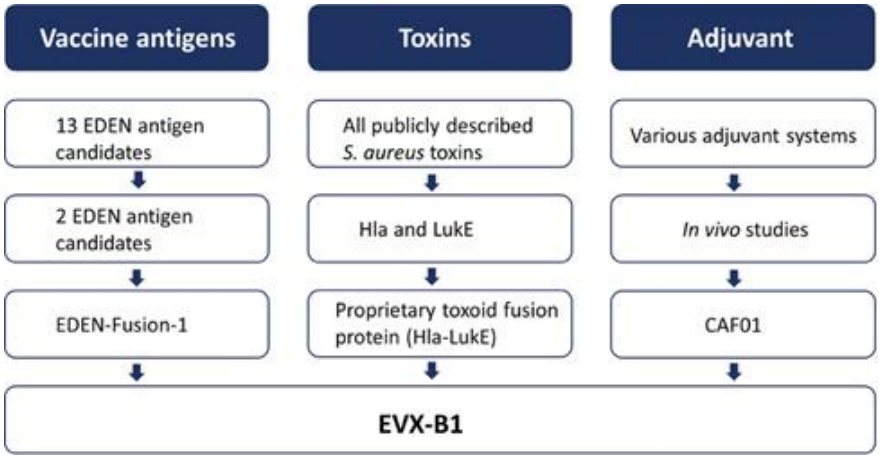

Figure 45: Multicomponent approach to the development of EVX-B1.

Evaluation and Selection of Vaccine Antigens

We applied EDEN to the proteome of *S. aureus* to predict the antigens most likely to induce protective immunity. Forty-four (44) novel vaccine antigens were identified, expressed as recombinant proteins and assessed for protection in a *S. aureus* mouse sepsis model. Of these, 13 antigens demonstrated consistent high and significant protection in this model. The protection data is summarized in the table below.

#	Protein ID	No. of Experiments	No. of Test Mice	No. of Control Mice	% Survival of Test Mice	% Survival of Control Mice	Difference in % Survival (Test vs. Control)
1	EDEN-1	4	59	60	76 %	28 %	48 %
2	EDEN-2	2	24	24	58 %	13 %	46 %
3	EDEN-3	3	43	44	77 %	32 %	45 %
4	EDEN-4	2	28	28	68 %	25 %	43 %
5	EDEN-5	2	28	28	68 %	25 %	43 %
6	EDEN-6	2	27	28	85 %	43 %	42 %
7	EDEN-7	3	36	36	61 %	19 %	42 %
8	EDEN-8	5	61	64	51 %	9 %	41 %
9	EDEN-9	3	43	44	63 %	30 %	33 %
10	EDEN-10	3	36	36	69 %	36 %	33 %
11	EDEN-11	3	32	35	53 %	20 %	33 %
12	EDEN-12	3	42	42	62 %	31 %	31 %
13	EDEN-13	3	36	36	47 %	28 %	19 %

The 13 antigens were further subject to extensive bioinformatic analyses to determine their function. Also, early production and formulation characteristics were addressed. Two antigens were selected based on the following parameters:

- Level of protection in different challenge models and against different *S. aureus* challenge strains as single antigens and as part of a fusion protein construct.
- Virulence functions critical for *S. aureus* pathogenicity and infection, including evasion of innate and adaptive immunity, secretion of virulence factors and toxins and replication , verified by functional assays.
- Attractive CMC profile of the individual constructs

The two lead antigens were designed and expressed as one fusion protein, EDEN-Fusion-1.

Evaluation and Selection of Toxins

We have evaluated multiple *S. aureus* toxins and selected the two most promising candidates for our proprietary toxoid fusion protein, which has demonstrated protection in sepsis models and skin abscess models of infection using two different challenge strains. Our toxoid fusion protein, Hla-LukE, includes inactivated forms of α-hemolysin (Hla) and Leukotoxin E (LukE), two toxoids having demonstrated high levels of protection when assessed in animal models amongst publicly described *S. aureus* toxins.

Evaluation and Selection of Adjuvant

The vaccine antigens and toxin constructs will be formulated with the potent adjuvant CAF01. CAF01 is a cationic liposomal formulation. The hallmark for CAF01 is its ability to induce CD4+ T-cell responses, especially Th1 cells and Th17 cells after parenteral vaccination with strong antibody response. CAF01 has been used in other vaccine programs undergoing clinical testing (in tuberculosis and chlamydia) and has an attractive safety and immunogenicity profile.

Our EVX-B1 Product Candidate

EVX-B1 will include two EDEN-predicted antigens as one fusion protein (EDEN-Fusion-1), two toxins as one toxoid fusion protein (Hla-LukE). EVX-B1 will therefore comprise a total of four antigens expressed as two fusion protein constructs and formulated with CAF01. All protein constructs are engineered to be proprietary to Evaxion.

Pre-clinical data testing our EVX-B1 product demonstrates highly significant levels of protection in two different challenge models (Figure 46-47) and high IgG titers (Figure 48), suggesting good overall immunogenicity.

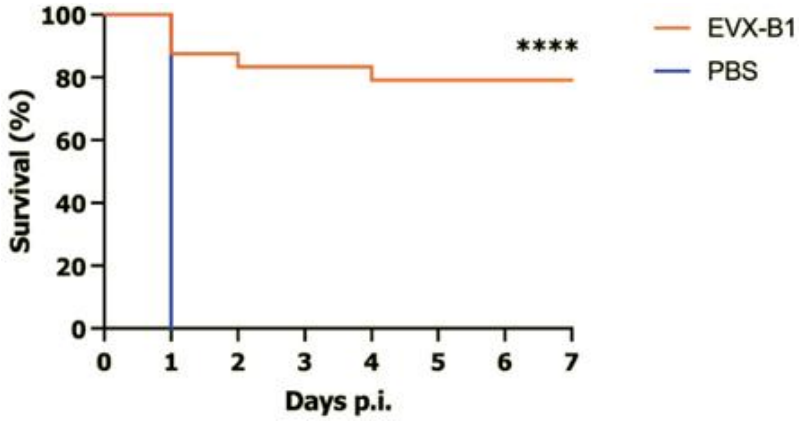

Figure 46: Assessing protection of EVX-B1 in a mouse sepsis model. Survival proportions of mice having received EVX-B1 product or PBS was followed for 7 days post infection (p.i.). Statistical analysis was performed using Log-rank Mantel-Cox test (p-value <0.0001*).***

Figure 46 above shows that EVX-B1 is inducing 79% protection compared to control (PBS) in a mouse sepsis model using *S. aureus* USA300 for challenge.

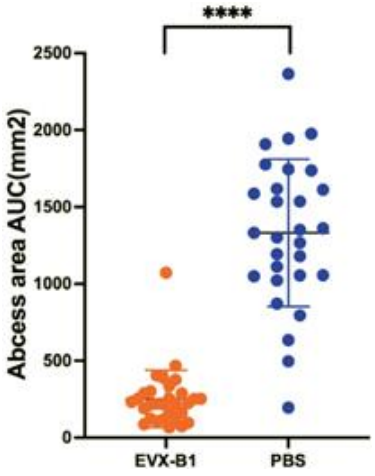

Figure 47: Assessing protection of EVX-B1 in a mouse skin infection model. Abscess sizes are presented as area under the curve (AUC) for individual mice and mean with standard deviation. Statistical significance was calculated with Mann-Whitney test (p-value <0.0001*).***

Figure 47 above shows that EVX-B1 is inducing highly significant protection compared to control (PBS) in an abscess mouse model of infection using *S. aureus* USA300 for challenge.

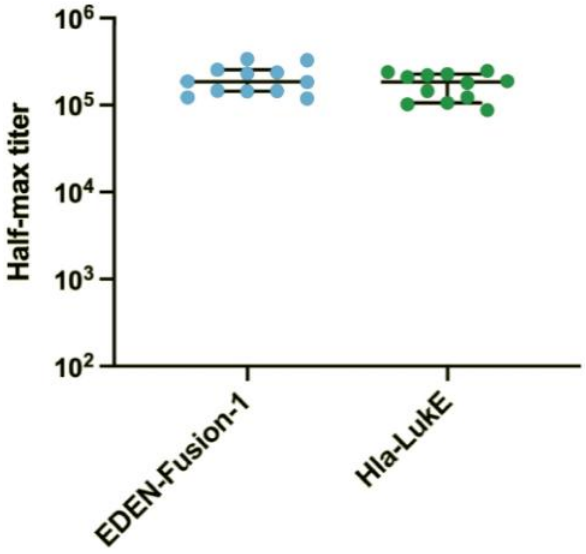

Figure 48: IgG titers. Mice were immunized with EVX-B1. IgG titers are shown as half-max titers for individual mice, groups median values and 95% confidence interwall are shown.

In order to study the immune response following immunization, IgG titers were investigated. Figure 48 above shows that the EVX-B1 product induce high IgG titers specific for both of the two fusion protein constructs, EDEN-Fusion-1 and Hla-LukE, and holds promise for continued development.

Our EVX-B1 Clinical Development Plan

EVX-B1 is currently in pre-clinical development. We intend to assess the final formulation of EVX-B1 in a non-clinical, repeat dose toxicity study for a regulatory filing in the second half of 2022.

The initial clinical development of EVX-B1, Phase 1 clinical trial, will include 20-30 subjects to evaluate the safety and immunogenicity of the vaccine. We plan to conduct the Phase 2 clinical trial in collaboration with Walter Reed Army Institute of Research, or WRAIR, utilizing their prior experience from *S. aureus* vaccine development, resources and know-how. Collaboration with WRAIR and the United States military has several advantages including high enrollment rate of eligible trial subjects, relatively high and defined attack rate in the control arm over a short period of time, enrollment of subjects with healthy immune systems, relative ease of data capture given the close monitoring of enrolled subjects that is feasible in such a situation. The high attack rate of *S. aureus* infections among army recruits will allow the trial to be relatively small and more cost-effective than any large-scale population-based development program, provided fast and clear clinical PoC, before initiation of a larger pivotal trial in hernia mesh elective surgery.

Our EVX-B2 Product Candidate

We intend to select our second bacterial product candidate, EVX-B2, in the first half of 2022.

Viral disease Background

So far in the 21st century, seven known coronavirus strains have made the transition from animals to humans causing significant morbidity/mortality around the world. Four of these strains (HCoV-229E, -OC43 -NL63 and -HKU1) cause approximately 30 % of common colds in developed countries, and, therefore, contribute to significant loss of productivity and quality of life. The remaining three strains emerging in 2003 (SARS-CoV-1), 2013 (MERS-CoV) and most recently COVID-19 in 2019 (SARS-CoV-2), have been more virulent with significant human mortality and economic burden. In addition, efforts by the United States Agency for International Development, through the Emerging Pandemic Threats program, have revealed several novel coronavirus strains in animals across the globe that are poised to become the next potential pandemic threat. These observations, combined with the ability of most coronaviruses to re-infect humans after first exposure, clearly underline the need for an effective vaccination strategy against both current coronavirus strains and any future pandemic strains. Research conducted to date on coronaviruses points to the fact that an effective coronavirus vaccine needs to provide a potent B-cell response that facilitates the generation of neutralizing antibodies that blocks viral cell entry. This mechanism needs further support from T cells that can actively locate infected cells and eliminate them before the virus spreads uncontrollably in the human body.

RAVEN – Our AI Platform for the Discovery and Design of Novel Prophylactic Vaccines for Viral Diseases

Overview

We are developing our third, proprietary AI platform, RAVEN, to apply our unique AI technology approach to vaccine design and development against viral diseases.

We believe our RAVEN platform will address the public health threat posed by emerging viral diseases in two key areas:

1. The need for a viral platform that can address unmet medical needs in viral diseases such as future coronaviruses, respiratory syncytial virus, or RSV, cytomegalovirus, or CMV and human immunodeficiency virus, or HIV, etc.

2. The need to act fast when the next pandemic virus emerges. RAVEN will allow for highly, broadly effective vaccines for human use in, initially, less than 11 weeks. We believe we will be able to significantly reduce this timeline in the coming years.

Initially, we plan to apply RAVEN for the development of a pan-beta-coronavirus vaccine that will protect against current and future beta corona strains. The development is funded through non-dilutive sources and will serve as a PoC for our RAVEN platform. Once PoC is achieved, we plan to apply RAVEN for commercial, viral targets such as RSV, CMV, HIV, etc.

RAVEN combines the essential AI tools from our PIONEER platform with structural in *silico* AI tools from EDEN to arrive at a novel potent B- and T-cell vaccine design concept (see Figure 49 below). Our goal with RAVEN is to identify minimal constructs from viral fusion proteins for the generation of neutralizing antibodies (B-cell driven) and to incorporate potent T-cell epitopes with high population coverage from the entire viral genome to ensure elimination of infected cells in any stage of the viral replication cycle.

Key Advantages of our RAVEN Platform

We believe, the combination of the B- and T-cell design approach results in a number of unique features of vaccine design by the RAVEN platform:

- **Promiscuous T-cell epitopes**: The AI components of our RAVEN platform enable the identification and combination of T-cell epitopes that cover the entire immunological diversity of the human populations (HLA type).

- **Multiple hits on target**: By combining multiple potent epitopes in one vaccine, different T cells will be able to target the same infected cell and curtail spread of the infection more effectively.

- **Coverage of entire viral cycle**: By selecting epitopes from all proteins in the viral genome, vaccine generated T cells will be able to kill infected cells at any stage of the viral replication cycle.

- **Mutation proof**: Combining multiple epitopes ensures that any given variant of a strain is covered by more than five conserved T-cell epitopes, hence new mutations are likely to have little effect on the vaccine efficacy.

- **Neutralizing focused**: Design of minimal constructs from viral fusion proteins for the generation of neutralizing antibodies.
- **Cross-reactive antibodies**: The RAVEN viral fusion protein antigen is designed using information from all available variants of the target strain to ensure that the generated antibodies offer cross-reactive neutralization.
- **Broadly applicable**: While being specialized in tackling the corona issue, the RAVEN platform can be applied to any known virus.

Early Pre-Clinical PoC for AICoV and RAVEN

To address the threats against human health posed by current and future coronavirus strains, with the support of the Danish government in the form of a grant, we have launched the Adaptive and Intelligent Vaccine for a Rapid Response against Corona Viruses, or AICoV. This program aims to improve our vaccine design and pandemic preparedness capabilities, not only for coronaviruses but also for other emerging viruses that pose a threat to human health. The backbone of AICoV is our RAVEN platform. We combine RAVEN with our proprietary APC targeting, DNA-based delivery technology to further improve the immunogenicity of the vaccine.

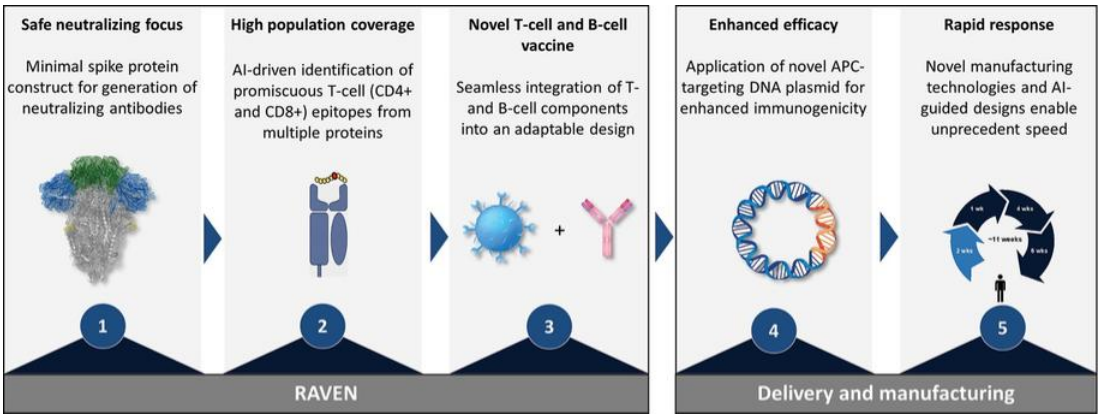

Figure 49: Current workflow for the design of an integrated B- and T-cell corona vaccine using our proprietary RAVEN platform.

Using a precursor to our RAVEN platform, we have demonstrated that an optimized B- and T-cell vaccine designed against influenza induces 10 to 20 times higher level of neutralizing antibodies against hemagglutinin, when compared to a strategy utilizing the protein alone. Hemagglutinin is a viral fusion protein located on the surface of the influenza virus where it facilitates cellular entry, serving the same purpose as the spike protein in coronaviruses and its neutralization is therefore key in the development of an effective vaccine.

To evaluate the applicability of our APC targeting DNA vaccine technology in coronavirus, a PoC pre-clinical study in mice was conducted utilizing the receptor-binding domain (RBD) from the spike protein inserted into our APC-targeting DNA technology to arrive at a SARS-COV-2 vaccine (EVX-APC-RBD). The ability of EVX-APC-RBD to induce both T-cell and a functional antibody response was then assessed using IFNγ ELISpot and a live virus neutralization assay, respectively. In Figure 50A, mice immunized with EVX-APC-RBD show induction of a strong T-cell response against peptide epitopes covering the entire RBD fragment. Figure 50B shows the ability of sera from vaccinated mice to neutralize live SARS-CoV-2 in a cytopathic effect microneutralization assay. The obtained neutralization titers are comparable to that of human convalescent sera derived from previously infected individuals.

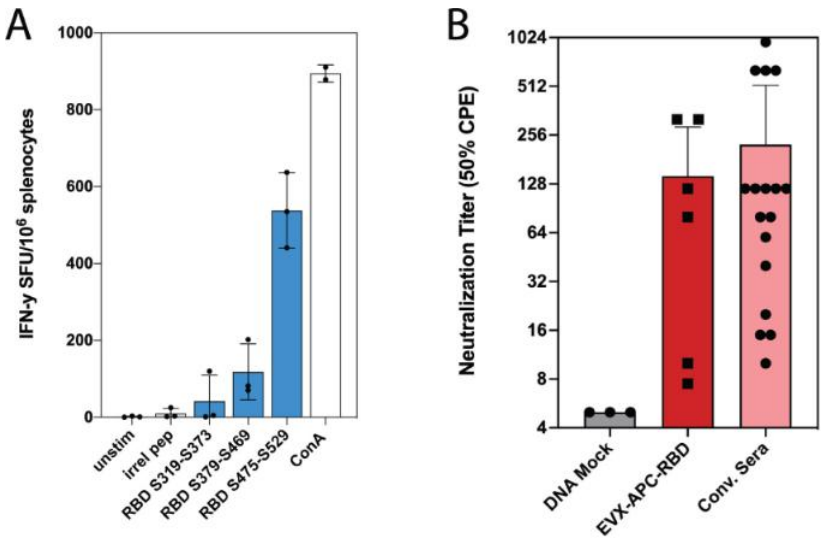

Figure 50: C57BL/6 mice were IM immunized once a week for five weeks with either 25 ug EVX-APC-RBD or empty plasmid (DNA mock). Splenic material and sera were collected one week post last immunization. A) The EVX-APC-RBD plasmid induced antigen reactive T cells across the RBD fragment as measured by IFNγ ELISpot upon stimulation of spleenocytes from vaccinated mice with three groups of RBD derived 20 mer peptides. Concanavalin A (ConA) is a lectin that activates IFN-γ release and functions as a positive control for the highest possible level of stimulation. B) A micro-neutralization assay using a cytopathic effect (CPE) read-out with live SARS-CoV-2 2019 nCOV ITALY/INMI1 was performed with sera derived from either DNA mock or EVX-APC-RBD vaccinated mice and found to be comparable to data from convalescent patients (PMC7781313, bioRxiv preprint).

A second mice immunogenicity study was performed to evaluate the ability of the RAVEN platform to identify immunogenic epitopes both within and outside the spike protein. Figure 51 shows a specific T-cell response for 15 of the 16 RAVEN predicted epitopes designed specifically for C57BL/6 mice as reported by IFN-y ELISpot, with the majority of the epitopes located outside the spike protein.

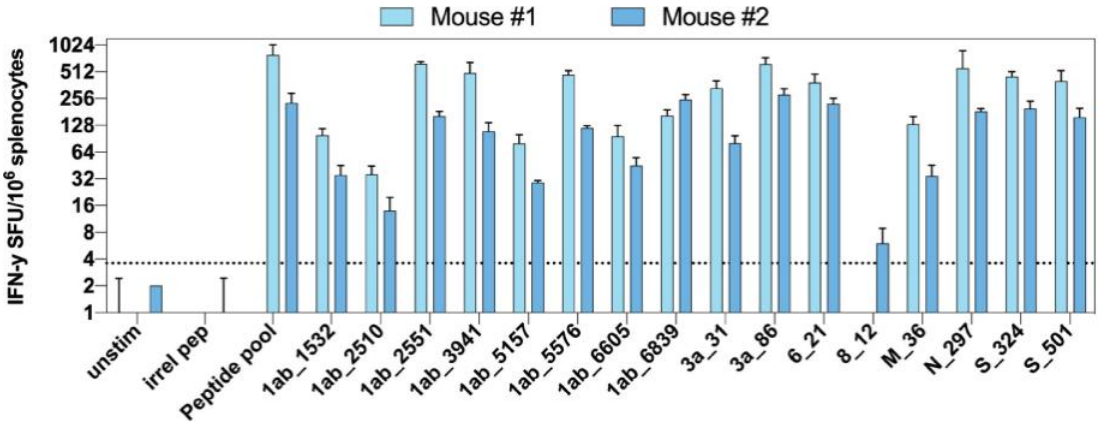

Figure 51: C57BL/6 mice were IM immunized once a week for five weeks with 25 ug APC targeting plasmid containing RAVEN predicted epitopes as "epitopes on a string". Splenic material was collected one week post last immunization. Epitopes were predicted as "hotspots" with a high density of MHCI/II ligands across the SARS-CoV-2 genome specific for the C57Bl/6 MHC haplotype. 15 out of the 16 RAVEN predicted SARS-COV-2 T cell epitopes gave high IFN-γ response in an ELISpot upon

restimulation with the corresponding peptides. Cut-off for a positive response was defined as the average value for irrelevant peptide stimulation + 3 standard deviations (- - -).

Our Adaptive Vaccine Approach and RAVEN Process

To shorten vaccine development timelines for pandemic viruses (including coronaviruses) in the future, we aim to rely on an adaptive vaccine approach, similar to that applied for pandemic Influenza (H1N1 2009), where a pre-developed vaccine design (Pandemic Preparedness Vaccine framework, EMA) against an already circulating strain is adapted to an emerging strain. As a PoC for this strategy, we believe that targeting SARS-CoV-2 or one of the strains causing the common cold would serve as a suitable basis for the Pandemic Preparedness Vaccine concept for coronavirus. We believe that our AI-CoV program in this setting will allow for a vaccine that can be rapidly developed in approximately 11 weeks from available genomic information to first human dose. Such a rapid vaccine response would allow for a targeted immunization strategy in the endemic area, thereby significantly reducing the effect on the global economy and human suffering.

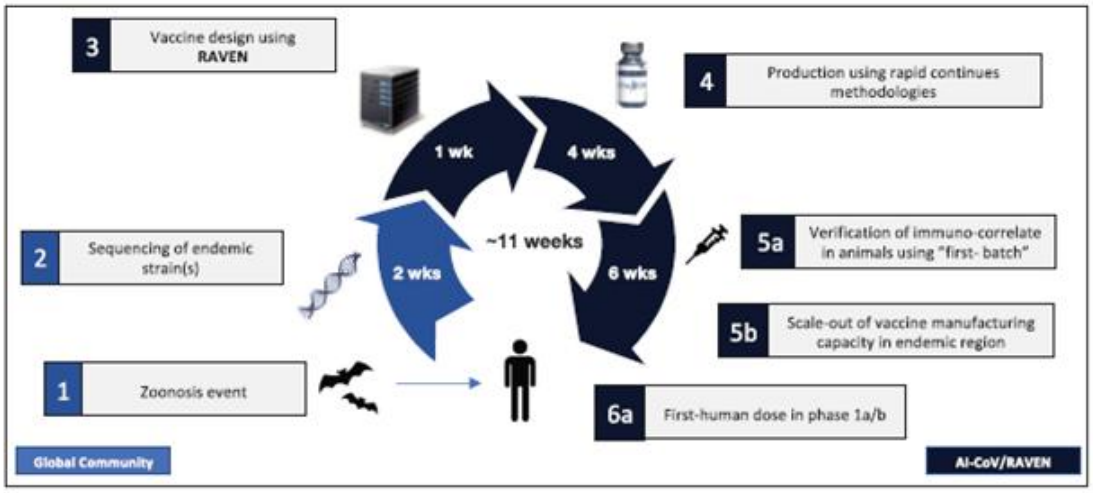

Figure 52: Overview of the planned response cycle for our AICoV program.

We anticipate that we, with our planned response cycle for our AICoV program and the RAVEN platform, will be able to effectively and rapidly address future corona outbreaks. From the time of a zoonosis event to first in human dose in a Phase 1 trial, we believe less than 11 weeks will be required using our approach as outlined in Figure 52 above.

Once we achieve PoC on our RAVEN platform, we plan to further utilize the built-in, adaptive nature of the platform to identity our first commercial, viral candidate in the second half of 2022 and subsequently apply RAVEN to target other viruses that display seasonal reoccurring and/or pandemic potential or general medical need. In addition, the patient-specific manufacturing pipeline and methodologies from our immuno-oncology portfolio have the potential to be combined with our RAVEN platform to generate truly patient-specific vaccines against persistent viruses such as RSV, CMV, HIV, etc.

Our EVX-V1 Product Candidate

We intend to select our first viral product candidate, EVX-V1, in the second half of 2022.

Third-Party Collaborations

We are collaborating with MSD on the Phase 2b clinical trial which will combine our patient-specific neoepitope cancer immunotherapy compound, EVX-01, with MSD's anti-PD-1 therapy KEYTRUDA compound, a humanized anti-human PD-1 monoclonal antibody.

The planned multi-center Phase 2b clinical trial will enroll patients with Stage III and IV advanced or metastatic unresectable melanoma and will investigate EVX-01 in combination with KEYTRUDA. We expect to initiate the trial during the first half of 2022. We will act as the sponsor of the clinical trial and MSD will supply all the necessary KEYTRUDA. We will continue to collaborate with MSD as the data mature.

We are also collaborating with the National Center for Cancer Immune Therapy (CCIT-DK) at Herlev Hospital, Department of Health Technology at Danish Technical University, Center for Genomic Medicine at University Hospital Copenhagen and the Center for Vaccine Research at SSI on the development and Phase 1/2a clinical trial of our EVX-01 product candidate.

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:

- pre-clinical 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 pre-clinical 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 pre-clinical 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.

Pre-Clinical Studies and IND Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo pre-clinical testing. Pre-clinical 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 pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical 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 producers.

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.

Review and Approval of an NDA or a BLA

The results of product candidate development, pre-clinical 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 FY2021 this application fee exceeds $2.8 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $300,000 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 pre-clinical 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 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 that is expected to culminate in November 2023. 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 28-member European Union, before we may commence clinical trials or market products in those countries or areas. It is not yet clear how the United Kingdom's withdrawal from the European Union, will affect the approval of medicinal products in the United Kingdom. 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, but it is not yet applicable in the European Union. The Clinical Trials Regulation will be 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 will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable 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 European Union 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 that is currently expected to take effect at earliest in 2020.

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 pre-clinical 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 pre-clinical 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 preliminary 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.

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 pre-clinical 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.

Rest of the World Regulation

For other countries outside of the European Union 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.

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 by 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 and false claims laws, 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. The current Presidential administration and members of the United States Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Acts was enacted in 2017, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. 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 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 that are important to our business. 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 technologies without disclosure to the public of the core elements in each technology. Furthermore, we have filed patent protection of aspects of our PIONEER platform, 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; neoepitopes identified by PIONEER are by nature unique for each patient, therefore, the precise nature of each neoepitope has no relevance as an object for intellectual property rights. We are therefore establishing a patent protection which protects generally applicable aspects of the PIONEER enabled patient-specific immunotherapy, 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 neoepitopes. 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 neoepitopes 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 EDEN technology, 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 draft 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 2nd and later generation patent applications that protect the final marketed product.

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 development of our product candidates, 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 the 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 immunotherapies, in which our PIONEER platform is an inherent part, and the platform predicted neoepitopes 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, 2021, we owned a total of 26 patent families, of which 13 are currently in their priority year or international phase and we own several granted patents in the United States (8), Germany (2), France (2) and Great Britain (2) two patents allowed in Europe and have 30 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, 2021 are summarized below.

EVX-01

EVX-01 is protected by trade secrets and the proprietary nature of the PIONEER technologies which cannot be copied. Our patent portfolio related to EVX-01 currently includes one patent family. The first patent family is directed to a method of treating cancer in a patient using EVX-01 and has entered national phase in CA, CN, US, EP, JP and AU. We expect the patent family to lapse in January 2040.

EVX-02

EVX-02 is protected by trade secrets and the proprietary nature of the PIONEER technologies which cannot be copied. Our patent portfolio related to EVX-02 currently includes two patent families. The first patent family, also related to EVX-03, is a method patent directed at inducing an anti-cancer immune response in patients by administrating EVX-02 immunotherapy concept comprising DNA plasmid and polaxomer 188, a novel adjuvant. The second patent family is directed at a method of inducing and anti-cancer immune response in patients by administrating the EVX-02 plasmid alone. As of December 31, 2021, the first patent family is in national phase in CA, CN, US, JP and AU and the second in the international phase. 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 and the proprietary nature of the PIONEER technologies which cannot be copied. Our patent portfolio related to EVX-03 currently includes two patent families. The first patent family is a composition of matter family directed

to the EVX-03 product concept. As of December 31, 2021, the patent family was in its international phase and is expected to lapse upon entering international and/or national phase in April 2041. The second patent family, also related to EVX-02, is a method patent directed at inducing an anti-cancer immune response in patients by administrating EVX-03 immunotherapy comprising DNA plasmid and polaxomer 188, a novel adjuvant.

EVX-B1

Our patent portfolio related to EVX-B1 currently includes five patent families. The patent families are composition of matter patents directed against compositions comprising one or more *S. aureus* antigens. As of December 31, 2021, the first patent family comprised five issued patents in the US, one in DE, one in FR and one in GB as well as one pending application in US and one pending in EP. The patent family is expected to expire in April 2032. The second patent family comprises one US and one EP pending application. We expect the patent family to lapse in December 2034. The third patent family currently comprises one US registered patent and one EP application which has been allowed by the EPO and is entering validation in EP countries. We expect the family to lapse in February 2037. Our fourth EVX-B1 related patent family has pending applications in EP and US jurisdictions. We expect this patent family to lapse in July 2037. The fifth family is in international phase and upon national phases, we expect this patent family to lapse in November 2041.

PIONEER

The PIONEER system is mainly protected as a trade secret as computational methods are complicated to patent and protect from infringement. However, our current patent portfolio comprises of two patent families related to PIONEER. Including a new patent family born in December 2021 with the filing of a European priority founding patent application. The first patent family is directed against a method for selecting a set of neoepitopes for treatment of cancer comprising the SLICE model used in PIONEER for epitope prioritization. As of December 31, 2021, the patent family is in its international phase and upon entry into national stages, we expect the family to lapse in July 2041. The technology covered by the new European patent family supplements the identification of neoepitopes with a system for identifying and utilising highly immunogenic hERVs (human endogenous retroviral sequences) and other, normally non-expressed DNA sequences found in the human genome.

AICoV

Our AICoV program is protected by trade secrets and the proprietary nature of the RAVEN platform. Our patent portfolio related to AICoV currently includes two patent families. The first patent family is a composition of matter family directed to the vaccine delivery concept in AICoV. This patent family entered international phase in July 2021 and will upon entering national phase lapse in July 2041. The second patent family is aimed at the design of vaccines using the RAVEN platform. As of December 31, 2021, this patent family was in its priority year and is expected to lapse upon entry into international and national phase, in 2042.

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 a non-exclusive, royalty-bearing sub-licensable license to SSI's adjuvant technology CAF®09b. 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 immunotherapies 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 immunotherapies 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 immunotherapies 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 immunotherapy 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 immunotherapy. However, if any PIONEER derived immunotherapies 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 immunotherapies 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 2b 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 lower double-digit range. If we enter into a sublicense agreement with a partner on our EVX-01 product candidate without initiating Phase 2b trial, we are required to pay to SSI a percentage of any sublicensing income in the mid double-digit range. Prior to any out-licensing or 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 immunotherapy 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 immunotherapy 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 immunotherapy administered together or in combination with licensed adjuvant.

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 and supply of the Stratis® device and disposable needle-free syringes and filling adapter items for use with any products derived 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, and invention assignment agreements with our employees. 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 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.

AI platforms

We face competition from several companies developing AI platforms and software including Schrodinger, BenevolentAI, Atomwise, AI Therapeutics, Insilico Medicine, Recursion Pharmaceuticals, Lantern Pharma, Adaptive Biotechnologies, Immatics, BIOVIA, and Citrine, among others. However, because most of these companies are not focused on developing therapeutic drug candidates centered around neoepitopes or bacteria-identified antigens, we do not consider the majority of them to be our direct competitors. Below is a description of the companies we consider to be our main competitors for each of our three platforms and their respective indications.

PIONEER – Immuno-Oncology

The immuno-oncology therapeutics landscape in general is highly competitive and includes large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. It includes both competition from marketed therapies as well as potential new therapeutics in development. We may compete with products with different mechanisms of action as well as against established standards of care. Well-established companies such as AstraZeneca, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceuticals, Merck & Co., Novartis, Pfizer, Roche and Sanofi are developing diversified immuno-oncology programs and have substantial resources. Smaller companies are also developing immuno-oncology drugs, such as Jounce Therapeutics, Arcus Biosciences, ALX Oncology, iTeos Therapeutics and Five Prime Therapeutics, among others. We expect our immunotherapy candidates for the treatment of solid tumors to face direct competition from companies such as Moderna in collaboration with Merck & Co., CureVac in collaboration with Eli Lilly, and BioNTech SE.

We also expect to face competition from smaller specialized oncology companies active in the neopepitope/personalized anti-cancer therapy space including Agenus, Gritstone Bio, Advaxis Immunotherapies, Achilles Therapeutics, NousCom, ISA Pharmaceuticals, Genocea Biosciences, Vaccibody, PACT Pharma, PersImmune, Geneos Therapeutics and ZIOPHARM Oncology.

EDEN – Bacterial Diseases

Our main competitors taking a prophylactic approach to bacterial diseases are GlaxoSmithKline and Sanofi Pasteur. Additional competitors within the bacterial disease space include well-established pharmaceutical companies including AbbVie, Bayer, Gilead, Janssen Pharmaceuticals, Merck & Co. and Novartis. In addition, Seqirus UK, Biomedical Corp. of Quebec and AstraZeneca produce vaccines.

RAVEN – Viral Diseases

As we intend to use our RAVEN platform to develop drug candidates for the current and future coronavirus pandemics, we face competition from all of the biotechnology and large pharmaceutical companies developing potential treatments for coronavirus including: Moderna, Pfizer/BioNTech, CureVac, AstraZeneca, Merck & Co., Novavax, Sanofi, Johnson & Johnson and the multitude of other companies currently developing COVID-19 vaccine candidates. Our plans to leverage our RAVEN platform to develop

vaccines for future coronaviruses and other viral diseases beyond coronavirus, will put us in competition with several other companies focused on viral vaccines including GSK, Merck & Co. and AstraZeneca.

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.

Employees

As of December 31, 2021, we had 61 full-time equivalent employees, of which 25 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of December 31, 2021 by function and by region:

Function	Number
Clinical Research & Development	8
Scientific Research & Development	38
Supporting Functions	11
Commercial & Business Development	4
TOTAL	**61**

Region	Number
Capital Region, Denmark	60
New York, United States	1
TOTAL	**61**

Since 2020, our workforce has grown by 74%, and we have plans to increase the size of our team over the next several years.

None of our employees have engaged in any labor strikes. We have no collective bargaining agreements with our employees. We consider our relationship with our employees to be positive and have not experienced any major labor disputes.

4.B. Organizational Structure

Evaxion was formed as a private limited liability company organized under Danish law on August 11, 2008 and re-registered as a public limited liability company on March 29, 2019. 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.C. Property and Equipment

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 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. The initial monthly payment is expected to be between $28,000 and $30,000, which consists of $12,000 for the office space, and is expected to be between $16,000 and $18,000 for the laboratory space. Through-out 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, or USD. Our functional currency is the Danish Krone, or DKK. Some Danish Krone amounts in this discussion and analysis have been translated solely for convenience into USD at an assumed exchange rate of DKK 6.5612 per $1.00, which was the official exchange rate of such currencies as of December 31, 2021 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. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly in sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." The financial statements as of December 31, 2021 and 2020 and for the years ended December 31, 2021, 2020 and 2019 were prepared in accordance with IFRS, as issued by the IASB.

Overview

We are a clinical-stage AI-immunology™ platform company using our proprietary artificial intelligence, or AI, technology, engineering expertise and drug development know-how to simulate the human immune system and generate predictive models to identify and develop novel immunotherapies for the treatment of various cancers, bacterial diseases and viral infections. Drug discovery and clinical development using historically prevailing techniques is a long, costly process with a high attrition rate. We believe our proprietary AI-immunology platforms, trained to translate vast amounts of data into a deep understanding of biological processes in the human body, can be harnessed to rapidly and cost effectively design and develop unique immunotherapies, thereby potentially revolutionizing the process of drug discovery and development. In an effort to validate the predictive power and scalability of our AI platforms, we have identified and are developing a pipeline of clinical product candidates initially focused in the areas of immuno-oncology and infectious disease. We are currently in the clinic with our two lead product candidates, EVX-01 and EVX-02, for the treatment of various cancers.

Our three proprietary platforms include (i) PIONEER, our immuno-oncology platform, (ii) EDEN, our bacterial disease platform, and (iii) RAVEN, our viral disease platform. Currently, we are focused on using PIONEER for the development of patient-specific immunotherapies for various cancers and using EDEN to develop immunotherapies for bacterial diseases. We plan to use our RAVEN platform to discover and develop vaccines against future coronaviruses as well as other viral infections. We may, in the future, develop additional platforms to address other conditions known to have a large immunological component, examples of which could include autoimmune diseases, microbiome dysbiosis, allergies and parasites.

Key Factors and Trends Affecting our Business

We believe that our performance and future success depend on several factors that present significant opportunities for us but also pose risks and challenges, including those discussed below and in the section of this annual report titled "Risk Factors."

COVID-19

In December 2019, a novel strain of coronavirus was reported in Wuhan, China and on March 11, 2020 the World Health Organization, or the WHO, declared COVID-19 a pandemic. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. Denmark, all states in the United States, and many local jurisdictions and countries around the world have, at times during the pandemic, issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and/or recommendations, and/or the perception that additional orders, restrictions or recommendations could occur, have, at times during the pandemic, resulted in widespread closures of businesses, including healthcare systems, work stoppages, slowdowns and/or delays, work-from-home policies and travel restrictions, among other effects.

The full extent to which the COVID-19 outbreak will impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets. As the COVID-19 pandemic continues, our results of operations, financial condition, and cash flows may be adversely affected, and may differ from current projections.

These uncertainties include, among others, the ultimate severity and duration of the pandemic; the emergence and prevalence of COVID-19 variants, such as the recent emergence of the Omicron variant; governmental, business or other actions that have been, are being or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions, and imposition of social distancing measures; impacts of the pandemic on our employees, the vendors or distribution channels in our supply chain and on the our ability to continue to manufacture its products; impacts of the pandemic on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems, impacts of the pandemic on the regulatory agencies with which we interact in the development, review, approval and commercialization of products derived from our product candidates, if any; impacts of the pandemic on reimbursement for products derived from our product candidates, if any, and for services related to the use of products derived from our product candidates, if any; and impacts of the pandemic on the Danish, United States and global economies more broadly.

In addition, we rely upon third parties for many aspects of our business, including the provision of goods and services related to the manufacture of our clinical products and the conduct of our clinical trials. Any prolonged material disruption to the third parties on which we rely could negatively impact our ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operations and financial condition.

COVID-19 or other public health epidemics, pandemics or outbreaks, and the resulting business or economic disruptions resulting therefrom, may adversely impact our business as well as our ability to raise capital. While we continue to conduct research and development, or R&D, activities, including our ongoing clinical trials, the COVID-19 pandemic has, at times, impacted the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. We work closely with our internal teams, our clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, any potential adverse impacts of COVID-19 on our R&D activities. We are closely monitoring the potential impact of COVID-19 on our business and operations, financial results and cash flows. Our top priority remains the health and safety of our staff and the patients in our studies.

Russia's Invasion of Ukraine

On February 24, 2022, Russia invaded Ukraine creating a global conflict. 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, and are likely to continue to have, short-term and more likely longer-term adverse impacts on Ukraine and Europe and around the globe. Potential ramifications include disruption of the supply chain including research activities and complications with the conduct of ongoing and future clinical trials of our product candidates, including patient enrollment. We rely on global networks of contract research organizations and clinical trial sites to enroll patients, Delays in research activities or in the conduct of our clinical trials could increase associated costs and, depending upon the duration of any delays, require us to find alternative suppliers at additional expense. In addition, the conflict between Russia and the Ukraine has had significant ramifications on global financial markets, which may adversely impact our ability to raise capital on favorable terms or at all.

Selected Financial Data

The selected historical consolidated financial information for the years ended December 31, 2021, 2020 and 2019 and the selected statements of financial position data as of December 31, 2021, 2020 and 2019 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,		
	2021	2020	2019
	(USD in thousands, except per share data)		
Consolidated Statement of Comprehensive Loss Data:			
Research and development expenses	$ 19,583	$ 10,902	$ 8,216
General and administrative expenses	6,251	5,666	2,647
Operating loss	(25,834)	(16,568)	(10,863)
Finance income	2,039	216	65
Finance expenses	(915)	(223)	(1,222)
Net loss before tax	(24,710)	(16,575)	(12,020)
Income taxes	178	1,557	825
Net loss for the period	$ (24,532)	$ (15,018)	$ (11,195)
Net loss attributable to equity holders of Evaxion Biotech A/S	$ (24,532)	$ (15,018)	$ (11,195)
Loss per share – basic and diluted	$ (1.26)	$ (0.97)	$ (0.81)
Number of shares used for calculation (basic and diluted)	19,493,143	15,434,758	13,892,314

Consolidated Statements of Financial Position Data

	December 31,		
	2021	2020	2019
		(USD in thousands)	
Consolidated Statements of Financial Position Data:			
Cash and cash equivalents	$ 32,166	$ 5,834	$ 9,559
Total assets	40,163	11,965	11,084
Total liabilities	7,726	4,927	1,722
Share capital	3,755	2,648	2,481
Other reserves	79,144	31,669	22,693
Accumulated deficit	(50,432)	(27,279)	(15,812)
Total equity	32,437	7,038	9,362
Total liabilities and equity	$ 40,163	$ 11,965	$ 11,084

Key Components of Our Results of Operations

Operating Expenses

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 platform.

The research activities are comprised of activities performed before filing an Investigational New Drug, or IND, or equivalent and necessary pre-clinical 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 expense or accrued expense.

For the year ended December 31, 2021, 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.

We will continue to increase our research and development expenses as we continue the development of our product candidates, our AI platforms, and our research activities for our pre-clinical and clinical-stage programs. We may receive government grants or tax credits in the future that may result in a reduction of our research and development expenses.

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 time 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 pre-clinical and nonclinical studies, and clinical trials of our product candidates due to the inherently unpredictable nature of pre-clinical 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.

As a result of the completion of our follow-on offering and initial public offering, we expect to incur additional general and administrative expenses as a result of expanding our corporate functions and operating as a public company.

Finance Income

Finance income consist primarily of foreign currency gains.

Finance Expenses

Finance expenses consist primarily of interest on lease liabilities, fair value adjustments of liability classified warrants being measured at fair value and interest on loan from lessor.

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 on 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. As part of the recovery of the Danish economy after COVID-19, the current tax credits in relation to research and development are increased from 103% (2020) and 105% (2021), respectively, to 130% (both years).

Results of Operations

Comparison of the years ended December 31, 2021, 2020 and 2019:

	Years Ended December 31,			Change	
	2021	2020	2019	2021 vs 2020	2020 vs 2019
	(USD in thousands)				
Operating expenses:					
Research and development	$ 19,583	$ 10,902	$ 8,216	$ 8,681	$ 2,686
General and administrative	6,251	5,666	2,647	585	3,019
Total operating expenses	25,834	16,568	10,863	9,266	5,705
Operating loss	**(25,834)**	**(16,568)**	**(10,863)**	**(9,266)**	**(5,705)**
Finance income	2,039	216	65	1,823	151
Finance expenses	(915)	(223)	(1,222)	(692)	999
Net loss before tax	**(24,710)**	**(16,575)**	**(12,020)**	**(8,135)**	**(4,555)**
Income taxes	178	1,557	825	(1,379)	732
Net loss for the year	**$ (24,532)**	**$ (15,018)**	**$ (11,195)**	**$ (9,514)**	**$ (3,823)**

Research and Development

Research and development expenses were $19.6 million for the year ended December 31, 2021 compared to $10.9 million for the year ended December 31, 2020. The increase in research and development expenses was primarily due to increased spending of $5.7

million, net of grant income of $0.3 million in 2021, for ongoing development on our platform, pre-clinical product candidates, and clinical trials. In addition, employee-related costs increased by $3.0 million due to higher headcount.

Research and development expenses were $10.9 million for the year ended December 31, 2020 compared to $8.2 million for the year ended December 31, 2019. The increase in research and development expenses was primarily due to increased spending of $1.5 million, net of grant income of $0.8 million in 2020, for ongoing development on our platform, pre-clinical product candidates, and clinical trials. In addition, employee-related costs increased by $1.2 million due to higher headcount.

General and Administrative

General and administrative expenses were $6.3 million for the year ended December 31, 2021, as compared to $5.7 million for the year ended December 31, 2020. The increase in general and administrative expenses was primarily due to a $1.4 million increase in professional fees related to the expansion of our corporate function for our IPO, partially offset by a decrease of $0.9 million in employee-related costs.

General and administrative expenses were $5.7 million for the year ended December 31, 2020, as compared to $2.6 million for the year ended December 31, 2019. The increase in general and administrative expenses was primarily due to a $1.2 million increase in employee-related costs due to increased headcount and a $1.9 million increase in professional fees related to the expansion of our corporate function for our IPO.

Finance Income

Finance income primarily related to foreign exchange gains recognized were $2.0 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively. Finance income for the year ended December 31, 2019 was immaterial.

Finance Expenses

Finance expenses for the year ended December 31, 2021 were $0.9 million, compared to $0.2 million for the year ended December 31, 2020. The increase in finance expenses were primarily related to an increase of $0.6 million in foreign exchange losses recognized.

Finance expenses for the year ended December 31, 2020 were $0.2 million, compared to $1.2 million for the year ended December 31, 2019. This decrease in finance expenses is primarily related to the conversion of our convertible debt instruments to equity in 2019, resulting in no related fair value changes in 2020.

Income Taxes

The benefits from income tax were $0.2 million for the year ended December 31, 2021, compared to $1.6 million for the year ended December 31, 2020. Our effective tax rates for the year ended December 31, 2021 and 2020 were different from the Danish effective statutory tax rate of 22% since we only recognize deferred tax assets on temporary differences to the extent the requirements for capitalization are met. Taxable income is mainly related to expected tax receivable from R&D Tax Schemes in Denmark and Australia based on tax losses incurred in the current financial year. In connection with our IPO, we incurred non-deductible expenses which resulted in differences in our effective tax rates. In December 2021, as a result of a tax ruling from the Australian tax authorities, we were forced to reevaluate our Australian tax benefit and reverse approximately $1.0 million of tax benefit previously reported in prior years.

The income tax benefit was $1.6 million for the year ended December 31, 2020, compared to $0.8 million for the year ended December 31, 2019. Our effective tax rates for the year ended December 31, 2020 and 2019 were different from the Danish statutory tax rate of 22% since we do not meet the requirement for capitalization of deferred tax assets, and we incurred non-deductible expenses which resulted in differences in our effective tax rates.

Tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position were $9.5 million for the year ended December 31, 2021 as compared to $3.8 million for the year ended December 31, 2020. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Currently no deferred tax assets from tax losses carried forward are recognized.

Tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position were $3.8 million for the year ended December 31, 2020 as compared to $1.3 million for the year ended December 31, 2019. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Currently no deferred tax assets from tax losses carried forward are recognized.

5.B. Liquidity and Capital Resources

Liquidity and Capital Resources

Overview

We are a clinical development stage AI-immunology company that has not generated revenues for the years ended December 31, 2021, 2020 or 2019. 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. As of December 31, 2021, we had an accumulated deficit of $50.4 million and expect to continue to incur significant losses for the foreseeable future.

As of December 31, 2021 and December 31, 2020, our available liquidity, comprised of cash and cash equivalents, was $32.2 million and $5.8 million, respectively and our total equity was $32.4 million and $7.0 million, respectively. We have not generated any revenues during the periods ended December 31, 2021 and December 31, 2020 and we do not anticipate generating significant revenues unless and until we successfully complete Phase 2b development and obtain an out-licensing partnership of any current or future product candidates.

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.

In September 2020, we received $6.6 million of additional funding from the issuance of 745,380 of our ordinary shares as part 1 of our "bridging round" with outside investors. On October 15, 2020, we successfully completed part 2 of our "bridging round" of capital with outside investors in the amount of $2.4 million from the issuance of 269,136 of our ordinary shares and received the proceeds in November 2020.

In October 2020, we 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. In October 2020, we entered into a lease for approximately 518 square meters, which was allocated for additional laboratory space, in Hørsholm, Denmark. The commencement date for the lease is 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. The initial monthly payment is expected to be between $28,000 and $30,000, which consists of $12,000 for the office space, and is expected to be between $16,000 and $18,000 for the laboratory space. Through-out the term, the lease is subject to annual increases ranging from two to four percent on the annual lease payment amount.

In addition to the ordinary lease payments, we obtained financing from DTU Science Park A/S ("DTU") for rebuilding the laboratory facility and engineering building to match ours 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. As of December 31, 2021, the Company is still in discussions with DTU on the final settlement terms. Consequently, no payments have been made to date and we continue to accrue interests on the outstanding balance.

On February 5, 2021, we completed our IPO through which we issued and sold 3,000,000 ADSs, each of which represents one ordinary share, at a price to the public of $10.00 per ADS. We received aggregate net proceeds of $25.3 million from the IPO, after deducting the underwriting discounts and commissions and offering expenses. Upon the completion of the IPO, our registered, issued, and outstanding share capital was nominal DKK 19,198,668.

On November 9, 2021, we completed a follow-on public offering through which we issued and sold 3,942,856 ADSs, each of which represents one ordinary share, at a price to the public of $7.00 per ADS. The shares issued were inclusive of the 514,285 ADSs issued to the underwriters pursuant to the full exercise of their option to purchase additional shares on November 5, 2021. We received aggregate net proceeds of $24.9 million from the follow-on public offering, which includes the funds received for the additional shares issued to the underwriters, after deducting the underwriting discounts and commissions and offering expenses. Upon the completion of the follow-on public offering, our registered, issued, and outstanding share capital was nominal DKK 23,141,524.

As of December 31, 2021, due to warrant exercise, our outstanding share capital was nominal DKK 23,203,808.

Financing Requirements

We anticipate incurring additional losses until such time, if ever, we can complete our research and development activities and obtain an out-licensing partnership for our product candidates and generate revenues from such product candidates. Substantial additional financing will be needed by us to fund our operations and to continue development of our product candidates.

Based on our current operating plans, we expect that our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the date of this annual report. However, our operating plans may change as a result of many 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 capital to achieve our goals. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and on going 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 amount of funds we will require for our developmental activities.

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;
- 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 collaboration, 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 the COVID-19 pandemic on the initiation or completion of pre-clinical studies or clinical trials and the supply of our product candidates;
- the effects of the recent 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;

- 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 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 expect to finance cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

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 product candidate development or grant rights to develop and market product candidates.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Cash Flow Data:			
Net cash used in operating activities	$ (21,933)	$ (12,438)	$ (7,019)
Net cash used in investing activities	(1,330)	(393)	(68)
Net cash provided by financing activities	49,805	8,817	9,508
Net (decrease)/increase in cash and cash equivalents	$ 26,542	$ (4,014)	$ 2,421

Operating Activities

Net cash used in operating activities was $21.9 million for the year ended December 31, 2021. The largest components of our cash used in operating activities during this period was a net loss for the year of $24.5 million offset by non-cash adjustments of $0.5 million, $0.8 million of income taxes received, and net cash change in our working capital during the period of $1.2 million. The non-cash charges primarily consisted of share-based compensation expense of $1.4 million. This non-cash charge was offset by a change in income tax benefit of $0.2 million and various other immaterial changes of $0.7 million. The positive net cash attributable to changes in our current operating assets (excluding cash) and our current operating liabilities during the period was primarily comprised of an increase of $1.9 million increase of receivables due to timing of prepayments in our research and development activities, offset by a decrease of $0.6 million in trade payables and a decrease of $0.1 million in other payables, both due to the timing of invoices received.

Net cash used in operating activities was $12.4 million for the year ended December 31, 2020. The largest component of our cash used in operating activities during this period was a net loss for the year of $15.0 million offset by non-cash charges of $1.6 million, $0.8 million of income taxes received related changes, and net cash change in our working capital during the period of $0.2 million. The

non-cash charges primarily consisted of share-based compensation expense of $3.4 million and various other immaterial changes of $0.3 million. These increases in non-cash charges were offset by a change in income tax benefit of $1.6 million and a change in tax credit schemes accounted for as grants of $0.5 million. The positive net cash attributable to changes in our current operating assets (excluding cash) and our current operating liabilities during the period was primarily comprised of an increase of $2.0 million in trade payables and an increase of $1.1 million in other payables, both due to the timing of invoices received, offset by a $2.7 million increase of receivables due to timing of prepayments in our research and development activities and other immaterial changes of $0.2 million.

Net cash used in operating activities was $7.0 million for the year ended December 31, 2019. The largest component of our cash used in operating activities during this period was a net loss for the year of $11.2 million, offset by non-cash charges of $3.0 million, $0.7 million of income taxes received related changes, and net cash change in our working capital during the period of $0.6 million. The non-cash charges primarily consisted of share-based compensation expense of $2.4 million, changes in fair value of convertible debt facilities of $1.2 million and various other immaterial changes of $0.2 million. These increases in non-cash charges were offset by a change in income tax benefit of $0.8 million. The positive net cash attributable to changes in our current operating assets (excluding cash) and our current operating liabilities (excluding convertible debt) during the period was primarily comprised of an increase of $0.5 million in trade payables and an increase of $0.4 million in other payables, both due to the timing of invoices received, offset by an increase of receivables due to timing of prepayments in our research and development activities.

Investing Activities

Net cash used in investing activities was primarily driven by the purchase of property and equipment in the amounts of $1.3 million, $0.1 million, and $0.1 million, and changes in leasehold deposits which were nominal, $0.2 million, and nominal, for the years ended December 31, 2021, 2020 and 2019, respectively. Net cash used in investing activities for the purchase of intangible assets was $0.1 million for the year ended December 31, 2021, and nominal for the year ended December 31, 2020. No intangible asset purchases were made in 2019.

Financing Activities

Net cash provided by financing activities was $49.8 million for the year ended December 31, 2021, which was primarily due to net proceeds from the issuance of shares of $53.9 million, partially offset by transaction costs of $3.8 million related to the issuance of shares and $0.3 million related to repayment of lease liabilities.

Net cash provided by financing activities was $8.8 million for the year ended December 31, 2020, which was primarily due to net proceeds from the issuance of shares of $9.0 million, partially offset by transaction costs of $0.1 million related to the issuance of shares and $0.1 million related to repayment of lease liabilities.

Net cash provided by financing activities was $9.5 million for the year ended December 31, 2019, which was primarily due to net proceeds from the issuance of shares of $9.4 million.

Off-balance Sheet Arrangements

As of December 31, 2021, 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, 2021.

Tabular Disclosure of Contractual Obligations

	Payments Due by Period				
	Within 1 Year	1 – 2 Years	2 – 5 Years	Over 5 Years	Total
	(USD in thousands)				
Leases[1]	$ 326	$ 332	$ 891	$ 2,149	$ 3,698
Loan from lessor[5]	192	192	577	497	1,458
Purchase obligations[2]	72	—	—	—	72
Total[3][4]	$ 590	$ 524	$ 1,468	$ 2,646	$ 5,228

(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) We enter into contracts in the normal course of business with Clinical Research Organizations, or CROs, and other third parties for clinical trials and pre-clinical 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.

(3) 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.

(4) 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 immunotherapies 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 immunotherapies 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."

(5) The loan amount as of December 31, 2021 is still subject to possible minor adjustment. Further information is provided in Note 17 to our financial statements appearing at the end of this annual report.

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 year ended December 31, 2021, our net foreign exchange gain was $1.3 million. For the years ended, 2020 and 2019, our foreign exchange loss was immaterial. 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 2 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

Our Management's Discussion and Analysis of Financial Condition and Results of Operations 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 2 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 during 2021 were valued using black-scholes option pricing model, using the below-mentioned assumptions.

The table below summarizes the fair value by grant:

Outstanding program	Per warrant grant date fair value (DKK)	Per warrant grant date fair value (USD)
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

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 2 and 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 share-based compensation.

Fair Value of Convertible Debt with Embedded Derivatives

Our convertible debt instruments contain embedded conversion features which allow for settlement in a variable number of shares. The embedded features were determined to be embedded derivatives. We elected not to bifurcate the embedded derivatives and to recognize the entire instrument at fair value. Accordingly, the entire instrument is recognized at fair value at inception and subsequently carried at fair value through the statement of comprehensive loss. The debt instrument was extinguished in July 2019 when the facilities were converted into our ordinary shares.

The convertible debt instruments were valued using the present value of a probability weighting of the mutually exclusive settlement alternatives. We contemplated a variety of inputs including the: USD to DKK exchange rate, the discount rate of the debt instrument, the probability of a qualifying financing event and the price of our ordinary shares. The key assumption used to determine the fair value of these debt instruments was the ordinary share valuation. See “Ordinary Share Valuation” in this annual report.

Refer to Note 2 to our consolidated financial statements included in this annual report for additional detail on our accounting policy, judgements and assumptions used in accounting for convertible debt instruments.

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.

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.

Our 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)
Executive Management:		
Lars Staal Wegner, M.D	47	Chief Executive Officer
Niels Iversen Møller, M.D.	42	Interim Chief Financial Officer and Chief Business Officer
Erik Deichmann Heegaard, PhD, DMSc	54	Chief Medical Officer
Birgitte Rønø, Ph.D.	45	Chief Scientific Officer
Andreas Holm Mattsson	46	Chief Innovation Officer
Jesper Nyegaard Nissen, MSc[(1)]	52	Chief Operating Officer
Bo Karmark, M.Sc[(2)]	56	Incoming Chief Financial Officer
Glenn S. Vraniak[(3)]	59	Former Chief Financial Officer

(1) Mr. Nissen entered into agreement to join us on January 16, 2022, and joined us in March 14, 2022.

(2) Mr. Karmark entered into agreement to join us on January 14, 2022, and is expected to join us by August 2022.

(3) Mr. Vraniak resigned effective November 1, 2021.

The following is a brief summary of the prior business experience of the members of our executive management:

Lars Staal Wegner, M.D. joined us in August 2017 as our Chief Executive Officer. Dr. Wegner is one of our founding investors and has previously been involved in multiple startups and early ventures. Dr. Wegner began his career as a medical doctor and worked for several years as a clinician. Since then, Dr. Wegner has gained extensive experience within the vaccine industry, first at Pfizer from 2006 to 2007 and then for ten years from 2007 to 2017 as member of senior management to Bavarian Nordic, a Nasdaq listed immuno-oncology and vaccine company. Dr. Wegner received his M.D. from the University of Southern Denmark.

Erik Deichmann Heegaard, Ph.D., DMSc joined us as our Chief Medical Officer pursuant to the terms of his Service Agreement entered into in November 2020. Dr. Heegaard has more than 25 years of experience within oncology and infectious diseases. Prior to joining us, Dr. Heegaard served as Nordic Medical Director at Novartis Oncology from 2015 and he was the Chief Medical Officer of the oral GLP-1 project at Novo Nordisk, from 2011 to 2014, where he successfully completed Phase 1 and 2 clinical trials for the project and served as chief architect of the global Phase 3 clinical development program for the project. Prior to that, Dr. Heegaard held numerous research and clinical positions in companies such as Sandia National Laboratories, Bavarian Nordic and SSI. Dr. Heegaard received his BA from the University of Copenhagen, Denmark (Cand. med), and both his Ph.D. and his DMSc from the Health Faculty, University of Copenhagen, Denmark.

Birgitte Rønø, Ph.D., joined us as Senior Director, Immuno-Oncology in September 2017. Dr. Rønø has successfully developed and led our pre-clinical and early clinical oncology pipeline. In September 2021, Dr. Rønø was appointed Chief Scientific Officer. Dr Rønø has more than 15 years' experience in biopharmaceutical drug discovery from academia and industry. Prior to joining Evaxion, Dr. Rønø served as a specialist, team leader and project manager at Novo Nordisk, from 2013-2017, where she was leading early drug discovery projects, evaluating in-licensing opportunities, and supporting drug development projects with pre-clinical and biomarker expertise. Dr. Rønø holds a bachelor's degree in medicine and a master's degree in human biology, both from the University of Copenhagen, Denmark. Dr. Rønø received her Ph.D.in experimental oncology and immunology from National Institutes of Health, Bethesda, USA and Copenhagen University Hospital, Denmark.

Niels Iversen Møller, M.D. is one of our co-founders. From our inception in 2008 until August 2017, Dr. Møller was our Chief Executive Officer and in 2016, he was awarded "CEO of the Year" in the vaccine industry by European CEO. Since August 2017, Dr. Møller has served as our Chief Business Officer. As of November 1, 2021, Dr. Møller replaced Mr. Vraniak as our Interim Chief Financial Officer. From 2009 to 2011 he was a Medical Director within the area of Companion Diagnostics for Medical Prognosis A/S and from 2008 to 2009 he was a Medical Advisor within the area of cancer and biopharmaceuticals for AstraZeneca. Dr. Møller began this career at Servier Pharmaceuticals as Marketing Manager. Dr. Møller received his M.D. from the University of Copenhagen and his BA in Economics from Copenhagen Business School.

Andreas Holm Mattsson is one of our Founders and has served as our Chief Innovation Officer since our inception. Mr. Mattsson is an experienced bioinformatician from the Technical University of Denmark. Prior to joining us Mr. Mattsson was at Novo Nordisk from 2004 to 2011 developing *in silico* platforms. Since founding of Evaxion in 2008, Andreas has worked on developing Evaxion's AI platforms including EDEN and PIONEER, as well as other *in silico* models enabling vaccine discovery and development in the areas of immuno-oncology and infectious disease.

Jesper Nyegaard Nissen, MSc joined us on March 14, 2022 as our Chief Operating Officer pursuant to the terms of his Service Agreement entered into on January 16, 2022. Mr. Nissen has more than 25 years of experience in the pharmaceutical industry across finance, investments, research and development. Mr. Nissen began his career in Novo Nordisk Corporate Finance being responsible for development of controlling and performance management processes followed by the role as finance responsible for different corporate business areas. In 2010, Mr. Nissen moved into senior leadership roles as Vice President and later as Corporate Vice President for Global Research Operations. with the focus on research and development and strategic and operational development which included responsibilities for clinical sourcing, development IT strategies, establishment of development shared service center in India, application of real world evidence, or RWE and health economics related to clinical trials, development of research strategies, research portfolio governance, operation of global research sites, design and operation of external research engagement models among others. Since January 2021 until joining us, Mr. Nissen has worked for Fujifilm Diosynth Biotechnologies in the program management team for large scale capital projects driving Fujifilm Diosynth Biotechnologies mission to become a global leader within CDMOs. Mr. Nissen received his MSc Business Economics (Cand. Oecon.) from the University of Aarhus, Denmark.

Glenn S. Vraniak joined us in October 2019 as our Chief Financial Officer. Prior to joining our company, Mr. Vraniak served as Chief Financial Officer of electroCore, Inc. from August 2016 until April of 2019 and was a key member of the management team that carried the company through a successful IPO in June of 2018. Prior to that, from February 2014 to January 2016, Mr. Vraniak served as Chief Financial Officer at G&W Laboratories, Inc., a specialty pharmaceutical company, where he executed the growth strategy by acquiring two companies and over 35 products. Prior to that, from October 2011 through July 2013, he was President of Aprecia Pharmaceuticals, Inc., a 3D printing technology enabled pharmaceutical company. From 2003 through 2011, Mr. Vraniak was the CFO and Head of Strategic Planning for Prasco Laboratories, a generic pharmaceutical company. From January 2000 to January 2002, he served as Executive VP for GE Capital, and subsequently founded Preceptus, a boutique consulting firm focused on helping small and mid-market companies achieve efficient and scalable growth in the healthcare and technology sectors. Mr. Vraniak received an Electronic Engineering Technology degree and a Managerial M.B.A. in Finance from the Rutgers University.

Executive Management Joining Us Subsequent to the Date of this Annual Report

Bo Karmark, M.Sc. will join us by August 2022 as our Chief Financial Officer pursuant to the terms of his Service Agreement entered into on January 14, 2022. Mr. Karmark is an experienced financial executive with a career spanning more than 25 years working for several multinational listed companies, primarily in the biotech, pharma, and bioscience industries. Before joining us, Mr. Karmark served as the Chief Financial Officer for Aquaporin A/S, a water technology company for the past seven years Aquaporin is listed on the Nasdaq Copenhagen stock exchange. Before that, Mr. Karmark held numerous financial management positions at various companies including Chr. Hansen Holding A/S, H. Lundbeck A/S, and NsGene A/S. Mr. Karmark received his M.Sc. in Business Administration and Auditing form the Copenhagen Business School, Denmark.

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

Our executive management consists of our Chief Executive Officer, Chief Business Officer, Chief Innovation Officer, Chief Medical Officer, Chief Scientific Officer and Chief Financial Officer. 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, 2021, 2020, and 2019.

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Lars Staal Wegner (CEO)			
Salary	378	321	238
Bonus	105	—	—
Other employee benefits	127	621	650
Total	610	942	888
Niels Iversen Møller (CBO) [3]			
Salary	245	202	175
Bonus	23	11	—
Other employee benefits	—	0	—
Total	268	213	175
Andreas Holm Mattson (CIO)			
Salary	245	202	175
Bonus	45	11	—
Other employee benefits	—	0	—
Total	290	213	175
Erik Deichmann Heegaard, Ph.D., DMSc (CMO)[4]			
Salary	214	—	—
Bonus	52	—	—
Other employee benefits	266	—	—
Total	532	—	—
Birgitte Rønø, Ph.D. (CSO) [5]			
Salary	110	—	—
Bonus	33	—	—
Other employee benefits	56	—	—
Total	199	—	—
Glenn S. Vraniak (CFO) [1]			
Salary	310	350	88
Bonus	73	43	—
Other employee benefits[2]	65	1,045	204
Total	448	1,438	292

(1) Mr. Vraniak resigned as the Chief Financial Officer of the Company effective November 1, 2021.

(2) As noted in Note 8 to our consolidated financial statements included in this annual report, in 2019, the CFO was issued 150,660 warrants. The terms of the warrants issued to the Company's CFO were amended, resulting in an acceleration of stock-based compensation expense in 2020. Mr. Vraniak resigned as our CFO effective November 1, 2021.

(3) Effective November 1, 2021, Mr. Møller became our Interim Chief Financial Officer.

(4) Dr. Heegaard joined our company in April 2021 as CMO and did not receive any compensation from us in 2019 and 2020.

(5) Dr. Rønø was appointed Chief Scientific Officer in September 2021. Prior to September 2021, Dr. Rønø was a non-executive employee. The salary above is for the period July 1, 2021 to December 31, 2021, as she took the responsibility on July 1, 2021.

The following table lists compensation to our board of directors for the years ended December 31, 2021, 2020, and 2019:

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Marianne Søgaard (Chairman of the Board of Directors) [1]			
Board and committee fees	121	—	—
Travel allowance	—	—	—
Share-based compensation	45	12	—
Total	166	12	—
Roberto Prego			
Board and committee fees	55	—	—
Travel allowance	—	—	—
Share-based compensation	14	62	61
Total	69	62	61
Steven Projan			
Board and committee fees	59	—	—
Travel allowance	—	—	—
Share-based compensation	14	98	62
Total	73	98	62
Lars Holtug[5]			
Board and committee fees	36	—	—
Travel allowance	—	—	—
Share-based compensation	14	—	—
Total	50	—	—
Helen M. Boudreau[3]			
Board and committee fees	24	—	—
Travel allowance	—	—	—
Share-based compensation	—	48	—
Total	24	48	—
Jo Ann Suzich[4]			
Board and committee fees	18	—	—
Travel allowance	—	—	—
Share-based compensation	—	26	63
Total	18	26	63
Thomas William Wylonis			
Board and committee fees	—	—	—
Travel allowance	—	—	—
Share-based compensation	—	60	166
Total	—	60	166
Kim Bjoernstrup [2]			
Board and committee fees	—	—	—
Travel allowance	—	—	—
Share-based compensation	—	52	—
Total	—	52	—

(1) Ms. Søgaard was appointed as Chairman of the Board on November 25, 2020.

(2) Mr. Bjoernstrup stepped down from his position as Chairman of the Board effective November 4, 2020.

(3) Ms. Boudreau elected not to stand for re-election to the Board in 2021.

(4) Ms. Suzich elected not to stand for re-election to the Board in 2021.

(5) Mr. Holtug was elected as a member of the Board at the 2021 Annual General Meeting held on May 25, 2021.

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 following table lists aggregate compensation to our employees, excluding executive management and board of directors, and subsequently aggregate executive management compensation and Board of Directors compensation for the years ended December 31, 2021, 2020 and 2019:

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Employee costs, excluding Executive Management and Board of Directors			
Salaries	5,094	2,717	1,919
Cash bonus	337	—	—
Share-based compensation	778	1,484	1,055
Pensions	649	206	96
Other social security contributions	28	17	12
Other staff costs	364	196	176
Total employee costs, excluding Executive Management and Board of Directors	7,250	4,620	3,258
Executive Management compensation			
Salaries	1,502	1,234	900
Cash bonus	331	65	—
Share-based compensation	514	1,565	956
Pensions	—	—	—
Other social security contributions	—	—	—
Other staff costs	—	—	—
Total Executive Management compensation	2,347	2,864	1,856
Board of Directors compensation			
Board and committee fees	313	—	—
Travel allowance	—	—	—
Share-based compensation	87	359	351
Total board of directors compensation	400	359	351
Total employee costs	9,997	7,843	5,465
Recognized as follows in the Statement of Comprehensive Loss:			
Research and development expenses	7,845	4,833	3,607
General and administrative expenses	2,152	3,007	1,858
Total employee costs	9,997	7,840	5,465
Average number of full-time employees	53	33	25
Number of full-time employees	61	35	31

Executive Management Agreements

Lars Staal Wegner, M.D.

In September 2020, we entered into an executive service contract with Dr. Wegner. The service contract confirms Dr. Wegner's employment by the Company since July 2017 and his 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. Dr. Wegner's employment under the executive service contract continues until terminated by us or Dr. Wegner. We may terminate Dr. Wegner's employment for any reason with 12 months' notice and Dr. Wegner may terminate his employment with three months' notice.

Niels Iversen Møller, M.D.

In September 2020, we entered into an executive service contract with Dr. Møller. The executive service contract confirms Dr. Møller'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. Dr. Møller's employment under the executive service contract continues until terminated by us or Dr. Møller. We may terminate Dr. Møller's employment for any reason with 12 months' notice and Dr. Møller may terminate his employment with three months' notice.

Erik Deichmann Heegaard, Ph.D., DMSc

In November 2020, we entered into an executive service contract with Dr. Heegaard. Dr. Heegaard'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. Dr. Heegaard's employment under the executive service contract continues until terminated by us or Dr. Heegaard. We may terminate Dr. Heegaard's employment for any reason with 12 months' notice and Dr. Heegaard may terminate his employment with three 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.

Jesper Nyegaard Nissen, MSc

In January 2022, we entered into an executive service contract with Mr. Nissen, with start in March 2022. Mr. Nissen'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. Nissen's employment under the executive service contract continues until terminated by us or Mr. Nissen. We may terminate Mr. Nissen's employment for any reason with 12 months' notice and Mr. Nissen may terminate his employment with three months' notice.

Glenn S. Vraniak

In October 2019, we entered into an executive employment contract with Mr. Vraniak. The executive employment contract confirms Mr. Vraniak's title, his base salary, his eligibility for a bonus contingent upon our obtaining certain equity based financing, his eligibility for a bonus based on certain new targets, and his eligibility for benefits and also provides for certain benefits upon termination of his employment under specified conditions. Mr. Vraniak's employment under the executive employment contract continues until terminated by us or Mr. Vraniak. We may terminate Mr. Vraniak's employment with six months' notice, however, we may terminate Mr. Vraniak's employment with one months' notice if, within a period of 12 consecutive months, Mr. Vraniak has been paid salary during an illness for a total of 120 days. Mr. Vraniak may terminate his employment voluntarily upon one month's notice.

On October 15, 2021, Glenn S. Vraniak, our Chief Financial Officer, informed us that effective November 1, 2021, he would be leaving to pursue other opportunities outside the biopharmaceutical industry. In his place, as of November 1, 2021, we appointed Niels Iversen Møller, as Interim Chief Financial Officer. Mr. Møller was one of our co-founders and is currently also our Chief Business

Officer, a position he will retain. As noted herein, in addition to his medical degree, Mr. Moller has a BA in Economics from Copenhagen Business School.

Mr. Vraniak had agreed to continue to act as our Chief Financial Officer on a full time basis until the effective date of his resignation in order to ensure an orderly transition. In addition, Mr. Vraniak has agreed to provide additional transition services beyond the effective date, as needed, including providing assistance in preparing our third quarter financial statements and earnings call. In exchange for these services, we agreed to continue to pay Mr. Vraniak his then current base salary until the effective date of his resignation and to waive Mr. Vraniak's one month's notice of voluntary termination requirement.

Incoming Executive Management Agreement

Bo Karmark, M.Sc.

In January 2022, we entered into an executive service contract with Mr. Karmark, with start in August 2022. Mr. Karmark'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. Karmark's employment under the executive service contract continues until terminated by us or Mr. Karmark. We may terminate Mr. Karmark's employment for any reason with 12 months' notice and Mr. Karmark may terminate his employment with three months' notice.

Board of Directors

Descriptions and summaries of the prior business experience of the members of our board of directors is described in "Item 6.C. Board practices" below.

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 meeting.

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 2021

In June 2021 62,147 warrants were granted to the Chief Medical Officer with an exercise price of DKK 1 per warrant. The warrants vest over 36 months.

In December 2021 523,599 warrants were granted to employees, the board of directors and executive management with an exercise price of USD 5.38 per warrant. The warrants vest over 36 months for employees and executive management. For the board of directors warrants vested immediately.

Warrants granted up until year-end 2020

On December 17, 2020 our board of directors approved the issuance and allocation of 581,796 warrants. Said warrants were granted in the years 2018, 2019 and the first quarter of 2020, but were only formally issued on December 17, 2020. Our board of directors additionally issued and approved the issuance and allocation of 175,824 warrants on December 17, 2020, which were granted during the second, third and fourth quarter of 2020. The terms and conditions of warrants granted for the years 2016 - 2018 are set out in appendices 1-3 of our articles of association and the terms and conditions of warrants granted for years 2019 and 2020 are set out in appendix 5 of our articles of association.

Each warrant grants the holder the right to subscribe for one ordinary share of nominal DKK 1 against cash payment of the exercise price of DKK 1.

General matters related to warrants

As of December 31, 2021, our board of directors is authorized to issue an additional 1,437,853 warrants during the period ending January 3, 2026.

The grant of warrants to any participant is at the discretion of our board of director 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.

Warrants granted for the years 2016 – 2018 vest upon certain exit or liquidation events, which include an event such as the closing of our IPO in February 2021. Warrants granted for the years 2019 - 2021 generally vest with 1/36th per month. However, in relation to all warrants granted and issued prior to the closing of our IPO, our board of directors established four annual exercise windows in which warrants may be exercised following the completion of our IPO. The first such exercise window began in November 2021.

Warrants granted before or during the second quarter of 2021 has an exercise price of DKK 1 per warrant.

Warrants granted before or during 2019 expires December 31, 2036. Warrants granted thereafter expires 10 years after grant date.

The table below provides an overview of the warrants granted to our board of directors and executive management as of December 31, 2021.

Name	Grant Date	Number of Ordinary Shares Underlying Warrants
Marianne Søgaard (Chairman)	2018-2021	103,487
Lars Holtug (Director).	2021	4,583
Roberto Prego (Director)	2017-2021	38,747
Steven Projan (Director)	2018-2021	46,631
Lars Staal Wegner (CEO)	2016-2021	916,251
Niels Iverson Møller (CBO)	—	—
Andreas Holm Mattson (CIO)	—	—
Erik Deichmann Heegaard (CMO)	2021	97,564
Birgitte Rønø (CSO)	2017-2021	74,376

Insurance and Indemnification

According to the Danish Companies Act, 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 and Compensation Act (*Erstatningansvarsloven*), 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

Our Board of Directors

The following table sets forth certain information relating to our board of directors as of the date of this annual report. The terms of office of all of our directors expire at the next annual general meeting to be held in 2022. All directors are eligible for re-election.

Name	Position	Age	Independent	Year of first appointment	Expiration of current term
Marianne Søgaard[(1) (3)]	Chairman	53	No	2020	2022
Steven Projan[(1)(2)(3)]	Member	69	Independent	2018	2022
Roberto Prego[(1)(2)]	Member	50	Independent	2018	2022
Lars Holtug[(2)(3)]	Member	62	Independent	2021	2022

(1) Member of Nomination and Corporate Governance Committee

(2) Member of Audit Committee

(3) Member of Compensation Committee

The following is a brief summary of the prior 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.

In preparation of becoming a publicly traded company in the United States and in order to ensure compliance with the requirements of a company listed on the Nasdaq Capital Market, we underwent a restructuring of our Board. In connection therewith, on November 4, 2020, we asked our Chairman, Kim Bjoernstrup, to step down from the Board, and Mr. Bjoernstrup submitted his resignation. In his place, the Board nominated Marianne Søgaard for the position of Chairman of the Board, subject to the approval of our shareholders. At a Special General Meeting of Shareholders held on November 25, 2020, Ms. Søgaard was elected as a member of our board of directors to serve until the next annual general meeting of Shareholders to be held in 2021.

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.

Steven Projan joined us in 2018. From 2010 until he retired in April 2018, Mr. Projan was a Sr V.P. R&D and Head of Infectious Disease & Vaccines at Medimmune. From 2008 until 2010, Mr. Projan served as V.P., Global and Head of Infectious Disease at Novartis. Mr. Projan was at Wyeth-Ayerst Research in various positions since 1993, with the most recent position from 2008 until 2010 being V.P. and Head of Biological. Mr. Projan is an expert in infectious diseases, having worked many years with both basic and applied research. He successfully led four programs resulting in the approval of novel anti-infective drugs as well as other drugs in various stages of development, and produced more than 110 peer-reviewed publications. Mr. Projan received his S.B. in Life Sciences (Nutrition & Food Sciences) from Massachusetts Institute of Technology, and his M.A., M. Phil.and Ph.D. from Columbia 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 as chairman of Gaming Investment A/S, a gaming solutions provider, and its 11 subsidiaries, and of MTI Caretag ApS, a company investing in healthcare technology. Mr. Holtug also currently serves as a board member of Frida Forsikring Agentur A/S and Domus Forsikring A/S, as well as the Audit Committee Chair of the board of Domus Forsikring A/S. 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.

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, 2021. 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 2021:

Board Member	Position	Committees	Retainer
Marianne Søgaard	Chairman	Nomination and Governance	$ 120,667
Roberto Prego	Director	Audit Committee, Nomination and Governance	$ 54,875
Steven Projan	Director	Audit Committee, Nomination and Governance, Compensation	$ 58,542
Lars Holtug	Director	Audit Committee, Compensation	$ 35,562

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 the completion.

Committees of our Board of Directors

Our board of directors has three standing committees: an audit committee, a compensation committee and a nomination and corporate governance committee.

Audit Committee

The audit committee consists of Lars Holtug, Steven Projan and Roberto Prego, and assists the board of directors in over, seeing 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. The audit committee will be 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 Steven Projan, Lars Holtug and Marianne Søgaard. Mr. Projan 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. Although foreign private issuers are not required to meet this heightened standard, all of our compensation committee members are expected to meet this heightened standard. Ms. Søgaard is 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. However, due to the fact that our Board of Directors, or the Board, consists of only four (4) members, three (3) of which are independent, and these three (3) independent directors serve on either our Audit Committee or our Nomination and Corporate Governance Committee or both, the Board believes that it would be unduly burdensome to have all of these same three (3) Board members also serve on the Compensation Committee. Based on these circumstances, and the fact that each of the independent members of the Board considers Ms. Søgaard to be highly qualified to serve on the Compensation Committee, the Board has determined that Ms. Søgaard's membership on the Compensation Committee is required by the best interests of our company and our shareholders and, therefore, is relying on the Exceptional and Limited Circumstance exception for non-independent nominations committee members provided by Nasdaq Rule 5605(d)(2)(B). The Board recognizes that Ms. Søgaard may only serve on the Compensation Committee for two (2) years under the exception provided by Rule 5605(d)(2)(B), unless she meets Nasdaq's independence requirements for serving on the Nomination and Corporate Governance Committee at the end of such two-year term.

The compensation committee's responsibilities include, among other things:

- continuously ensuring that the compensation of the members of our board of directors and our executive management is in accordance with our compensation policy and is consistent with the performance of the relevant member;
- annually reviewing and, if relevant, making recommendations for amendment of the compensation policy for the members of our board of directors and our executive management;
- annually reviewing the compensation level of our executive management and comparing it to the market level of management compensation among comparable companies;
- ensuring that agreements with the members of our executive management entitle us under special circumstances to reclaim in full or in part variable compensation that is paid on the basis of information, which subsequently proves to be manifestly misstated ("claw-back") and that termination/severance payments shall not exceed the aggregate compensation for the last two years;
- reviewing any proposals and make recommendations to our board of directors regarding any change to the compensation or contract terms of our executive management;
- reviewing any proposals and make recommendations to our board of directors regarding any severance payment to our executive management;
- making recommendations to our board of directors regarding the compensation of the members of our board of directors, including components and levels thereof.
- monitoring that the information in the annual report regarding the compensation of our board of directors and our executive management is correct, sufficient, and gives a true and fair view;
- ensuring that key compensation terms are disclosed accurately in connection with our annual reporting;
- making recommendations regarding the criteria for assessing the annual incentive and performance pay for our executive management;
- making recommendations to our board of directors at the start of each financial year regarding the criteria for determining the size of our incentive and performance pay for all employees for the present year and at the conclusion of each financial year,

review and make recommendations to our board of directors regarding the size and allocation of the incentive and performance pay; and

- such other matters that are specifically delegated to the compensation committee by our board of directors from time to time.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee consists of Roberto Prego, Steven Projan and Marianne Søgaard. Mr. Prego serves as chairperson of the nomination and corporate governance committee. Both Mrs. Prego and Mr. Projan meet Nasdaq's independence requirements for membership on the Nomination and Corporate Governance Committee. Ms. Søgaard is 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. However, due to the fact that our Board of Directors, or the Board, consists of only four (4) members, three (3) of which are independent, and these three (3) independent directors serve on either our Audit Committee or our Compensation Committee or both, the Board believes that it would be unduly burdensome to have all of these same three (3) Board members also serve on the Nomination and Corporate Governance Committee. Based on these circumstances, and the fact that each of the independent members of the Board considers Ms. Søgaard to be highly qualified to serve on the Nomination and Corporate Governance Committee, the Board has determined that Ms. Søgaard's membership on the Nomination and Corporate Governance Committee is required by the best interests of our company and our shareholders and, therefore, is relying on the Exceptional and Limited Circumstance exception for non-independent nominations committee members provided by Nasdaq Rule 5605(e)(3). The Board recognizes that Ms. Søgaard may only serve on the Nomination and Corporate Governance Committee for two (2) years under the exception provided by Rule 5605 (e)(3), unless she meets Nasdaq's independence requirements for serving on the Nomination and Corporate Governance Committee at the end of such two-year term.

The Nomination and Corporate Governance Committee's responsibilities include, among other things:

- assisting the chairman of our board of directors with the annual evaluation of the effectiveness, achievements and competencies of our board of directors and executive management;

- annually reviewing developments in respect of independence criteria for our board of directors and executive management and review the composition of our board of directors and executive management in relation to independence;

- ensuring a formal, thorough and transparent process for selection and nomination of candidates to our board of directors taking into consideration the need for diversity as well as recommending that the majority of the members of our board of directors elected by the general meeting be independent;

- reviewing and recommending to our board of directors the target figures and policy for the gender composition of our board of directors and other managerial positions;

- considering proposals for candidates to our board of directors and executive management submitted by relevant persons, including shareholders and members of our board of directors and executive management;

- recommending to our board of directors candidates and any changes to our board of directors and executive management, which shall include a review and assessment of potential candidates for our board of directors and executive management, including their qualifications, experience and other competences as well as any possible conflicts of interests such candidates may have;

- ensuring that recommendations for the nomination and/or replacement of members of our board of directors and executive management shall be prepared on the basis of the qualifications and competences deemed to be required by the Nomination Committee;

- ensuring that recommendations for the nomination and/or replacement of members of our board of directors and executive management shall be prepared in accordance with the target figures and policy for the gender composition of our board of directors and other managerial positions as set out by our board of directors;

- prepare descriptions of nominated candidates' qualifications, including information on other executive functions (e.g. memberships of management boards, boards of directors, supervisory boards, board committees etc.) in Danish and foreign companies as well as any demanding positions and tasks in organizations;
- annually make suggestions for appointment of members to the committees established by our board of directors; and
- such other matters that are specifically delegated to the nominating committee by our board of directors from time to time.

6.D. Employees

As of December 31, 2021, 2020 and 2019, Evaxion had 61, 35 and 31 employees, respectively. All of our employees are engaged in either general and administrative or research and development functions. None of our employees are represented by a labor union or covered under a collective bargaining agreement. For a further description of our employees, see the section entitled "Business - Employees" in this annual report.

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, 2021, 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, 2021 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 outstanding ordinary shares is computed on the basis of 23,203,808 ordinary shares, DKK 1 nominal value per share, each outstanding as of December 31, 2021. Ordinary shares that a person has the right to acquire within 60 days of December 31, 2021 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, except with respect to the percentage ownership of all members of our board of directors or executive management as a group. 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 Hoersholm, Denmark.

Name of Beneficial Owner	Shares Beneficially Owned	
	Number	Percent
5% or Greater Shareholders		
NIMedical Holding ApS[(1)]	4,292,604	18.50
Mattsson Holding af 2008 ApS[(2)]	4,163,832	17.94
Executive Management		
Lars Staal Wegner	1,039,076	4.32
Niels Iverson Møller[(1)]	4,292,604	18.50
Andreas Holm Mattson[(2)]	4,163,832	17.94
Glenn S. Vraniak[(3)]	—	—
Birgitte Rønø	27,953	*
Erik Deichmann Heegaard	27,358	*
Directors		
Roberto Prego	348,995	1.50
Steven Projan	73,919	*
Lars Holtug	4,583	*
Marianne Søgaard	144,642	*
All current directors and executive management, as a group (9 persons)	10,122,962	41.64

* Represents beneficial ownership of less than 1%

(1) Consists of 4,292,604 ordinary shares held by NIMedical Holding ApS, which is a personal investment company wholly-owned by Dr. Møller.

(2) Consists of 4,163,832 ordinary shares held by Mattsson Holding af 2008 ApS, which is a personal investment company wholly-owned by Mr. Mattsson.

(3) Mr. Vraniak resigned as our Chief Financial Officer effective November 1, 2021.

Holdings by United States Shareholders

As of December 31, 2021, approximately 8% of our issued and outstanding ordinary shares were held by eight United States record holders. The number of individual holders of record is based exclusively upon our share register and does not address whether a share or shares may be held by the holder of record on behalf of more than one person or institution who may be deemed to be the beneficial owner of a share or shares in our company.

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, 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

Below is a summary of our grants, agreements, and transactions since January 1, 2017 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 to 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. The 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 23 to the audited consolidated financial statements included elsewhere in this annual report.

Item 9. The Offer And Listing

9.A. Offer and Listing Details

ADSs/Ordinary shares

Our ADSs, each representing one ordinary shares of ours, with a DKK 1 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.

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, 2021, our registered, issued and outstanding share capital was nominal DKK 23,203,808 divided into 23,203,808 ordinary shares of DKK 1. The development of our share capital since December 31, 2016 to December 31, 2021 is set forth in the table below. The below Price Per share (DKK) is based on the registrations with the Danish Business Authority.

Date	Transaction	Share Capital After Transaction	Price Per Share (DKK)
August 2008	Formation (Nominal DKK 1)	250,000	1.00
March 2014	Cash contribution (Nominal DKK 1)	268,148	120.00
December 2014	Cash contribution (Nominal DKK 1)	316,751	178.22
December 2015	Cash contribution (Nominal DKK 1)	336,549	435.76
March 2016	Cash contribution (Nominal DKK 1)	342,880	432.12
September 2017	Cash contribution (Nominal DKK 1)	358,806	1,034.75
March 2019	Transfer of reserves (Nominal DKK 1)	717,612	1.00
July 2019	Cash contribution and debt conversion (Nominal DKK 2)	836,994	914.71 (avg)
December 2019	Cash contribution (Nominal DKK 1)	843,564	1,037.50
September 2020	Cash contribution (Nominal DKK 1)	884,974	1,002.90
October 2020	Cash contribution (Nominal DKK 1)	899,926	1,008.45
January 2021	Share split 2-for-1 (Nominal DKK 1)	899,926	—
January 2021	Bonus share issuance 17-for-1 (Nominal DKK 1)	16,198,668	—
February 2021	Initial public offering (3,000,000 ADSs / 3,000,000 new share issue)	19,198,668	61.99
November 2021	Follow-on public offering (3,942,856 ADSs / 3,942,856 new share issue)	23,141,524	45.00
November 2021	Cash contribution (Nominal DKK 1)	23,203,808	1.00

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 the registration statement of which this annual report is a part.

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 and our telephone number is +45 53 53 18 50. Our website address is

www.evaxionbiotech.com. 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

Our board of directors is authorized to increase the share capital as follows:

- Our board of directors is authorized to increase our share capital (i) by up to nominal DKK 5,500,000 without pre-emptive subscription rights for existing shareholders in connection with cash contributions, debt conversion and contributions in kind; provided, however, that the capital increases are carried out at market value and (ii) by up to nominal DKK 5,500,000, with preemptive subscription rights for existing shareholders in connection with cash contributions.

- Our board of directors is authorized to issue warrants and to increase our share capital by up to nominal DKK 1,500,000 without pre-emptive subscription rights for existing shareholders in connection with the exercise, if any, of said warrants and to determine the terms and conditions thereof.

- Our board of directors is, without pre-emptive rights for the existing shareholders, authorized to obtain loans against issuance of convertible bonds which confer the right to subscribe up to nominal DKK 1,000,000. The convertible bonds shall be offered at a subscription price and a conversion price that corresponds in aggregate to at least the market price of the shares at the time of the decision of our board of directors. The loans shall be paid in cash and our board of directors shall determine the terms and conditions for the convertible bonds.

The above authorizations are valid until January 3, 2026.

The ADSs

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 January 1, 2022, we have issued and outstanding 2,732,618 warrants (excluding the EIB warrants) that each confer the right to subscribe to nominal DKK 1 shares. 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, 2032	DKK 1.0	62,147
December 2021	See vesting principles below	December 31, 2032	USD 5.38	523,599
Exercised				(62,284)
Lapsed or annulled without exercise				(81,416)
				2,732,618

On December 17, 2020, our board of directors issued 757,620 warrants related to 2018 – 2020. In addition, we have issued 351,036 to EIB on December 17, 2020, which are expected to be cash settled. For a more detailed description of the EIB Warrants see the section below entitled “Our EIB Warrants.”

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 each 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.

There are certain restrictions on exercise in the event that 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.

Our EIB Warrants

In connection with the EIB Loan Agreement, we agreed to issue the EIB Warrants to EIB in the event we make draws 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 draw down of a tranche of the EIB Loan in accordance with the following schedule: (i) 351,036 EIB Warrants upon a draw down of the first tranche of the EIB Loan in the amount of €7.0 million; (ii) 345,672 EIB Warrants upon a draw down 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 draw down 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. Mattson 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 exercise 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 a portion of the proceeds from our initial 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.

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. As of December 15, 2019, the Danish Companies Act includes a provision whereby 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 this provision, 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 10, 15, 20, 25, 50, 90, and 100%.

Articles of Association and Danish Corporate Law

At the extraordinary general meeting of shareholders on January 4, 2021 our shareholders resolved to amend our articles of association. The following resolutions came into effect:

- Adoption of the authorizations set out above in the section entitled "Authorizations to the Board of Directors";
- A stock split of 2-for-1 ordinary share, changing the nominal denomination of our shares from DKK 2 to DKK 1; and

- A bonus share issuance of 17-for-1 ordinary share.

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 an 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 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 about the full name, address or, in the case of undertakings, registered office, the number of shares and their nominal value and share classes 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.

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 at our offices.

- 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.

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 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 (i.e. currently the Copenhagen City Court).

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 in 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 and are divided into two classes. 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. However, our company currently employees less than an average of 35 employees and consequently our employees are not entitled to demand representation on our board of directors.

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 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.

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. To the extent that the discussion below relates to matters of Danish tax law, it represents the opinion of KPMG Acor Tax P/S. The summary is for general information only and does not purport to constitute exhaustive 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 a 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 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 unlisted shares in the company for Danish tax purposes, as the company's ordinary shares are not admitted to trading on a regulated market. However, recent communications from the Danish Tax authorities indicate that based on an individual analysis based on the actual facts and circumstances and terms and conditions of the depositary agreement, a holder of ADSs may not be treated as holding unlisted shares in the company for Danish tax purposes, which has hitherto been assumed when the underlying asset consists of an unlisted share. Furthermore, the communications from the Danish Tax authorities indicate if the holders of ADSs are not treated 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.

However, the tax position and treatment of ADSs under Danish law are still unclear. In the event that the holders of ADSs are not treated as holding unlisted shares in the company, it is likely that they will be treated as either holding listed shares or financial instruments for tax purposes.

As described above, the below summary assumes that the holders of ADSs listed in the United States should be treated as holding unlisted 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 unlisted shares under Danish tax law

For individual investor in 2022, gains from the sale of shares are include in the computation of the annual share income subject to 27% tax on the first DKK 57,200 (for cohabiting spouses, a total of DKK 114,400) and at a rate of 42% on share income exceeding DKK 57,200 (for cohabiting spouses over DKK 114,400). Such amounts are subject to annual adjustments and include all share income (*i.e.*, all capital gains and dividends derived by the individual or cohabiting spouses, respectively).

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 the company.

As the ADSs, for the purpose of this tax description, are considered unlisted shares for Danish tax purposes, losses may be offset against other share income, (*i.e.*, received dividends and capital gains on the sale of shares). Unused losses will automatically be offset against a cohabiting spouse's share income. In case the share income becomes negative, a negative tax on the share income will be calculated and offset against the individual's other final taxes. Unused negative tax on share income will be offset against a cohabiting spouse's final taxes. If the negative tax on share income cannot be offset against a cohabiting spouse's final taxes, the negative tax can be carried forward indefinitely and offset against future year's taxes. The tax treatment follows from the realization principle.

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 are applied on the basis of the number of all shares issued by the 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.

Gains or losses on disposal of Subsidiary Shares and Group Shares and Tax-Exempt Portfolio Shares are 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.

Dividends (Individuals)

As described above, it is uncertain if holders of ADSs for Danish tax purposes are treated as holders of the ordinary shares in the company. Therefore, it is highly uncertain if the actual distribution of dividends on ADSs to Danish investors are considered dividends for Danish tax purposes. However, if 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 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 is equivalent to an effective taxation of 15.4% (70% of 22%) irrespective of ownership period.

The actual withholding tax rate is as a starting point 27%, while it can be reduced (0%, 15.4%, 22%) if certain requirements are met. A claim for repayment can be made within two months or the excess tax will offset the corporation income tax for the year. The statute of limitation is three years. However, in recent unpublished case law this has been extended to five years. This case law is still pending with the courts.

Taxation of Shareholders Residing Outside Denmark

It is currently not clear under the Danish tax legislation or case law how listed ADSs are treated for tax purposes, and therefore no level of assurance can be given on this matter. For the purpose of this summary, it is assumed that a holder of ADSs listed in the United States should be treated as holding non-listed shares in the company, as the company's ordinary shares are not admitted to trading on a regulated market. However, recent communications from the Danish Tax authorities indicate that based on an individual analysis based on the actual facts and circumstances and terms and conditions of the depositary agreement, a holder of ADSs may not be treated as holding unlisted shares in the company for Danish tax purposes, which has hitherto been assumed when the underlying asset consists of an unlisted share. Furthermore, the communications from the Danish Tax authorities indicate if the holders of ADSs are not treated 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.

However, the tax position and treatment of ADSs under Danish law are still unclear. In the event that the holders of ADSs are not treated as holding unlisted shares in the company, it is likely that they will be treated as either holding listed shares or financial instruments for tax purposes.

As described above, the below summary assumes that the holders of ADSs listed in the United States should be treated as holding unlisted 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 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 are 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, it is uncertain if holders of ADSs for Danish tax purposes are treated as holders of the ordinary shares in the company. Therefore, it is highly uncertain if the holders of ADSs are entitled to apply for a refund of Danish withholding tax on dividends paid by the company. If the holders of ADSs are not entitled to apply for a refund of Danish withholding tax on dividends paid by the company, then the depository bank may according to the recent communications from the Danish Tax authorities in certain circumstances be entitled to apply for a refund of Danish withholding tax.

However, 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*" which encompasses American Samoa, Fiji, Guam, Palau, Panama, Samoa, Trinidad and Tobago, US Virgin Islands, Vanuatu. 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.

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 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.

Dividends (Companies)

As described above, it is uncertain if holders of ADSs for Danish tax purposes are treated as holders of the ordinary shares in the company. Therefore, it is highly uncertain if the holders of ADSs are entitled to apply for a refund of Danish withholding tax on dividends paid by the company. If the holders of ADSs are not entitled to apply for a refund of Danish withholding tax on dividends paid by the company, then the depository bank may according to the recent communications from the Danish Tax authorities in certain circumstances be entitled to apply for a refund of Danish withholding tax.

However, 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.

Non-residents of Denmark are not subject to additional Danish income tax in respect to dividends received on shares.

If the investors 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.

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 not impose any tax at all. 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 withholding tax at a rate of 27% 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. If the withholding tax rate applied is higher than the applicable final tax rate for the shareholder, a request for a refund of Danish tax in excess hereof can be made by the shareholder in the following situations:

Reduction According to Tax Treaty

In the event that the shareholder 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 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 shareholder 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 shareholder 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 shareholder is obligated to exchange information with Denmark, dividends are generally subject to a tax rate of 15%. If the shareholder is tax resident outside the European Union, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders 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 shareholder 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.

If a reclaim is not possible in accordance with above or an applicable Tax Treaty to a rate which is lower than 22% then a reclaim can always be made to 22% unless the beneficial owner holds Group Shares or Subsidiary Shares and is tax resident in a Blacklisted Jurisdiction.

Share Transfer Tax and Stamp Duties

No Danish share transfer tax or stamp duties are payable on transfer of the shares.

Certain Material United States Federal Income Tax Considerations

The following discussion describes certain material United States federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a United States 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 United States 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 United States 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 United States 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 United States legal counsel has been requested, or will be obtained, regarding the United States federal income tax consequences of the acquisition, ownership and disposition of the ADSs.

This discussion does not address all aspects of United States 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, bank thrifts, 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 our 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 subject to alternative minimum tax or 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 section 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 state or non-U.S. taxing jurisdiction or any U.S. estate 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 United States 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 United States 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 United States 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 the 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 United States 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 United States 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 United States federal income tax purposes) and their future partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for United States 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 United States federal income tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than United States federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the United States federal, state and local, and non-United States tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the United States federal income tax laws, and subject to the PFIC 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 United States federal income tax purposes, constitute dividends for United States 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 United States federal income tax purposes) is includible in income for a U.S. Holder and subject to United States 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-United States 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 therefore expect that dividends we pay with respect to the ADSs generally will constitute qualified dividend income. There can be no assurance, however, that our ADSs will be considered readily tradeable on an established securities market in later years.

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 dividend paid even though the holder does not in fact receive it. The dividend is taxable to the holder when the depositary receives the dividend, actually or constructively. Because we are not a United States corporation and do not expect to meet the dividends-received deduction eligibility criteria for non-United States corporations, the dividend is not expected to be eligible for the dividends-received deduction generally allowed to United States corporations in respect of dividends received from other United States 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 United States 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."

Because we do not intend to determine our earnings and profits on the basis of United States federal income tax principles, all distributions paid will generally be treated as "dividends" for United States federal income tax purposes.

Dividends paid by the Company generally will be treated as income from foreign sources for United States 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 our 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 United States 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 United States federal income tax liability. See "– Danish Taxation – Withholding Tax Refund for United States Treaty Beneficiaries" above for the procedures for obtaining a tax refund. 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.

Gain on Sale, Exchange or Other Taxable Disposition

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 United States 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 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 taxable years. The determination of PFIC status is inherently factual, is subject to a number of uncertainties, 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 United States 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 United States tax advisors regarding our PFIC status.

If we were classified as a "passive foreign investment company", or a "PFIC", for United States 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-United States corporation, such as the Company, will be classified as a PFIC for United States 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 "– Taxation of 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, 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.

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, shares of 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. Our ADSs will be considered marketable stock as long as they remain listed on The Nasdaq Capital Market and are regularly traded. We anticipate that our 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 United States 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 shares 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 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 United States 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 United States 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 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 redemption of our ADSs may be subject to information reporting to the IRS and possible United States backup withholding (currently at a 24% rate). 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 redemption 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. U.S. Holders are urged to consult their tax advisors regarding the application of the United States 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 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 a 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-biotech.com.

10.I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

See "Item 5. 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:**	• **For:**
• $5.00 (or less) per 100 ADSs (or portion of 100 • ADSs)	• 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
• $.05 (or less) per ADS	• Any cash distribution to ADS holders
• 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	• Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
• $.05 (or less) per ADS per calendar year	• Depositary services
• Registration or transfer fees	• 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
• Expenses of the depositary	• Cable and facsimile transmissions (when expressly provided in the deposit agreement) • Converting foreign currency to United States dollars
• 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	• As necessary
• Any charges incurred by the depositary or its agents	• 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, 2021, 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 ineffective due to the material weaknesses as of December 31, 2021 which are detailed in the accompanying Item 15(b), Management's Annual Report on Internal Control over Financial Reporting.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. 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 identified the following weaknesses in our internal control over financial reporting and therefore determined that our internal control over financing reporting were not effective at the reasonable assurance level as of December 31, 2021.

As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Material weaknesses related to the lack of sufficiently designed internal controls

During 2021 we identified this material weakness which arose because we did not design or operate sufficient internal controls to support mitigate risks of material errors in our financial statement. Additionally, we did not appropriately implement certain components of the COSO framework, including elements of the control environment, information and communication, risk assessment, control activities and monitoring activities. Therefore, we have assessed that we lacked sufficient internal controls to support effective financial reporting as of December 31, 2021, which constitutes a material weakness.

Material weaknesses relating to establishing an effective control environment over financial reporting

In connection with the preparation of our financial statements for the years ended December 31, 2020 and 2019, we had identified material weakness in our internal control over financial reporting, which remained unremediated as of December 31, 2021.

The material weaknesses identified related to the lack of accounting and supervisory personnel that possessed an appropriate level of technical accounting experience and training, and their lack of supervision over third party service providers in areas such as bookkeeping, financial controlling, and financial statements preparation.

Remediation plans

To remediate our identified material weaknesses, we will allocate more internal resources to internal controls and engage external advisors to provide training and to assist with reassessing and redesigning processes and developing new controls as appropriate, including assisting with the evaluation and documentation of the risk assessment, design, and operating effectiveness of our internal controls over financial reporting and assist with the remediation of any deficiencies. Furthermore, we retained accounting advisors to provide additional depth and breadth to our technical accounting and financial reporting capabilities and are taking steps such as the hiring of additional finance staff. We also plan to hire additional accounting personnel with financial statement closing experience and technical IFRS knowledge for the purposes of timely and reliable financial reporting in accordance with IFRS and the requirements set forth by the SEC, to perform specific functions, design and implement improved processes and internal controls, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures, including ongoing senior management review and audit committee oversight. In addition, we recently announced that we have hired a new Chief Financial Officer who has considerable public company experience.

While we intend to implement this plan to remediate these material weaknesses, we cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate these material weaknesses in our internal control or that other material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future.

(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

Except as described above in Management’s Annual Report on 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 the Evaxion Board—Audit and Risk 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 www.evaxion-biotech.com . 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, 2021 and 2020 (in thousands):

	Years Ended December 31,	
	2021	2020
Audit fees	$ 613	$ 333
Audit related fees	—	—
Other fees	—	—
Total fees	$ 613	$ 333

In 2021, audit fees relate to audit of the annual consolidated financial statements and for review services, and fees related to the prospectus for our initial public offering, our follow-on public offering, and related filing comfort services provided to us by EY Godkendt Revisionspartnerselskab.

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; 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(c)(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, we intend to comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

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 direct or indirect 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 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. 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. It is possible under Danish law to pay out interim dividends. The decision to pay out interim 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 interim dividend payment shall be prepared. If interim 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. 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 depositary, 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.

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 BIOTECH A/S
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Evaxion Biotech A/S

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Evaxion Biotech A/S (the Company) as of December 31, 2021 and 2020, the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting 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 United States 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 audits 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.

/s/ EY Godkendt Revisionspartnerselskab

We have served as the Company's auditor since 2019.

Copenhagen, Denmark
March 31, 2022

EVAXION BIOTECH A/S
Statements of Comprehensive Loss

	Note	Years Ended December 31, 2021	2020	2019
		(USD in thousands, except per share amounts)		
Operating expenses:				
Research and development	*6,7*	$ 19,583	$ 10,902	$ 8,216
General and administrative	*6,7*	6,251	5,666	2,647
Total operating expenses		25,834	16,568	10,863
Operating loss		**(25,834)**	**(16,568)**	**(10,863)**
Finance income	*9*	2,039	216	65
Finance expenses	*9*	(915)	(223)	(1,222)
Net loss before tax		**(24,710)**	**(16,575)**	**(12,020)**
Income tax benefit	*10*	178	1,557	825
Net loss for the year		**$ (24,532)**	**$ (15,018)**	**$ (11,195)**
Net loss attributable to shareholders of Evaxion Biotech A/S		**$ (24,532)**	**$ (15,018)**	**$ (11,195)**
Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax):				
Exchange differences on translation of foreign operations		(83)	(18)	—
Exchange rate adjustments of investments in subsidiaries		93	—	—
Tax on other comprehensive income, income/(expense)		(5)	—	—
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax):				
Exchange differences on currency translation to presentation currency		(1,547)	412	2
Other comprehensive loss for the year, net of tax		**$ (1,542)**	**$ 394**	**$ 2**
Total comprehensive loss		**$ (26,074)**	**$ (14,624)**	**$ (11,193)**
Total comprehensive loss attributable to shareholders of Evaxion Biotech A/S		**$ (26,074)**	**$ (14,624)**	**$ (11,193)**
Loss per share – basic and diluted	*11*	$ (1.26)	$ (0.97)	$ (0.81)

The accompanying notes are an integral part of these financial statements.

EVAXION BIOTECH A/S
Statements of Financial Position

	Note	December 31, 2021	December 31, 2020
		(USD in thousands)	
ASSETS			
Non-current assets			
Intangible assets	*12*	$ 93	$ 100
Deferred tax assets	*10*	—	262
Property and equipment, net	*13*	5,174	221
Government grants receivables		—	194
Leasehold deposits	*17*	191	238
Total non-current assets		**5,458**	**1,015**
Current assets			
Prepayments and other receivables	*14*	1,138	1,553
Deferred offering costs	*2*	—	1,729
Government grants receivable		563	418
Tax receivables		838	1,416
Cash and cash equivalents	*16*	32,166	5,834
Total current assets		**34,705**	**10,950**
TOTAL ASSETS		**$ 40,163**	**$ 11,965**
EQUITY AND LIABILITIES			
Share capital	*19*	$ 3,755	$ 2,648
Other reserves	*19*	79,114	31,669
Accumulated deficit	*19*	(50,432)	(27,279)
Total equity		**32,437**	**7,038**
Non-current liabilities			
Lease liabilities, non-current	*17*	2,206	—
Loan from lessor, non-current	*17*	1,044	—
Provisions	*23*	153	—
Total non-current liabilities		**3,403**	—
Lease liabilities	*17*	314	20
Loan from lessor, current	*17*	126	—
Trade payables		2,848	3,673
Other payables	*15*	1,035	1,234
Total current liabilities		**4,323**	**4,927**
Total liabilities		**7,726**	**4,927**
TOTAL EQUITY AND LIABILITIES		**$ 40,163**	**$ 11,965**

The accompanying notes are an integral part of these financial statements.

EVAXION BIOTECH A/S
Statements of Changes in Equity

	Note	Share capital	Other reserves: Share premium	Other reserves: Foreign currency translation reserve	Accumulated deficit	Total equity
				(USD in thousands)		
Equity at December 31, 2018		**$ 2,113**	**$ 4,106**	**$ (171)**	**$ (6,979)**	**$ (931)**
Net loss for the year		—	—	—	(11,195)	(11,195)
Other comprehensive income		—	—	2	—	2
Share-based compensation	*8*	—	—	—	2,362	2,362
Issuance of shares for cash	*19*	181	9,261	—	—	9,442
Transaction costs	*19*	—	(13)	—	—	(13)
Settlement of convertible debt instruments	*20*	187	9,508	—	—	9,695
Equity at December 31, 2019		**$ 2,481**	**$ 22,862**	**$ (169)**	**$ (15,812)**	**$ 9,362**
Net loss for the year		—	—	—	(15,018)	(15,018)
Other comprehensive income		—	—	395	—	395
Share-based compensation	*8*	—	—	—	3,551	3,551
Issuance of shares for cash	*19*	167	8,853	—	—	9,020
Transaction costs	*19*	—	(272)	—	—	(272)
Equity at December 31, 2020		**$ 2,648**	**$ 31,443**	**$ 226**	**$ (27,279)**	**$ 7,038**
Net loss for the year		—	—	—	(24,532)	(24,532)
Other comprehensive income		—	—	(1,537)	—	(1,537)
Tax effect on OCI items		—	—	(5)	—	(5)
Share-based compensation	*8*	—	—	—	1,379	1,379
Issuance of shares for cash	*19*	1,107	56,502	—	—	57,609
Transaction costs	*19*	—	(7,515)	—	—	(7,515)
Equity at December 31, 2021		**$ 3,755**	**$ 80,430**	**$ (1,316)**	**$ (50,432)**	**$ 32,437**

The accompanying notes are an integral part of these financial statements.

EVAXION BIOTECH A/S
Statements of Cash Flows

	Note	Years Ended December 31, 2021	2020	2019
			(USD in thousands)	
Operating activities:				
Net loss for the year		$ (24,532)	$ (15,018)	$ (11,195)
Adjustments for non-cash items	*16*	541	1,583	2,945
Interest received		—	—	9
Interest paid		(25)	(30)	(39)
Income taxes received		846	812	688
Cash flow from operating activities before changes in working capital		(23,170)	(12,653)	(7,592)
Cash flow from changes in working capital:				
Changes in net working capital	*16*	1,237	215	573
Net cash used in operating activities		**(21,933)**	**(12,438)**	**(7,019)**
Investing activities:				
Investment in intangible assets	*12*	(60)	(35)	—
Purchase of property and equipment	*13*	(1,300)	(149)	(61)
Payment of non-current financial assets – leasehold deposits		30	(209)	(7)
Net (cash used in)/ provided by investing activities		**(1,330)**	**(393)**	**(68)**
Financing activities:				
Proceeds from issuance of shares and exercise of warrants, less underwriter discounts	*19*	53,854	9,019	9,442
Transaction costs related to issuance of shares		(3,760)	(128)	(13)
Proceeds from issuance of convertible debt instruments	*20*	—	—	152
Repayment of loan from lessor		(63)	—	—
Leasing installments	*16,17*	(226)	(74)	(73)
Net cash provided by financing activities		**49,805**	**8,817**	**9,508**
Net (decrease)/increase in cash and cash equivalents		**26,542**	**(4,014)**	**2,421**
Cash and cash equivalents at January 1	*16*	5,834	9,559	7,433
Exchange rate adjustments on cash and cash equivalents		(210)	288	(295)
Cash and cash equivalents at December 31	*16*	**$ 32,166**	**$ 5,834**	**$ 9,559**
Supplemental disclosure of cash flow information				
Non-cash investing and financing activities				
Capitalized intangible assets included in trade payables	*12*	—	60	—
Acquisition of property and equipment included in trade payables		90	—	—

The accompanying notes are an integral part of these financial statements.

EVAXION BIOTECH A/S
Notes to Financial Statements

Note 1. General Company Information

Evaxion Biotech A/S (the "Company" or "Evaxion") is an artificial intelligence ("AI")-immunology platform company that uses its proprietary AI technology, engineering expertise and drug development know-how to simulate the human immune system and generate predictive models to identify and develop efficacious immunotherapies for patients in the global market. Unless the context otherwise requires, references to the "Company," "we," "us," and "our", refer to Evaxion Biotech 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 Hoersholm, Denmark.

On February 5, 2021, the Company completed an initial public offering ("IPO"), which resulted in the listing of American Depository Shares ("ADS") representing the company's ordinary shares, under the symbol "EVAX" in the United States on the NASDAQ Capital Market. Through the IPO, the Company sold 3,000,000 ADSs, each of which represents one ordinary share, at a price to the public of $10.00 per ADS. The Company received net proceeds of $25.3 million from the IPO, after deducting the underwriting discounts and commissions and offering expenses. Upon the completion of the IPO, authorized share capital consists of 3,000,000 shares of ordinary shares, par value DKK 1 per share.

On November 9, 2021, the Company completed a follow-on public offering through which we issued and sold 3,942,856 ADSs, each of which represents one ordinary share, at a price to the public of $7.00 per ADS. The shares issued were inclusive of the 514,285 ADSs issued to the underwriters pursuant to the full exercise of their option to purchase additional shares on November 5, 2021. The Company received aggregate net proceeds of $24.9 million from the follow-on public offering, which includes the funds received for the additional shares issued to the underwriters, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Upon the completion of the follow-on public offering, the Company's registered, issued, and outstanding share capital was nominal DKK 23,141,524.

At year end, due to warrant exercise, the outstanding share capital was nominal DKK 23,203,808.

The consolidated financial statements of Evaxion Biotech and its subsidiaries (collectively, the "Group") for the year ended December 31, 2021, were approved, and authorized for issuance, by the Board of Directors on March 31, 2022.

Basis of Going Concern

The Company's Board of Directors has, at the time of approving the consolidated financial statements, a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Based on the Company's net proceeds secured through its recent IPO and follow-on public offering, together with access to its EIB loan, of which the Company has already received the proceeds from tranche no. 1 of €7 million on February 17, 2022, and the current cash on hand will allow the Company to meet its liabilities as they fall due for at least 12 months from the issuance of this Form 20-F. Thus, these consolidated financial statements are prepared on a going concern basis of accounting.

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 International Financial Reporting 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 $1.07 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

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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.

COVID 19

In December 2019, a novel strain of coronavirus ("COVID-19") was reported in Wuhan, China and on March 11, 2020 the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has resulted in a widespread health crisis and numerous disease control measures being taken to limit its spread. As the pandemic unfolds throughout the world, the healthcare systems of the countries in which the Company is conducting its studies have experienced great disruption. Governments have instituted quarantining and mandated business and school closures. Travel has been severely restricted.

The Company has closely been monitoring the impact of COVID-19. The Company's top priority remained the health and safety of its staff and the patients in the studies. The Company maintains compliance with government and health authorities.

The Company has worked closely with laboratories and investigators to ensure safe continuation and working requirements of our ongoing research activities and human clinical trials. The Company has not experienced a materially negative impact from COVID 19. As of December 31, 2021, the impact of the COVID-19 pandemic continues to unfold. As events continue to evolve and additional information becomes available, our estimates may change materially in the future.

While business travel has been limited, the Company has remained active and effective in the process of raising capital with institutional investors by conducting key meetings on a virtual basis.

Note 2. Summary of Significant Accounting Policies

Basis of preparation

The financial statements have been prepared in accordance with IFRS as issued by the IASB. The Company adopted IFRS in 2019 and applied it from the beginning of the period preceding adoption, starting on January 1, 2018.

Management has assessed the impact of new or amended and revised accounting standards and interpretations (IFRSs) issued by the IASB and IFRSs endorsed by the European Union effective on or after January 1, 2021. It is assessed that application of amendments effective from January 1, 2021 has not had a material impact on the consolidated financial statements for 2021. Furthermore, Management does not anticipate any significant impact on future periods from the adoption of these amendments.

The 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, AUD for Australia, and USD for the United States. The 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.

Reclassifications of prior period presentation

Certain items in prior year consolidated financial statements have been reclassified to conform to the current period's presentation.

Basis of consolidation

The audited consolidated financial statements of the Company comprise the Statement of Financial Position as of December 31, 2021 and 2020, and the Statement of Comprehensive Loss for the twelve months ended December 31, 2021, 2020 and 2019. 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 audited consolidated financial statements from the date that control commences until the date that control ceases. 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 the control.

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All intra-Group assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Retrospective effect of share split and bonus share issuance

All share and per share data, including that related to warrants, in the consolidated financial statements give retroactive effect to a 2:1 share split and a bonus issue of shares in the ratio of 17:1 of the Company's authorized, issued and outstanding ordinary shares, which was effective on January 4, 2021, with the corresponding impacts on both share capital and share premium also retroactively recognized.

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 statements of comprehensive loss. Non-monetary items in foreign currency which are measured at cost at the 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.

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 pre-clinical 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 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.

Contract Research Organizations expenses and related prepayments and accruals

Substantial portions of the Company's clinical studies are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively, the "CROs"). The CROs generally bill monthly or quarterly for services performed. For studies, the Company accrues expenses based upon estimated percentage of work completed.

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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 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 accumulated deficit. 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

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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 2021 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.

Post-employment benefit costs

The Company contributes to a defined contribution plan covering eligible employees. The contribution amount is based upon a fixed percentage of employee compensation and such contributions are expensed as incurred.

Accounting for joint operations – Southern Denmark University

The Company enters into agreements from time to time that may be subject to the requirements of IFRS 11, *Joint Arrangements*. The Company evaluates these agreements on execution and applies the requirements of the guidance. The collaboration agreement with *Southern Denmark University* ("SDU") is considered a joint operation as defined in IFRS 11, with the principal place of business being Denmark. In September 2020, the Company terminated its existing agreement with SDU. For the years ended December 31, 2020, and 2019, the Company recorded $0.3 million and $0.3 million, respectively, in compensation cost for SDU employees which was reported in research and development costs in the statement of comprehensive loss.

Accounting for joint operations - MSD International GmbH and MSD International Business GmbH

The Company has entered into a collaboration agreement with MSD International GmbH and MSD International Business GmbH (jointly 'MSD'). Under the arrangement, the Company will share its clinical trial in which the Company's compound and MSD's compound is dosed in combination.

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, Joint Arrangements), or rather, a vendor-customer contract (to be accounted for in accordance with IFRS 15, Revenue from Contracts with Customers).

Management has determined that MSD 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.

Finance Income

Finance income is comprised primarily of foreign currency gains.

Finance Expense

Finance expense is comprised primarily of changes in fair value of the Company's convertible debt instruments and interest on the Company's lease liability.

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 statement of comprehensive loss, except to the extent that it relates to items recognized in equity.

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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 which method the entity expects to better predict the resolution of the uncertainty. Tax benefits are not recognized unless the tax positions will probably be accepted by the tax authorities. This is based upon management's interpretation of applicable laws and regulations and the expectation of how the tax authority will resolve the matter. Once considered probable of not being accepted, management reviews each material tax benefit and reflects the effect of the uncertainty in determining the related 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 at December 31, 2021 and 2020, 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 it is probable 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 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.

Deferred offering costs

Offering costs, consisting of legal, accounting, printer and filing fees directly attributable to the issuance of new shares relating to the Company's initial public offering ("IPO") in February 2021, were deferred and were offset against proceeds from the IPO upon the effectiveness of the offering. Deferred offering costs recorded as of December 31, 2020 were $1.7 million.

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.

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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:

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 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.

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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 recognized 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.

The capitalized assets are amortized over their useful lives, which are determined on the basis of the expected pattern of consumption of the expected future economic benefits embodied in the license or similar development agreement. Amortization commences only once the necessary regulatory and marketing approval has been received for the product candidates to which they relate. To date, the Company has not received any regulatory and marketing approval for any of its product candidates. Consequently, the Company did not recognize any amortization expense for its intangible assets.

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.

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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 are originated. 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, receivables and receivables from unpaid capital) 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. The Company does not have any cash equivalents for the years ended December 31, 2021 and 2020.

(ii) Non-derivative financial liabilities

Non-derivative financial liabilities comprise other payables which are measured initially at fair value and subsequently at amortized cost.

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 are comprised 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.

Debt

Debt is comprised of debt agreements that are carried at amortized cost using the effective interest method.

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(iii) Derivative financial liabilities

Convertible debt instruments

During 2018, the Company issued two convertible debt instruments which are determined to be financial instruments. As required by IAS 32 and IFRS 9, these instruments were separated into their components: debt, and embedded derivatives related to the conversion features, early settlement mechanism and change of control prepayment provision. The Company elected the fair value option and accounts for both the debt and the embedded derivatives as a single instrument that is measured at fair value. Details of the significant inputs and assumptions into the fair values of these instruments are provided in Note 20.

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 revenue and there are no material non-current assets attributable to countries other than Denmark.

Shareholders' Equity

The share capital comprises the nominal amount of the company's ordinary shares, each at a nominal value of DKK 1.

Other Reserves includes the share premium comprising the amount received, attributable to shareholders' equity, in excess of the nominal amount of the shares issued at the company's capital increases, reduced by any expenses directly attributable to the capital increases as well as translation reserves. Translation reserves include exchange rate adjustments of equity and intragroup receivables forming part of the net investments in our group enterprises.

Accumulated Deficit include the accumulated profit or loss as well as well as the reserve for share-based payment representing the corresponding entries to the share-based payment recognized in the profit or loss, arising from our warrant programs.

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 Biotech A/S and on the weighted average number of ordinary shares outstanding during the year. The number of shares outstanding take in effect the 2 for 1 stock split and the 17 for 1 bonus share issuance on January 4, 2021. 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.

Standards issued but not yet effective

There were a number of standards and interpretations which were issued but were not yet effective at December 31, 2021 and have not been adopted for these financial statements:

- Amendment to IAS 37 Provisions, contingent liabilities and contingent assets, Onerous Contracts— Cost of Fulfilling a Contract (January 1, 2022)
- Amendments to IAS 16 Property, Plant and Equipment, proceeds before intended use (January 1, 2022)
- Annual Improvements 2018-2020 (January 1, 2022)
- Amendment to IAS 1 Presentation of Financial Statements: Disclosure of Accounting Policies (January 1, 2023)

- Amendment to IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (January 1, 2023)

- Amendments to IFRS 16 Leases: COVID-19-Related Rent Concessions beyond June 30, 2021 (April 1, 2021)

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 financial statements in the period of initial application and future reporting periods.

Note 3. First-Time Adoption of IFRS

IFRS 1 – First-time adoption of IFRS

Impact of initial application of IFRS 1 – first-time adoption of International Financial Reporting Standards

The Company adopted IFRS as issued by IASB in the accompanying financial statements. The figures for 2019 in the statements of comprehensive loss have been prepared in accordance with IFRS as issued by the IASB.

The disclosures required by IFRS 1, *First-Time Adoption of IFRS*, concerning the transition from Danish Financial Statement Act ("Local GAAP") to IFRS were presented in the prior year financials. The financial statements for the year ended December 31, 2019 are the first the Company has prepared in accordance with IFRS. For periods up to and including the year ended December 31, 2018, the Company prepared its financial statements in accordance with the Danish Financial Statements Act. Accordingly, the Company has prepared financial statements that comply with IFRS applicable as at December 31, 2021, together with the comparative period data for the years ended December 31, 2020 and 2019.

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 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 8 for further detail surrounding share-based compensation.

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Leasehold Improvements and Loan from Lessor

A significant judgment was made in respect of 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 2.

There have been no other changes to the application of critical accounting judgments, or estimation uncertainties regarding accounting estimates.We refer to note 2 for a summary of significant accounting policies for further discussion.

Note 5. 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

The exposure to liquidity risk primarily relates to the risk of failure to meet the Company's obligations when they become due, which could happen if current assets are not enough to cover the amount of short-term liabilities. The Company has been dependent on its shareholders to fund its operations. The Company's ability to continue as a going concern is dependent on its ability to raise financing to enable it to complete its product development and clinical trials. Management has determined that there is not substantial doubt about the Company's ability to continue as a going concern for one year from the latest balance sheet date.

As of December 31, 2021 and December 31, 2020, our available liquidity, comprised of cash and cash equivalents, was $32.2 million and $5.8 million, respectively and our total equity was $32.4 million and $7.0 million, respectively.

On February 5, 2021, the Company completed our initial public offering through which we issued and sold 3,000,000 ADSs, each of which represents one ordinary share, at a price to the public of $10.00 per ADS. We received aggregate net proceeds of $25.3 million from the initial public offering, after deducting the underwriting discounts and commissions and offering expenses payable by us. Upon the completion of the initial public offering, our registered, issued, and outstanding share capital was nominal DKK 19,198,668 divided into 19,198,668 ordinary shares of DKK 1 each.

On November 9, 2021, we completed a follow-on public offering through which we issued and sold 3,942,856 ADSs, each of which represents one ordinary share, at a price to the public of $7.00 per ADS. The shares issued were inclusive of the 514,285 ADSs issued to the underwriters pursuant to the full exercise of their option to purchase additional shares on November 5, 2021. We received aggregate net proceeds of $24.9 million from the follow-on public offering, which includes the funds received for the additional shares issued to the underwriters, after deducting the underwriting discounts and commissions and offering expenses payable by us. Upon the completion of the follow-on public offering, the Company's registered, issued, and outstanding share capital was nominal DKK 23,141,524.

At year end, due to warrant exercise, the outstanding share capital was nominal DKK 23,203,808.

We expect that the net proceeds from our initial public offering, our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months subsequent to the issuance of this annual report.

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 their reputation.

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The following are the contractual undiscounted outflows associated with the Company's financial liabilities in the current and prior year:

	December 31, 2021 (USD in thousands)					
	Carrying amount	Contractual cash flows	<1 year	1 – 5 years	>5 years	Total
Loan from lessor [1]	$ 1,170	$ 1,458	$ 192	$ 769	$ 497	$ 1,458
Lease liabilities	2,520	3,698	326	1,223	2,149	3,698
Trade payables	2,848	2,848	2,848	—	—	2,848
Provisions	153	153	—	—	153	153
Other payables	46	46	46	—	—	46
Total	$ 6,737	$ 8,203	$ 3,412	$ 1,992	$ 2,799	$ 8,203

[1] The loan amount as of December 31, 2021 is still subject to possible minor adjustment. Further information is provided in Note 17.

	December 31, 2020 (USD in thousands)					
	Carrying amount	Contractual cash flows	<1 year	1 – 5 years	>5 years	Total
Lease liabilities	$ 20	$ 20	$ 20	$ —	$ —	$ 20
Trade payables	3,673	3,673	3,673	—	—	3,673
Other payables	180	180	180	—	—	180
Total	$ 3,873	$ 3,873	$ 3,873	$ —	$ —	$ 3,873

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 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.

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The Company raises capital from the issue of equity, grants or convertible loan notes. 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.

Fair values

Financial instruments measured at fair value in the 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 I – quoted prices in active markets for identical assets or liabilities.

2. Level II – inputs other than quoted prices included within Level I that are observable for the instrument, either directly (i.e. as prices) or indirectly (i.e. derived from prices).

3. Level III – inputs for instrument that are not based on observable market data (unobservable inputs).

There were no financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2021 and 2020.

Convertible debt instruments

The Company's convertible debt instruments are Level III financial instruments and are carried at fair value through profit and loss. The convertible debt instruments were valued based on the present value of a probability weighting of the mutually exclusive settlement alternatives. Key inputs for this valuation were: (i) the exchange rate between USD and DKK, (ii) the discount rate on the issuance, (iii) the probability of a qualifying financing event and (iv) the Company's share price. The most significant assumptions used in the valuation were the: Company's share price, the probability of a qualifying financing event, the discount rate and the USD to DKK exchange rate. An increase or decrease in the key input ranging from 10 percent, depending on the input analyzed, would not result in a material change in the fair value of the convertible debt instruments. There were no transfers into or out of any classification of financial instruments in any period

See Note 20 for the change in fair value of convertible debt during the year ended December 31, 2019.

Note 6. Operating Activities

Research and Development Expenses

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Employee salary and benefit expenses, excluding share-based compensation	$ (6,794)	$ (3,337)	$ (2,586)
Share-based compensation expenses	(1,051)	(1,496)	(1,021)
Depreciation	(273)	(92)	(65)
External expenses	(11,465)	(5,977)	(4,544)
Total research and development expenses	$ (19,583)	$ (10,902)	$ (8,216)

During the years ended December 31, 2021, 2020 and 2019, the Company recognized $0.3 million, $0.8 million and $0.5 million, respectively, related to government grants as a reduction of research and development expenses.

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General and Administrative Expenses

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Employee salary and benefit expenses, excluding share-based compensation	$ (1,824)	$ (1,098)	$ (517)
Share-based compensation expenses	(328)	(1,912)	(1,341)
Professional and other fees	(4,028)	(2,644)	(773)
Depreciation	(71)	(12)	(16)
Total general and administrative expenses	$ (6,251)	$ (5,666)	$ (2,647)

Note 7. 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,		
	2021	2020	2019
Average number of full-time employees	53	33	25
Number of employees at end of period:			
Denmark and United States	61	35	31
Total employees, at end of period	61	35	31

Employee Costs:

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Wages and salaries	$ 6,909	$ 4,016	$ 2,819
Cash bonus	668	—	—
Share-based compensation expenses	1,379	3,408	2,362
Defined contribution plans	649	206	96
Other social security expenses	28	17	12
Other staff expenses	364	196	176
Total	$ 9,997	$ 7,843	$ 5,465

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Total Employee costs classified as:			
Research and development expenses	$ 7,845	$ 4,833	$ 3,607
General and administrative expenses	2,152	3,010	1,858
Total	$ 9,997	$ 7,843	$ 5,465

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Non-management employee benefit expenses classified as:			
Research and development expenses	$ 6,414	$ 4,009	$ 2,590
General and administrative expenses	836	611	668
Total	$ 7,250	$ 4,620	$ 3,258

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Remuneration to the Board of Directors and Executive Management

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Remuneration to the Executive Management:			
Wages and salaries	$ 1,833	$ 1,298	$ 900
Share-based compensation expenses	514	1,566	956
Total	2,347	2,864	1,856
Remuneration to the Board of Directors:			
Wages and salaries	313	—	—
Share-based compensation expenses	87	359	351
Total	400	359	351
Remuneration to the Board of Directors and Executive Management classified as:			
Research and development expenses	1,431	824	1,017
General and administrative expenses	1,316	2,399	1,190
Total	$ 2,747	$ 3,223	$ 2,207

The Executive Management was comprised of four members in January 2019 and expanded again to five members in October 2019, of which one member resigned in 2020 and one other member resigned in 2021. It was expanded to 5 members again in 2021.

Note 8. Share-Based Payments

Warrant Program and Amendments

The Company's Articles of Association allow for the granting of equity compensation, in the form of equity settled warrants, to employees, consultants 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 before become exercisable upon an exit event, which triggers an immediate vesting, or at any time as determined by the board of directors in accordance with the terms of the plan. The warrants granted in 2021 vest gradually over 36 months after grant date or in the case of warrants to the Board of Directors vest immediately. 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 up until 2019 expire on December 31, 2036. Warrants granted in 2021 and 2020 expire on December 31, 2032 and 2031, respectively. For the years ended December 31, 2021, 2020 and 2019, the number of warrants outstanding as a percentage of outstanding ordinary shares was 11.8%, 13.8% and 13.5%, respectively.

In the second quarter of 2021, the Company granted 62,147 warrants to its Chief Medical Officer ("CMO") which vest over 36 months.

In 2019, the Company granted 150,660 warrants to its Chief Financial Officer ("CFO") which were exercisable upon an exit event. In December 2020, the terms of the warrants issued to the Company's CFO were amended to no longer comprise exercisability upon an exit event. Consequently, these warrants did not vest upon the IPO in February 2021 and will vest in accordance with the vesting schedule for warrants granted in 2020.

On January 4, 2021, the Company's board of directors and shareholders approved (i) a 2-for-1 stock split of its issued and outstanding ordinary shares and (ii) a bonus share issuance in the ratio of 17-for-1 of its issued and outstanding ordinary shares. The stock split also resulted in a reduction of the nominal value of the Company's ordinary shares from DKK 2 to DKK 1. In accordance with the anti-dilution provisions of the warrant agreements, the number of warrants was increased by a ratio of 36 and the exercise price was decreased from DKK 2 to 1 DKK. Accordingly, information related to the Company's warrants, have been retroactively adjusted to reflect the stock split and the bonus shares for all periods presented.

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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, 2018	1,674,324	DKK 1	18
Warrants granted[1]	257,832	DKK 1	17
Warrants granted as at December 31, 2019	1,932,156	DKK 1	17
Warrants granted	363,168	DKK 1	11
Warrants forfeited	(45,216)	DKK 1	16
Warrants cancelled	(22,032)	DKK 1	16
Warrants granted as at December 31, 2020	2,228,076	DKK 1	15
Warrants granted during 2021[2]	63,802	DKK 1	10
Warrants granted December 2021	523,599	USD 5.38	10
Warrants exercised	(62,284)[3]	DKK 1	
Warrants forfeited	(10,178)	1	
Warrants cancelled	(10,397)	1	
Warrants granted as at December 31, 2021	2,732,618	DKK 7.53 [4]	13
Warrants exercisable as at December 31, 2019	—	—	—
Warrants exercisable as at December 31, 2020	—	—	—
Warrants exercisable as at December 31, 2021	2,072,122		

(1) The warrants are not incorporated in the articles of association. Rectification conducted in October 2020.

(2) Of which 62,147 warrants were legally granted in June 2021 and the remaining 1,655 warrants were legally granted in December 2020.

(3) The share price at the exercise date was USD 5.59.

(4) December 31, 2021 USD-end rate used.

During 2019 employees, external consultants, executive management and board members became contractually entitled to warrants that was rectified on December 17, 2020:

- In January 2019, 45,216 warrants granted to a member of executive management. They vest from December 2020 – December 2022. Fair value at grant date amounted to $0.3 million.
- In February 2019, 7,956 warrants granted to an employee. They vest from December 2020 – December 2022. Fair value at grant date amounted to $0.1 million.
- In September 2019, 54,000 warrants granted to an employee. The warrants vested immediately. Fair value at grant date amount to $0.5 million.
- In October 2019, 150,660 warrants granted to a member of executive management. The warrants vest annually over 3 years. Fair value at grant date amounted to $1.3 million.
- In December 2020, an aggregate of 126,972 warrants attributable to 2019 entitlements were granted to employees, members of our board of directors and consultants who provide similar services as employees. 63,612 warrants vested immediately and 63,360 warrants vest monthly over three years from January 2020 – December 2022. Fair value at grant date amounted to $1.2 million.

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- In December 2020, an aggregate of 236,196 warrants attributable to 2020 entitlements were granted to employees, members of our board of directors and consultants who provide similar services as employees. Of the warrants granted, 120,888 warrants vested immediately and 115,308 warrants vest monthly over three years from January 2020 – December 2022. Fair value at grant date amounted to $2.3 million.

- In June 2021, 62,147 were granted to a member of Executive Management. Fair value at grant date amounted to $0.4 million.

- During 2021, an aggregate of 523,599 warrants attributable to 2021 entitlements were granted to employees, member of our board of directors and executive management. Of the warrants 22,916 were granted to our board of directors vested immediately. The warrants granted to employees and executive management vest over 36 months. Fair value at grant date amounted to $1.5 million.

- For the year ended December 31, 2019 the Company had 22,032 outstanding warrants to SDU employees and recognized an immaterial amount of expense for these warrants as research and development expenses in the statement of comprehensive loss. In September 2020, the Company terminated its existing agreement with SDU for business reasons. Under the terms of the SDU agreement, the Company did not incur a termination penalty and has no further obligations under this agreement.

- A member of the executive board terminated his employment contract as of April 30, 2020 and forfeited his right to 45,216 unvested warrants.

- A member of the executive board terminated his employment contract as of October, 2021 but no granted warrants remained unvested as of that date.

Share-based compensation expenses included in the statements of comprehensive loss:

	Years Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Research and development expenses	$ 1,051	$ 1,496	$ 1,021
General and administrative expenses	328	1,912	1,341
Total	$ 1,379	$ 3,408	$ 2,362

In 2020 an amount of $0.1 million related to warrants issued as compensation for arranging investors to subscribe for shares has been recognized in equity as a share-based compensation expense related to the capital increase.

Determination of Fair Value of Warrants

The warrants issued under the share-based payment arrangement until December 2021 are exercisable for nominal consideration compared to the fair value of the shares resulting in virtually no time value. The Company values these warrants based on the intrinsic value of the shares measured as the difference between the fair value of the Company's Ordinary shares and the warrant exercise price. Due to the highly specialized nature of services provided by consultants who provide services similar to those provided by employees of the Company, transactions with those consultants are measured at fair value of the equity instruments granted.

Under the share-based payment arrangement, there is no protection against capital increases at a discount and dividend distribution. However, dividends are not likely to be distributed and there is generally no reason to raise new capital at below the current share price. On this basis, the Company has assessed that it is generally appropriate to assume that no such transactions will take place during the holding period. When issuing warrants in 2018, convertible bonds with a potential dilutive effect were outstanding, and fair value was adjusted to reflect this potential dilution.

The stock split and bonus share issuance executed on January 4, 2021 resulted in a dilution of the warrant holders due to the increase of the exercise price compared to the pre stock split and bonus share issue. For warrants granted on December 17, 2020, the fair value was adjusted to reflect this dilution. For other grants, no such adjustment has been made.

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The fair values of the warrants are measured with reference to the share price of the underlying share. Up until December 2020, this share value was determined using the value established in different financing transactions with unrelated parties. In each of these transactions, the relative ownership of the Company was changed, and a share value was established using these fund-raising transactions. The fair values of warrants are estimated using a linear interpolation in USD of the share value on grant date based on the value established on capital event dates before and after the grant date.

For warrants granted in December 2020, the Probability-Weighted Expected Return Method ("PWERM") was applied, based on the weighted value of the share in a stay private scenario and an IPO scenario. 40% weight was put to the stay private scenario applying a share price equal to the share price of USD 8.89 at the November 2020 capital increase and 60% weight was put to the IPO scenario applying the mid-price of the indicative IPO price range of USD 11.00 available on the balance sheet. A 10% lack of marketability discount (DLOM) was applied to the IPO price.

Warrants granted prior to December 2020 are exercisable only upon an exit event or upon the Board of Director's decisions, which is a post vesting restriction. Since the warrants granted prior to 2020 do not expire until December 31, 2036, Management considers it highly unlikely that the warrants will not become exercisable and no downward adjustment to reflect the risk of the warrant not becoming exercisable is made to the fair value of the warrants.

During 2020, the Company revised the estimated date of an IPO exit event to occur in February 2021. As of December 31, 2019, the estimated IPO exit event was December 2021. As a result of this change in estimate, the Company recognized an acceleration of expense of $0.8 million for the year ended December 31, 2020.

Subsequent to the Company's initial public offering 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. Due to the fact that as of 2021, warrants was granted at the share price on the date of grant, fair value comprises a time value which is significantly affected by the expected life and estimated 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 estimated 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 in December 2021:

Expected term (in years)		6.5
Risk-free interest rate		1.34
Expected volatility		85.0 %
Share price	$	4.20

The exercise price of the warrants issued in June 2021 was DKK 1 and consequently, the warrants have virtually no time value. Therefore, fair value of the warrants has been determined as the intrinsic value based on a share price of $6.24.

Amendments to Warrants

As discussed above, the terms of the warrant granted to the company's CFO were amended to no longer comprise an accelerated vesting upon an exit clause. This is considered a non-beneficial change, and consequently the accelerated vesting upon an exit event clause is deemed to continue to exist.

For warrants to which the employees became entitled in 2019 but were not granted until December 2020, the Company recognized stock-based compensation expenses during the year ended December 31, 2019 and the interim period ended September 30, 2020, based on the terms expected to apply for these awards. Management expected the terms to be similar to the terms applicable to warrants granted up until 2018, including the accelerated vesting upon an exit clause. However, these warrants were granted subjected

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to a vesting schedule up to three years and did not allow for immediate vesting upon an exit event. Because the warrants were not granted until December 2020, the Company recognized the difference in expenses as a change in accounting estimate and not a modification of existing awards. As a result of this change in the accounting estimate, the share-based payment expense for 2020 was reduced by $0.4 million.

The following schedule specifies the outstanding warrants as at December 31, 2021:

Outstanding program	Per warrant grant date fair value (DKK)	Number of warrants outstanding	Average exercise price per warrant (DKK)	Remaining term to maturity (years)
Grant (December 2016)	20.91	701,356	1	15
Grant (September 2017)	28.71	617,184	1	15
Grant (December 2017)	28.71	122,040	1	15
Grant (during 2018)	37.05	174,564	1	15
Grant (February 2019)	42.57	7,956	1	15
Grant (September 2019)	56.35	54,000	1	15
Grant (October 2019)	56.97	150,660	1	15
Grant (December 2020)	56.75	317,457	1	9
Grant (April 2021)	45.31	1,655	1	10
Grant (June 2021)	40.86	62,147	1	10
Grant (December 2021)	19.22	523,599	USD 5.38	10
Granted at December 31, 2021		2,732,618		
Warrants exercisable at December 31, 2021		—		

The following schedule specifies the outstanding warrants as at December 31, 2020:

Outstanding program	Per warrant grant date fair value (DKK)	Number of warrants outstanding	Average exercise price per warrant (DKK)	Remaining term to maturity (years)
Grant (December 2016)	20.91	712,332	1	16
Grant (April 2017)	24.05	13,896	1	16
Grant (September 2017)	28.71	617,184	1	16
Grant (December 2017)	28.71	127,044	1	16
Grant (during 2018)	37.05	181,836	1	16
Grant (February 2019)	42.57	7,956	1	16
Grant (September 2019)	56.35	54,000	1	16
Grant (October 2019)	56.97	150,660	1	16
Grant (December 2020)	56.75	363,168	1	11
Granted at December 31, 2020		2,228,076	1	15
Warrants exercisable at December 31, 2020		—		

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The following schedule specifies the outstanding warrants as at December 31, 2019:

Outstanding program	Per warrant grant date fair value (DKK)	Number of warrants outstanding	Average exercise price per warrant (DKK)	Remaining term to maturity (years)
Grant (December 2016)	20.91	712,332	1	17
Grant (April 2017)	24.05	13,896	1	17
Grant (September 2017)	28.71	617,184	1	17
Grant (December 2017)	28.71	138,384	1	17
Grant (during 2018)[1]**	37.05	192,528	1	17
Grant (January 2019)[1]**	37.05	45,216	1	17
Grant (February 2019)**	42.57	7,956	1	17
Grant (September 2019)**	56.35	54,000	1	17
Grant (October 2019)**	56.97	150,660	1	17
Granted at December 31, 2019		1,932,156	1	17
Warrants exercisable at December 31, 2019		—		

(1) Awards valued on December 31, 2018 and January 1, 2019, respectively.

** The warrants are not incorporated in the articles of association. Rectification was conducted in December 2020.

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The Board of Directors and Executive Management holding of share awards for the years ended December 31, 2019, 2020 and 2021 is shown below:

Number of warrants held	December 31, 2018	Granted	December 31, 2019	Warrants held when becoming or leaving as a member of management	Granted	Forfeited	December 31, 2020	Warrants held when becoming or leaving as a member of management	Granted	Exercised	Forfeited	December 31, 2021
Thomas William Wylonis(former)[1]	342,612	—	342,612	(369,252)	26,640	—	369,252	—	—	—	—	369,252
Steven Projan	23,436	—	23,436	—	18,612	—	42,048	—	4,583	—	—	46,631
Roberto Prego	19,800	—	19,800	—	14,364	—	34,164	—	4,583	—	—	38,747
Joann Suzich(former)[7]	—	—	—	—	10,260	—	10,260	—	—	—	—	10,260
Marianne Søgaard[2]	—	—	—	65,952	28,368	—	94,320	—	9,167	—	—	103,487
Helen Boudreau (former)[3]	—	—	—	—	5,436	—	5,436	—	—	(5,436)	—	—
Kim Bjørnstrup (former)[4]	—	—	—	(5,868)	5,868	—	—	—	—	—	—	—
Lars Holtug	—	—	—	—	—	—	—	—	4,583	—	—	4,583
Board of Directors in total	385,848	—	385,848	(309,168)	109,548	—	555,480	—	22,916	(5,436)	—	572,960
Lars Aage Staal Wegner	844,416	—	844,416	—	7,668	—	852,084	—	64,167	—	—	916,251
Birgitte Rønø	—	—	—	—	—	—	—	29,376	45,000	—	—	74,376
Thomas Bogenrieder (former)[5]	4,356	45,216	49,572	(4,356)	—	(45,216)	4,356	—	—	—	—	4,356
Erik Heegaard	—	—	—	—	—	—	—	—	97,564	—	—	97,564
Glenn S. Vraniak (former)[6]	—	150,660	150,660	—	—	—	150,660	—	—	—	—	150,660
Executive Management in total	848,772	195,876	1,044,648	(4,356)	7,668	(45,216)	1,007,100	29,376	206,731	—	—	1,243,207

(1) Board member until June 30, 2020, 252 warrants were granted for services provided after retirement from the Board of Director position.

(2) As of November 25, 2020, 26,964 warrants were granted for services provided before taking on the Board of Directors position.

(3) Board member from June 30, 2020 to May 25, 2021.

(4) Board member from June 30, 2020 to November 4, 2020.

(5) Part of Executive Management until March 31, 2020.

(6) Mr. Vraniak resigned as the Chief Financial Officer of the Company effective November 1, 2021.

(7) Board member until May 25, 2021.

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Note 9. Financial Income and Expenses

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Financial income:			
Interest income, bank	$ —	$ —	$ 8
Interest income, other	—	—	1
Foreign exchange gains	2,039	216	56
Total financial income	2,039	216	65
Financial expenses:			
Interest expenses	(5)	(29)	(36)
Changes in fair value of convertible debt instruments	—	—	(1,183)
Interest expenses, lease liabilities	(123)	—	(3)
Interest, loan from lessor	(31)	—	—
Foreign exchange losses	(756)	(194)	—
Total financial expenses	(915)	(223)	(1,222)
Net financial items	$ 1,124	$ (7)	$ (1,157)

Note 10. Income Taxes

(a) Analysis of charge/(credit) for the year:

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Income tax expense/(benefit)	$ (178)	$ (1,557)	$ (825)
Total income taxes for the year	$ (178)	$ (1,557)	$ (825)

On December 31, 2021, the Company had tax loss carry-forwards in Denmark of $9.5 million (2020: $3.8 million in Denmark; 2019: $1.3 million in Denmark) for income tax purposes, all of which can be carried forward infinitely according to Danish Corporate Income Tax Act. As of December 31, 2021, 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

	Year Ended December 31,		
	2021	2020	2019
Statutory corporate income tax rate in Denmark	22 %	22 %	22 %
Difference in corporate income tax rate in subsidiaries	— %	—	—
Non-deductible income / (expenses)	— %	(1)%	(5)%
Non-taxable income / (expenses)	— %	1 %	—
Additional tax deduction R&D expenses	6 %	3 %	—
Tax credit research and development expenditures	(4)%	9 %	7 %
Change in deferred tax asset not capitalized	(23)%	(25)%	(17)%
Total effective tax rate	1 %	9 %	7 %

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(c) Deferred tax in the statements of financial position

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Deferred Tax Positions:			
Warrants	$ 2,118	$ 4,289	$ 3,034
Loss carry forward	9,530	3,759	1,270
Research and development expenditures	—	262	—
Other items	(98)	(6)	(34)
Valuation allowance on deferred tax assets	(11,550)	(8,042)	(4,270)
Total capitalized	$ —	$ 262	$ —

Deferred tax attributable to research and development expenditures relates to development costs recognized as an expense in the consolidated financial statements in 2020 and are tax deductible in 2021.

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 11. 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 Biotech 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 2021, 2020 and 2019, the dilutive potential shares are anti-dilutive for the earnings per share calculation.

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands, except share amounts and per share amounts)		
Loss per share before and after dilution			
Net loss attributable to shareholders of Evaxion Biotech A/S	$ (24,532)	$ (15,018)	$ (11,195)
Weighted-average number of ordinary shares outstanding	19,493,143	15,434,758	13,892,314
Loss per share before and after dilution	$ (1.26)	$ (0.97)	$ (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:

	December 31,		
	2021	2020	2019
Warrants	2,732,618	2,228,076	2,059,128

Note 12. Intangible Assets

In June 2020, the Company entered into a license agreement for the rights to certain intellectual properties. Upon execution of the license agreement, the Company was obligated to make a milestone payment of $35,000. The agreement remains in effect until the Company completes a Phase I/IIa clinical study, after that the Company has an option to extend the agreement for an additional 10-year term. Over the initial term of the agreement, the Company is obligated to make various additional milestone payments based on the progress of developed drug candidates. The Company determined that the milestone payments meet the definition of intangible assets and will be capitalized.

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During the twelve months ended December 31, 2020, the Company capitalized $35,000 as intangible assets for the acquisition of a non-exclusive technology license. 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. As of December 31, 2020, the Company accrued for an additional $60,000 related to the license. The Company did not recognize any amortization expense for the years ended December 31, 2021 and 2020 as the asset has not been put in use. No intangible assets were recognized in earlier periods as the Company's expenditures did not qualify for capitalization.

During the twelve months ended December 31, 2020, the Company capitalized $60,000 as intangible assets for the acquisition of a non-exclusive technology license from SSI. Subject to successful commercialization of any Evaxion product utilizing the in-licensed technology, Evaxion is required to pay to the seller a royalty on net sales in the low teens. In the event any Evaxion product utilizing the in-licensed technology are commercialized by one of the Company's partners, Evaxion is required to pay to the seller a percentage of any out-licensing revenue earned by the Company or its affiliates. If Evaxion enters into a sublicense agreement with a partner subsequent to the initiation of a Phase 2b clinical trial, Evaxion is required to pay to the seller a percentage of any sublicensing income in an amount in the lower double-digit range. If Evaxion enters into a sublicense agreement with a partner subsequent to the initiation of a Phase 3 trial, Evaxion is required to pay to the seller a percentage of any sublicensing income in the lower double-digit range. If Evaxion enters into a sublicense agreement with a partner without initiating a Phase 2b trial, Evaxion is required to pay to SSI a percentage of any sublicensing income in the mid double-digit range.

The Company did not recognize any amortization expense for the years ended December 31, 2021, and 2020 as the asset has not been put in use.

	Intangible Assets	Total
	(USD in thousands)	
Cost at December 31, 2020	$ 100	$ 100
Additions during the year	—	—
Exchange rate adjustments	(7)	(7)
Cost at December 31, 2021	93	93
Amortization at December 31, 2020	—	—
Amortization for the year	—	—
Exchange rate adjustment	—	—
Amortization at December 31, 2021	—	—
Carrying amount at December 31, 2021	$ 93	$ 93

	Intangible Assets	Total
	(USD in thousands)	
Cost at December 31, 2019	$ —	$ —
Additions during the year	95	95
Exchange rate adjustments	5	5
Cost at December 31, 2020	100	100
Amortization at December 31, 2019	—	—
Amortization for the year	—	—
Exchange rate adjustment	—	—
Amortization at December 31, 2020	—	—
Carrying amount at December 31, 2020	$ 100	$ 100

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Note 13. Property and Equipment, Net

	Property	Other Equipment	Leasehold Improvements	Total
	(USD in thousands)			
Cost at December 31, 2020	$ 257	$ 263	$ —	$ 520
Additions during the year	2,891	1,025	1,634	5,550
Disposals during the year	(244)	—	—	(244)
Exchange rate adjustments	(148)	(63)	(67)	(278)
Cost at December 31, 2021	2,756	1,225	1,567	5,548
Depreciation at December 31, 2020	$ (237)	$ (62)	$ —	$ (299)
Depreciation for the year	(179)	(105)	(59)	(343)
Depreciation reversed on disposals during the year	244	—	—	244
Exchange rate adjustment	17	6	1	24
Depreciation at December 31, 2021	(155)	(161)	(58)	(374)
Carrying amount at December 31, 2021	$ 2,601	$ 1,064	$ 1,509	$ 5,174
Carrying amount of right-of-use assets at December 31, 2021	$ 2,601	$ —	$ —	$ 2,601

	Property	Other Equipment	Total
		(USD in thousands)	
Cost at December 31, 2019	$ 179	$ 93	$ 272
Additions during the year	55	149	204
Exchange rate adjustments	23	21	44
Cost at December 31, 2020	257	263	520
Depreciation at December 31, 2019	(144)	(27)	(171)
Depreciation for the year	(71)	(34)	(105)
Exchange rate adjustment	(22)	(1)	(23)
Depreciation at December 31, 2020	(237)	(62)	(299)
Carrying amount at December 31, 2020	$ 20	$ 201	$ 221
Carrying amount of right-of-use assets at December 31, 2020	$ 20	$ —	$ 20

Depreciation included in the statement of comprehensive loss:

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Research and development	$ 270	$ 90	$ 64
General and administrative	73	15	16
Total depreciation included in the statement of comprehensive loss	$ 343	$ 105	$ 80
Total accumulated depreciation of right-of-use assets at December 31,	$ 557	$ 236	$ 145

Note 14. Prepayments and other receivables

	December 31,	
	2021	2020
	(USD in thousands)	
VAT receivables	$ 387	$ 376
Prepayments	638	1,175
Other receivables	113	2
Total prepayments and other receivables	$ 1,138	$ 1,553

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Note 15. Other Payables

	December 31,	
	2021	2020
	(USD in thousands)	
Employee cost liabilities	$ 989	$ 1,054
Other liabilities	46	180
Total other payables	$ 1,035	$ 1,234

Note 16. Cash and Cash Equivalents

	December 31,	
	2021	2020
	(USD in thousands)	
Cash and cash equivalents	$ 32,166	$ 5,834
Total cash and cash equivalents	$ 32,166	$ 5,834

Cash and cash equivalents consist mainly of cash on deposit with banks.

Changes in Net Working Capital

	December 31,		
	2021	2020	2019
	(USD in thousands)		
Changes in receivables and tax receivables	$ 1,863	$ (2,501)	$ (337)
Changes in trade payables	(647)	1,798	507
Changes in other payables	21	918	403
Changes in net working capital	$ 1,237	$ 215	$ 573

Working capital is defined as current assets (excluding cash) less current liabilities (excluding convertible debt) and measures the net liquid assets the Company has available for the business.

Adjustments for non-cash items

Adjustments of non-cash items in the statements of comprehensive loss:

	Year Ended December 31,		
	2021	2020	2019
	(USD in thousands)		
Income taxes	$ (178)	$ (1,557)	$ (825)
Tax credit schemes accounted for as grants	(12)	(510)	—
Depreciation	344	105	81
Interest income	—	—	(9)
Interest expense	159	30	39
Share-based compensation expenses	1,379	3,408	2,362
Acquisition of property, plant and equipment	(90)	—	—
Change in fair value of convertible debt instruments	—	—	1,183
Other adjustments: Other adjustments, primarily exchange rate adjustments	(1,061)	107	114
Total adjustments for non-cash items	$ 541	$ 1,583	$ 2,945

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Reconciliation of Liabilities from Financing Activities

(USD in thousands)	December 31, 2020	Cash flows	Accumulated interest	Additions	Exchange rate adjustment	December 31, 2021
Lease liabilities	$ 20	$ (226)	$ 123	$ 2,731	$ (128)	$ 2,520
Loan from lessor	—	—	31	1,269	(130)	1,170
Provisions	—	—	—	161	(8)	153
Total liabilities from financing activities	$ 20	$ (226)	$ 154	$ 4,161	$ (266)	$ 3,843

(USD in thousands)	December 31, 2019	Cash flows	Accumulated interest	Additions	Exchange rate adjustment	December 31, 2020
Lease liabilities	$ 36	$ (74)	$ 1	$ 54	$ 3	$ 20
Total liabilities from financing activities	$ 36	$ (74)	$ 1	$ 54	$ 3	$ 20

Note 17. Leases

As a result of the lease accounting of IFRS 16, the Company has capitalized the only right-of-use asset being the domicile lease. Upon implementation on January 1, 2018, the Company has recognized a liability to make lease payments (i.e. the lease liabilities) of $0.2 million and an asset representing the right to use the underlying asset during the lease term (i.e. the right-to-use asset) of $0.2 million. The liability was measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of the standard adoption date of January 1, 2018. The Company applied an incremental borrowing rate of 3.8%. For the years ended December 31, 2019,2020 and 2021, the expense related to variable lease payments not included in the lease liabilities was immaterial and was recognized in operating expense.

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. The initial monthly payment is expected to be between $28,000 and $30,000, which consists of $12,000 for the office space, and is expected to be between $16,000 and $18,000 for the laboratory space. Through-out 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 operating lease in Copenhagen, Denmark as of December 31, 2020.

We also occupied an office space in New York, New York, United States. The terms of the lease agreement included a 13 month occupancy period from January 2, 2020 through January 31, 2021. A termination notice was provided in November 2020 and the lease and occupancy terminated on January 31, 2021.

For the years ended December 31, 2021, 2020 and 2019, the expense related to variable lease payments not included in the lease liabilities was immaterial and was recognized in operating expense.

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Set out below are the carrying amounts of the Company's right-of-use assets and lease liabilities and the movements during the period:

	Right-of-Use Asset	Lease liabilities
	(USD in thousands)	
At December 31, 2020	$ 20	$ 20
Additions	2,891	2,731
Depreciation	(179)	—
Interest Expense	—	123
Payments	—	(226)
Translation	(131)	(128)
At December 31, 2021	$ 2,601	$ 2,520

	Right-of-Use Asset	Lease liabilities
	(USD in thousands)	
At December 31, 2019	$ 35	$ 36
Additions	54	54
Depreciation	(73)	—
Interest Expense	—	—
Payments	4	(74)
Translation	—	4
At December 31, 2020	$ 20	$ 20

The total cash outflow for leases was $0.2 million in 2021, and $0.2 million in 2020.

Loan from Lessor

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 costs, which approximates fair value at the time of issuance. As of December 31, 2021, the Company is still in discussions with DTU on the actual costs incurred.

As a result of the finance structure this amount is not included as Purchase of property and equipment within the consolidated statements of cash flows. The leasehold improvements recognized will be subject for adjustment when the actual costs incurred are made available from DTU.

The following table sets forth the finance liability (in thousands):

	December 31, 2021
Loan from lessor	$ 1,170
Total Loan from lessor	1,170
Less: Loan from lessor, current portion	(126)
Total Loan from lessor, net of current portion	$ 1,044

Note 18. Debt

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 1,047,744 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

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31, 2021, the Company 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.

Note 19. Capital Structure and Financial Matters

Share Capital – Ordinary Shares

Loss of subscribed share capital

On December 31, 2018, the Company had lost more than 50% of its subscribed share capital. At the annual general meeting of the shareholders held on March 29, 2019, the Board of Directors gave, in accordance with section 119 of the Danish Companies Act, an account of the Company's financial position. As part of the account, the Board of Directors stated that in its view, special actions were not required. The share capital of the Company was subsequently re-established through the conversion of the convertible debt instruments and issue of new shares during 2019.

Capital transactions

In September 2020, the Company issued 745,380 shares of ordinary shares to existing investors in the Company. The purchase price was $8.89 per share for aggregate proceeds of $6.6 million. The Company incurred immaterial issuance costs. The proceeds were received by the Company on September 17, 2020. On August 10, 2020, the Company's articles of association were amended in connection with the execution of this transaction. The revised articles increased the authorized number of shares the Company can issue by: (i) the 745,380 shares issued in this transaction, as well as (ii) an additional 1,800,000 shares of Common ordinary share at a nominal price of DKK 1, to be issued any time prior to June 1, 2025. The amended articles also allow the Company to issue an additional 1,298,196 of compensatory ordinary share warrants to employees and consultants any time prior to June 1, 2025.

In October 2020, we successfully completed part 2 of our "bridging round" of capital with outside investors in the amount of $2.4 million with a purchase price of $8.89 per share from the issuance of 269,136 of our ordinary shares and received the proceeds in November 2020. Transaction costs directly attributable to the third quarter of 2020 "bridging round" of capital with outside investors have a total amount of $144,022.

In February 2021, we completed our IPO through which we issued and sold 3,000,000 American Depositary Shares, or ADSs, each of which represents one ordinary share, at a price to the public of $10.00 per ADS. We received aggregate net proceeds of $25.3 million from the IPO, after deducting the underwriting discounts and commissions and offering expenses. Upon the completion of the IPO, our registered, issued, and outstanding share capital was nominal DKK 19,198,668.

In November 2021, we completed a follow-on public offering through which we issued and sold 3,942,856 ADSs, each of which represents one ordinary share, at a price to the public of $7.00 per ADS. The shares issued were inclusive of the 514,285 ADSs issued to the underwriters pursuant to the full exercise of their option to purchase additional shares on November 5, 2021. The Company received aggregate net proceeds of $24.9 million from the follow-on public offering, which includes the funds received for the additional shares issued to the underwriters, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Upon the completion of the follow-on public offering, the Company's registered, issued, and outstanding share capital was nominal DKK 23,141,524.

At year end, due to warrant exercise, the outstanding share capital was nominal DKK 23,203,808.

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The following are changes in the Company's share capital for the years ended December 31, 2019, 2020 and 2021:

	Number of Ordinary Shares	Share Capital (DKK in thousands)
Share capital, December 31, 2018	12,917,016	12,917
Capital increase at July 17, 2019 (issuance of shares for cash)	997,668	998
Capital increase at July 17, 2019 (conversion of Convertible Debt 1)	302,976	303
Capital increase at July 17, 2019 (conversion of Convertible Debt 2)	848,232	848
Capital increase at December 19, 2019 (issuance of shares for cash)	118,260	118
Share capital, December 31, 2019	15,184,152	15,184
Capital increase at September 17, 2020 (issuance of shares for cash)	745,380	745
Capital increase at October 15, 2020 (issuance of shares for cash)	269,136	269
Share capital, December 31, 2020	16,198,668	16,198
Capital increase at February 9, 2021 (for initial public offering)	3,000,000	3,000
Capital increase at November 9, 2021 (for follow-on offering)	3,942,856	3,943
Capital increase November 2021 (exercised warrants)	62,284	63
Share capital, December 31, 2021	23,203,808	23,204

The Company's share capital consists of the following ordinary shares:

	December 31,	
	2021	2020
	(USD in thousands)	
Authorized, issued and fully paid		
23,203,808 (2020: 16,198,668) ordinary shares of DKK 1 each (2020: ordinary shares of DKK 1 each)	$ 3,755	$ 2,648
	$ 3,755	$ 2,648

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, the board of directors and executive management held the following shareholdings in the Company:

Number of ordinary shares owned	2021	2020	2019
Niels Iversen Møller	4,292,604	4,292,604	4,292,604
Andreas Holm Mattsson	4,163,832	4,163,832	4,163,832
Lars Aage Staal Wegner	182,124	182,124	182,124
Executive Management in total	**8,638,560**	**8,638,560**	**8,638,560**

Number of ordinary shares owned	2021	2020	2019
Roberto Prego	310,248	310,248	310,248
Thomas William Wylonis (former)	—	485,676	481,860
Marianne Søgaard	41,652	41,652	—
Steven Projan	27,288	27,288	11,736
Board of Directors in total	**379,188**	**864,864**	**803,844**

Note 20. Convertible Debt Instruments

During 2018, the Company issued two types of convertible debt instruments, ("Convertible Debt 1") and one ("Convertible Debt 2") for total proceeds of $8.0 million, of which $0.1 million was received from related parties, including members of the Board of Directors and Executive Management. The Company originally recorded both debt instruments at fair value as a financial liability and

subsequently remeasured the instruments with the change being presented on the statement of comprehensive income for the reporting period. In July 2019, both instruments were converted into ordinary shares as a result of a qualified capital increase triggering a conversion based on the terms of the agreements.

The following table summarizes the changes in the convertible debt instruments during the year ended December 31, 2019:

	Convertible loans (USD in thousands)
Carrying amount at December 31, 2018	$ 8,569
Amount received in 2019	152
Fair value adjustment included in finance expenses	1,183
Currency adjustment	(209)
Converted to equity during 2019	(9,695)
Carrying amount at December 31, 2019	$ —

The main terms of Convertible Debt 1 were:

- Term: 12 months from issuance;
- Interest coupon 7.5 percent p.a. accruing over the term of the loan;
- Loan currencies: $0.9 million is USD denominated and $1.0 million is denominated in DKK (DKK 7.1 million);
- Lender conversion option if a capital increase in excess of DKK 9.8 million (or a qualified capital increase event) takes place before maturity. The conversion price is the share price obtained at the qualified capital increase event less a 20 percent discount;
- Repayment in cash of principal + accrued interest at a premium of 50 percent if all shares of the Company are sold; and
- Lender conversion option to a fixed number of shares if the loan has not been repaid or converted under the other settlement terms of the agreement.

The main terms of Convertible Debt 2 were:

- Term: Expires on December 31, 2020;
- Interest coupon 7.5 percent p.a. accruing over the term of the loan;
- Loan currencies: $5.4 million is USD denominated and $0.7 million is denominated in DKK (DKK 5.0 million);
- Mandatory conversion if a capital increase in excess of $10.0 million (qualified capital increase) takes place before maturity. The conversion price is the share price obtained less a 5 percent discount if the capital increase take place in 2018, 10 percent if it takes place in 2019 and 20 percent if it takes place in 2020;
- Repayment in cash of principal + accrued interest at a premium of 50% if all shares of the Company are sold; and
- Mandatory conversion at maturity with a conversion price of $160.41. 10 days before conversion, USD denominated loans will convert into DKK whereas the conversion price remains denominated in USD.

Convertible debt instruments were classified as financial liabilities until such time that the Company had an unconditional right to avoid settlement in cash and had no obligation to settle in a variable number of shares.

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For Convertible Debt 1, the Company did not have an unconditional right to avoid settlement in cash. In addition, Convertible Debt 2 comprised an obligation to settle in a variable number of shares at maturity. Therefore, both convertible debt instruments comprised a debt host instrument.

Conversion features comprising a fixed number of the entity's shares in exchange for a fixed principal in the entity's functional currency were equity instruments and separated from the debt host contract as the residual between fair value of the contract and fair value of a similar debt instrument without the conversion feature. All other equity conversion features were embedded derivatives.

Both convertible debt instruments included a conversion feature resulting in settlement in a variable number of shares. Consequently, none of the instruments comprised an equity component. They included the following non-closely related embedded derivatives:

- At maturity conversion options for Convertible Debt Instrument 1;
- At maturity conversion provisions for Convertible Debt Instrument 2;
- Early settlement mechanism on both issuances through delivery of a variable number of shares at a discounted price; and
- Change of control prepayment provision.

Note 21. Related Party Transactions

	December 31,		
	2021	2020	2019
		(USD in thousands)	
The Company's transactions with other related parties:			
Transactions with related parties (expenses):			
Accrued interest on convertible debt instruments issued to members of executive management and board of directors	$ —	$ —	$ (4)
Balances with related parties at year-end (asset):			
Prepaid rent and deposit for a leased property from a related party	$ —	$ 7	$ —
Balances with related parties at year-end (liabilities):			
Convertible debt instruments issued to members of executive management and board of directors (nominal value plus accrued interest of 7.5%)	$ —	$ —	$ —

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 persons.

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, 2021, 2020 and 2019.

Note 22. Contractual Obligations

Litigations and investigations

The Company is not involved in any pending litigations, claims and investigations that individually and in the aggregate that is expected to have a material impact on the financial position, operating profit or cash flow.

The contractual obligations are similarly individually and, in the aggregate, not material to the future financial position, operating profit or cash flow.

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Contractual obligations

At December 31, 2021, the Company had the following contractual commitments which fall due as follows:

	December 31, 2021 (USD in thousands)					
	Contractual cash flows	<1 year	1 – 2 years	2 – 5 years	>5 years	Total
Purchase obligations	$ 72	$ 72	$ —	$ —	$ —	$ 72
Total	$ 72	$ 72	$ —	$ —	$ —	$ 72

The Company has purchase obligations of $72 thousand due to CRO's and a nominal amount due system provider as of December 31, 2021.

At December 31, 2020, the Company had the following contractual commitments which fall due as follows:

	December 31, 2020 (USD in thousands)					
	Contractual cash flows	<1 year	1 – 2 years	2 – 5 years	>5 years	Total
Purchase obligations	$ 712	$ 712	$ —	$ —	$ —	$ 712
Total	$ 712	$ 712	$ —	$ —	$ —	$ 712

The Company has purchase obligations of $0.6 million due to CRO's and $0.1 million due to university future partners as of December 31, 2020.

Note 23. 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, 2021 are as follows:

	Provisions (USD in thousands)
Carrying amount at January 1, 2021	$ —
Provision recognized	161
Additions	—
Utilization of provision	—
Change in the provision	—
Currency adjustment	(8)
Carrying amount at December 31, 2021	$ 153

EVAXION BIOTECH A/S
Notes to Financial Statements

Note 24. 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 Statement of Profit or Loss for the years ended December 31, 2021 and 2020. This note was prepared in accordance with the requirements of the Danish Financial Statements Act:

	December 31,	
	2021	2020
	(USD in thousands)	
Audit fees	$ 177	$ 308
Audit related fees	108	119
Other fees	328	253
Total fees	$ 613	$ 680

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 initial public offering.

Note 25. Events After the Reporting Period

EIB Loan Drawdown

As of December 31, 2021, the Company 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.

Executive Management Agreements

The Company entered into agreements to hire executives in its Chief Operating Officer and Chief Financial Officer roles subsequent to the date of this annual report. The Chief Operating Officer joined the Company on March 14, 2022 and the Chief Financial Officer is expected to join the Company in August 2022.

Russia's Invasion of Ukraine

On February 24, 2022, Russia invaded Ukraine creating a global conflict. 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, and are likely to continue to have, short-term and more likely longer-term adverse impacts on Ukraine and Europe and around the globe. Potential ramifications include disruption of the supply chain including research activities and complications with the conduct of ongoing and future clinical trials of our product candidates, including patient enrollment. The Company relies on global networks of contract research organizations and clinical trial sites to enroll patients, Delays in research activities or in the conduct of our clinical trials could increase associated costs and, depending upon the duration of any delays, require us to find alternative suppliers at additional expense. In addition, the conflict between Russia and the Ukraine has had significant ramifications on global financial markets, which may adversely impact our ability to raise capital on favorable terms or at all.

Item 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Form	Date	Incorporated by Reference Number	File Number	Provided Herewith
1.1	Articles of Association currenty in effect (including English translation)	6-K	3/23/2022	1.1	001-39950	
2.1	Form of Deposit Agreement among the Registrant, the depositary 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	
8.1	List of Subsidiaries of the Registrant	F-1/A	11/03/2021	21.1	333-260493	
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
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 Inline 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 Biotech 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 BIOTECH A/S
/s/ Lars Staal Wegner
Name: Lars Staal Wegner
Title: Chief Executive Officer
Date: March 31, 2022

/s/ Niels Iversen Møller
Name: Niels Iversen Møller
Title: Interim Chief Financial Officer
Date: March 31, 2022

Exhibit 12.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lars Staal Wegner, certify that:

1. I have reviewed this annual report on Form 20-F of Evaxion Biotech 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 31, 2022

By: /s/ Lars Staal Wegner, M.D.
Name: Lars Staal Wegner
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Niels Iversen Møller, certify that:

1. I have reviewed this annual report on Form 20-F of Evaxion Biotech 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 31, 2022

By: /s/ Niels Iversen Møller
Name: Niels Iversen Møller
Title: Interim Chief Financial Officer

Exhibit 13.1

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 Biotech A/S (the "Company") for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lars Staal Wegner, 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 31, 2022

By: /s/ Lars Staal Wegner
Name: Lars Staal Wegner
Title: Chief Executive Officer

Exhibit 13.2

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 Biotech A/S (the "Company") for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Niels Iversen Møller, as Interim 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 31, 2022

By: /s/ Niels Iversen Møller
Name: Niels Iversen Møller
Title: Interim Chief Financial Officer

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (No. 333-255064) on Form S-8 of our report dated March 31, 2022, with respect to the consolidated financial statements of Evaxion Biotech A/S included in this Annual Report (Form 20-F) for the year ended December 31, 2021.

/s/ EY Godkendt Revisionspartnerselskab

Copenhagen, Denmark

March 31, 2022