and other factors could cause our future performance to differ materially from our assumptions and estimates. See *"Forward-Looking Statements"* above.

ENFORCEABILITY OF CIVIL LIABILITIES

We are organized under the laws of Denmark, with a domicile in the municipality of Copenhagen, Denmark.

A majority of the members of our Board of Directors and Executive Management are residents of Denmark or other jurisdictions outside the U.S. A substantial portion of our and such persons' assets are located in Denmark or other jurisdictions outside the U.S. As a result, it may not be possible for investors to effect service of process upon such persons or us with respect to litigation that may arise under U.S. law or to enforce against them or our company judgments obtained in U.S. courts, whether or not such judgments were made pursuant to civil liability provisions of the federal or state securities laws of the U.S. or any other laws of the U.S.

The U.S. and Denmark do not have a treaty providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment (other than an arbitration award) rendered by a U.S. court based on civil liability would not be enforceable in Denmark. However, if the party in whose favor such final judgment is rendered brings the lawsuit in a competent court in Denmark, that party may submit to the Danish court the final judgment that has been rendered in the U.S. A judgment by a federal or state court in the U.S. against the Company will neither be recognized nor enforced by a Danish court, but such judgment may serve as evidence in a similar action in a Danish court.

PART I

ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2 OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3 KEY INFORMATION

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary

Our business is subject to numerous risks and uncertainties. You should carefully consider these risks and uncertainties when investing in our ordinary shares or American depositary shares ("**ADSs**"). The principal risks and uncertainties affecting our business include the following:

- Our financial results and near-term prospects are substantially dependent on the commercial success of DARZALEX, our royalties on which are limited in time, and our relationship with Janssen.

- We have identified a material weakness in our internal control over financial reporting, which could, if not remediated, adversely affect our ability to report our financial results accurately or in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our ADSs.
- Sales of our products will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.
- We have a limited history of commercializing our marketed products, and the launch of a new product or of an existing product in a new indication or territory is subject to a number of risks and uncertainties and may not be successful.
- Our business and operations have experienced rapid growth that needs to be carefully managed.
- We rely on our collaboration partners in many aspects of our business.
- We rely on third parties to conduct clinical trials.
- We rely on a limited number of third-party manufacturers for our product supply.
- Biopharmaceutical product development involves a substantial degree of uncertainty.
- Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.
- Any approval granted for our products or product candidates in the United States does not assure approval of such products in Japan and the EU or other foreign jurisdictions.
- We may be affected by reports of adverse events or safety concerns relating to our products or product candidates.
- We may face product liability claims related to the use or misuse of our products or technologies.
- Our internal computer systems, or those of our collaboration partners, contractors or consultants, may fail or suffer cyber or other security breaches.
- Our ability to compete may decline if we or our collaboration partners are unable to or do not adequately protect intellectual property rights or if our intellectual property rights are inadequate.
- Government restrictions on pricing and reimbursement, as well as other healthcare payer cost-containment initiatives, may negatively impact our ability to generate revenue.
- Even if approved, our products will be subject to extensive post-approval regulation, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.
- Future laws and regulations and changes to existing ones may have an adverse impact on our business.
- We and our business arrangements with third parties are subject to fraud, abuse and other healthcare laws and regulations.

Risks Related to Our Business and Financial Condition

Our financial results and near-term prospects are substantially dependent on the commercial success of DARZALEX, our royalties on which are limited in time, and our relationship with Janssen.

In 2023, royalties and milestone payments from Janssen Biotech, Inc. ("**Janssen**") related to daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the U.S. and as DARZALEX SC in Europe for subcutaneous ("**SC**") administration) for certain indications of multiple myeloma ("**MM**") and light-chain ("**AL**") amyloidosis, accounted for 68% of our revenue, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. Janssen is currently fully responsible for developing and commercializing daratumumab, and all costs associated therewith, and consequently, our revenue and resulting operating profit and near-term prospects are substantially dependent on Janssen's efforts and the success of this collaboration.

The royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including for lack of patent coverage or upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen's obligation to pay royalties under this agreement will expire on a country-by-country basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration or invalidation of the last-to-expire relevant Genmab patent (as defined in the agreement) covering daratumumab in such country. We have issued patents and pending patent applications covering daratumumab in numerous jurisdictions, including patents issued in the U.S., Europe and Japan. Our patents do not begin to expire until March 2026. The issued U.S., European and Japanese patents, including relevant patent term extensions ("**PTE**") and supplementary protection certificates ("**SPC**"), expire in late 2020s and early 2030s.

Genmab had been engaged in arbitration with Janssen since September 2020 concerning certain matters related to its license agreement relating to daratumumab. The arbitration is now concluded. See "*Item 8 – Financial Information—Legal Proceedings*" for more information.

There can be no assurance that, even with the expansions to the prescribing label for DARZALEX in the U.S. and the EU, DARZALEX sales will remain at or near current levels or will continue to grow. In particular, DARZALEX is subject to intense competition in the MM therapy market. In addition to numerous other U.S Food and Drug Administration ("**FDA**") approved treatments for the same indications, we are also aware of several additional investigational agents and technologies that are currently being studied for the treatment of MM, any of which may compete with DARZALEX in the future. If Janssen is unable to successfully compete with these or other agents and technologies, DARZALEX sales could decline materially.

We currently rely on our daratumumab collaboration with Janssen to support our business. If we do not realize the anticipated benefits from our collaboration with Janssen, our business, financial condition and results of operations may be materially harmed. In particular, the termination of our collaboration with Janssen could significantly delay the development and commercialization of our products and product candidates and impact our financial results and future prospects. Our licensing collaboration partners generally have the right to terminate our collaborations with notice at any time.

Future prospects for daratumumab are subject to the risks outlined below with respect to our other product candidates, including risks related to clinical trials, adverse events, regulatory requirements and approvals, intellectual property matters, competition, manufacturing, pricing, reimbursement and marketing. In addition, future prospects for daratumumab are also subject to the risk that we will be unable to successfully manage our relationship with Janssen and other risks described herein that are applicable to all our collaborations.

We have a limited history of commercializing our marketed products, and the launch of a new product or of an existing product in a new indication or territory is subject to a number of risks and uncertainties and may not be successful.

We are continuing to develop and expand our commercialization capabilities, including sales, distribution and marketing, to allow us to market our own products for the indications and in the geographies we determine would be most effective to create value for patients and our shareholders. Our goal is to continue to expand our commercialization capabilities, with an initial focus on successfully commercializing our first two approved proprietary products, tisotumab vedotin and epcoritamab. The co-commercialization of tisotumab vedotin and epcoritamab is at an early stage (launch) and may not be successful. The continued commercialization of these products could be impaired, and the launch and commercialization of any future products could be delayed or impaired, due to a variety of factors, including supply constraints, delays or challenges in arranging a commercial infrastructure, delays in obtaining or failure to obtain pricing and reimbursement approvals, or other factors, including those described elsewhere herein. We had no prior experience as an organization launching or commercializing a product prior to tisotumab vedotin and epcoritamab, which could adversely affect our ability to maximize their commercial potential.

We continue to develop our market-based commercialization operations in the U.S. and Japan. Building comprehensive commercialization capabilities requires substantial investment of time and money and significant management focus and resources. We are competing with pharmaceutical and biotechnology companies with established commercialization and marketing capabilities. Without additions to our internal team or the support of third parties, we may be unable to compete successfully against these more established companies as we expand into new territories. In addition, we may be unable to develop productive relationships with local medical experts, patients and other key stakeholders or may face barriers due to cultural or regulatory differences. We also compete for staffing with transnational and local pharmaceutical and biotechnology firms and local medical, healthcare and research organizations. Accordingly, there can be no assurance that our efforts to build and expand comprehensive commercialization capabilities will be successful in an acceptable time frame, without disproportionately substantial expenses or at all.

Even if another of our proprietary product candidates obtains regulatory approval, we may determine that commercializing such product candidate ourselves would not be the most effective way to create value for our shareholders. In addition, if we choose to commercialize any of our product candidates, our marketing efforts may be unsuccessful as a result of unfavorable pricing or reimbursement limitations, delays, competition or other factors. We are also subject to extensive and costly government regulation and are required to obtain and maintain governmental approvals in order to successfully commercialize our products. Failure to successfully market one or more of our approved products, or delays in our commercialization efforts, may diminish the commercial prospects for such products and may result in financial losses or damage to our reputation, each of which may have a negative impact on our financial condition, results of operations and future growth prospects.

Our business and operations have experienced rapid growth that needs to be carefully managed.

We have experienced rapid growth over the last several years, and we anticipate further growth as our pipeline advances and we further commercialize our products. Since 2019 Genmab has grown from 548 employees to 2,204 at the end of 2023. In 2019 there were 12 active industry sponsored clinical trials for Genmab proprietary products, which are those owned at least 50% by Genmab. By the end of 2023 this number had more than doubled to 28, including multiple Phase III trials. Such growth has put significant demands on our management and infrastructure, including new operational and financial systems, expanding commercial capabilities, as well as extended manufacturing and commercial outsourcing arrangements. Our success will depend in part upon our ability to manage this growth effectively, including by maintaining our collaborative culture. As we continue to grow, we must continuously improve our operational, financial and management controls and our reporting systems and procedures. We must ensure that our policies and procedures evolve to reflect our dynamic operating model and implementation of financial systems. We must also continue to effectively retain existing employees and to attract, hire, train and retain new employees. Any failure to expand these areas and implement appropriate procedures and controls in an efficient manner and at a pace consistent with our business objectives could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We have identified a material weakness in our internal control over financial reporting, which could, if not remediated, adversely affect our ability to report our financial results accurately or in a timely manner, which may adversely affect our business, investor confidence in our company and the market value of our ADSs.

In connection with the preparation of the Company's financial statements for the year ended December 31, 2023, management identified a material weakness in internal control over financial reporting and, as such, concluded that we did not maintain effective internal control over financial reporting as of December 31, 2023. A material weakness in internal control over financial reporting is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented or detected on a timely basis. Company management did not design and maintain an effective internal control relating to the recording of royalty revenue, specifically for inadequately assessing the accounting for royalty reduction provisions within the Company's commercial agreements with collaboration partners. While this material weakness did not cause a material misstatement of the Company's consolidated financial statements for any period, the underlying control deficiency resulted in immaterial errors in reported royalty revenue, current receivables and retained earnings in periods prior to December 31, 2023. The Company has revised the annual periods of fiscal years 2022 and 2021 financial statements and related notes. See Note 1.4 to our Audited Financial Statements included in our Annual Report 2023.

Management has commenced remediation efforts. However, this material weakness will not be considered remediated until the applicable controls are designed and operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. In addition, as we implement these remediation efforts, we may determine that additional steps may be necessary to remediate the material weakness, or we may identify other material weaknesses or control deficiencies. We cannot provide assurance that these remediation efforts will be successful, that we will not identify new material weaknesses or that our internal control over financial reporting will be effective in accomplishing all control objectives. For more information, see "*Item 15 - Controls and Procedures''*.

We may acquire businesses or products, form collaborations or enter into other strategic transactions in the future. We may need to raise additional capital to fund these transactions and we may not realize their benefits.

Should attractive opportunities arise, we may acquire companies or technologies, form collaborations or enter into other strategic transactions that facilitate our access to new products, research projects or geographical areas, or that enable us to achieve synergies with our existing operations. However, we may not be able to identify appropriate targets, make acquisitions or form collaborations under satisfactory financial and other conditions. If we acquire or enter into collaborations or other strategic transactions with businesses, we may not be able to realize the benefits of such acquisitions or collaborations, including if we are unable to successfully integrate them with our existing operations and company culture, or if we encounter difficulties in developing, manufacturing and marketing any new products resulting from such acquisitions, collaborations or transactions. The inability to achieve the expected synergies of any such transaction could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors' ability to realize on their investments.

In addition, we may need to seek additional funds to finance such transactions, and we may be unable to obtain financing on favorable terms, in a timely manner or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from factors that include but are not limited to, inflation, the conflict between Russia and Ukraine and other factors, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability, increases in interest rates and potential for economic recession. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive.

If we are unable to raise capital, we may need to finance transactions using cash and cash equivalents and marketable securities that could otherwise be allocated to other purposes in the context of our existing operations, issue equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders and adversely affect the market price of our ADSs, or incur indebtedness, which would result in increased fixed payment obligations and may require us to agree to certain restrictive covenants that could adversely impact our ability to conduct our business.

Sales of our products will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

If any of our product candidates receive marketing approval or if any of our marketed products receive marketing approval for additional indications, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payers and others in the medical community, due to not being as well-established or known as conventional cancer therapies or otherwise. Accordingly, our commercial opportunity may be limited and/or our revenues from sales of these products may be negatively impacted. The degree of market acceptance will depend on a number of factors, including: the price, efficacy, safety, convenience and ease and safety of administration of such products, along with their competitive advantages vis-à-vis other therapies, designation as a first-, second- or third-line treatment, changes in the relevant standard of care and any labeling restrictions or warnings, the willingness of the target patient population to try and of physicians to prescribe our products, the availability and amount of coverage and reimbursement from government payers, managed care plans and other third-party payers, and the strength of the sales, marketing and distribution support provided by us or our collaboration partners.

We may not meet publicly announced product development objectives.

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific trials or clinical trials, the submission of regulatory filings or the achievement of commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones is outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the timeframes we expect, or at all, it may have a material adverse effect on our business, financial condition and results of operations and the price of our ADSs may be adversely affected.

Our target patient population may be lower than our estimates and we may be unable to recoup our development investments.

Periodically, we and our collaboration partners make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various sources and internally generated analysis and use such estimates in making decisions regarding product development strategy, including determining indications on which to focus in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data, or patient incidence and prevalence for selected indications may evolve over time as treatments and patient outcomes change. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to.

Even if our product candidates obtain significant market share for their approved indications, because certain potential target populations are small, we may never recoup our investment in such product candidates without obtaining regulatory approval for additional indications for such product candidates. We expect that we or our collaboration partners will initially seek approval of some of our product candidates as second- or third-line therapies for patients who have failed other approved treatments, which further limits the size of the potential patient population for such indication. If we or our collaboration partners are unable to obtain regulatory approval for such products for frontline or second-line therapy, we may be unable to recoup our investment in such products.

We are exposed to foreign exchange risk.

Most of our financial transactions are made in Danish kroner, U.S. dollars and Euro. As our reporting currency is Danish kroner, we experience exchange rate risk with respect to our holdings and transactions denominated in currencies other than Danish kroner. Our U.S. dollar currency exposure is mainly related to cash deposits, marketable securities, and receivables related to our collaborations with Janssen, AbbVie Inc.(“**AbbVie**”), and F. Hoffmann-La Roche AG (“**Roche**”). In addition, our reported revenue is affected by the translation of milestone payments, royalties and other income denominated in foreign currencies, primarily U.S. dollars, into DKK as our reporting currency.

We do not generally hedge our currency exposure on our milestone payments, royalties or other income and expense items in the ordinary course of business. Due to long-standing policy of Denmark's National Bank with respect to the €/DKK exchange rate, we believe that there are currently no material transaction exposure or exchange rate risks regarding transactions in Euros. However, should Denmark's policy towards the Euro change, the DKK values of our Euro-denominated assets and costs could be materially different compared to what is calculated and reported under the existing Danish policy towards the €/DKK exchange rate.

If we fail to manage our foreign exchange risk adequately, our business, financial condition, results of operations and future growth prospects and the value of our ADSs may be adversely affected.

Risks Related to Partners and Other Third Parties

We rely on our collaboration partners in many aspects of our business.

We rely on our collaboration partners in many aspects of our business, including to assist with, or to conduct, clinical and regulatory development, manufacturing and/or commercialization of certain of our partnered and proprietary products and product candidates or to provide access to antigens, technologies, skills and information that we do not possess.

If we are not able to maintain our existing material collaborations (or replace them if terminated), establish additional collaborations on favorable terms or realize the anticipated benefits from our collaborations, our business, financial condition and results of operations may be materially harmed. In particular, the termination of any of our key collaborations could significantly delay the development and commercialization of our products and product candidates and impact our financial results and future prospects. Our licensing collaboration partners generally have the right to terminate our collaborations with notice at any time. Our ability to continue our current collaborations and to enter into additional ones will depend in large part on whether we are able to successfully maintain, expand and demonstrate our research, development and commercialization capabilities and the benefits of our technologies relative to those of our competitors.

We also rely on our collaboration partners to periodically provide us with information about the status, progress and results of clinical trials and regulatory processes that they are conducting, sponsoring, or pursuing with respect to products that are the subject of the collaboration. For products and product candidates being developed by our collaboration partners, we generally do not have direct access to the underlying data or direct communications with the relevant regulators. As a result, our knowledge of material clinical events or data or material regulatory communications or developments, and our corresponding ability to report these to our shareholders, may be limited or delayed.

In addition, our reliance on our collaboration partners subjects us to a number of additional risks, including the following:

- our collaboration partners have significant discretion regarding whether and on what timeline to pursue planned activities;
- we cannot control the quantity and nature of the resources our collaboration partners may devote to the development, commercialization, marketing and distribution of products or product candidates;
- our collaboration partners may not develop products generated using our antibody technology as expected;
- disputes between us and our collaboration partners may delay or terminate the research, development or commercialization of the applicable products and product candidates or result in costly litigation or arbitration that diverts management's attention and resources;

- with respect to collaborations under which we have an active role, we and our collaboration partners may have differing opinions or priorities, or we may encounter challenges in joint decision making, which may delay or terminate the research, development or commercialization of the applicable products and product candidates;

- we may not receive milestone payments from our collaboration partners, at the expected time or at all, if our collaboration partners do not achieve future milestones or if we and our collaboration partners disagree about whether a milestone has been reached;

- our collaboration partners may require, terminate or repeat clinical trials or require a new formulation of a product candidate for clinical testing, or may abandon a product candidate;

- our relationships with our collaboration partners may divert significant time and effort of our scientific staff and management team;

- our collaboration partners may be subject to regulatory sanctions that could adversely affect the development, approval or commercialization of the applicable products or product candidates;

- our collaboration partners may not properly maintain or defend relevant intellectual property rights, or may infringe the intellectual property rights of third parties, or may use our or third parties' proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- our collaboration partners may develop competing products, therapeutic approaches or technologies;

- business combinations, financial difficulties, strategic transactions, or significant changes in a collaboration partner's business strategy, including as a result of pandemics, epidemics or other public health crises, may adversely affect that collaboration partner's willingness or ability to continue to pursue our products or product candidates and make payments under collaboration agreements to us when due; and

- our collaborations may be terminated, breached, or allowed to expire, or our collaboration partners may reduce the scope of our agreements with them.

Any one or more of the foregoing risks, if realized, could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct clinical trials.

We rely on third parties, such as CROs, to conduct clinical trials on product candidates we are developing. Our collaboration partners may similarly rely on such parties. The third parties with whom we and our collaboration partners contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and in compliance with applicable regulations and standards, commonly referred to as cGCPs.

If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to cGCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be costly, and our clinical trials may need to be extended, delayed, terminated or repeated. We may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such trials.

We rely on a limited number of third-party manufacturers for our product supply.

To ultimately be successful, our antibody products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Janssen is responsible for the manufacture of daratumumab, amivantamab, teclistamab and talquetamab. Novartis International AG ("**Novartis**") is responsible for the manufacture of ofatumumab, Amgen Inc. ("**Amgen**") is responsible for the manufacture of teprotumumab, AbbVie is responsible for the manufacturing of epcoritamab, and Pfizer Inc. ("**Pfizer**") is responsible for the manufacturing of tisotumab vedotin (Pfizer closed the acquisition of Seagen Inc. ("**Seagen**") on December 14, 2023. All references to Seagen have been changed to Pfizer).

For the product candidates we are entirely responsible for manufacturing, we currently rely on a limited number of CMOs and specific sites at those CMOs to manufacture and supply large quantities of our product candidates. We expect to negotiate contracts for commercial production on a product-by-product basis for products that we choose to commercialize entirely by ourselves.

We are aware of only a limited number of companies on a worldwide basis that operate manufacturing facilities in which our product candidates can be manufactured under cGMP regulations. It would take a substantial period of time for a contract facility that has not been producing antibodies to begin producing antibodies under cGMP. We cannot be certain that we will be able to contract with any of these companies on acceptable terms, if at all. New suppliers would also need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients. In addition, significant cancellation penalties and the long lead times required for initial orders or to make any changes to existing orders, including changing the scale of production, limit our flexibility in connection with product development, clinical trials or commercial sales. For example, we may be required to order products for the second part of a clinical trial or for a proposed follow-on clinical trial before we have initial results from the trial, which could result in a loss if we terminate the trial or need to make changes to the product.

We and our manufacturing partners must comply with applicable laws and regulations, including cGMPs.

In order to commercialize new pharmaceutical and biologic products, manufacturers must comply with the laws and regulations, including drug and biologic cGMPs, of the applicable governmental authorities. Compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturing facilities are also subject to pre-approval and ongoing periodic inspection by applicable governmental agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our technology. The FDA, the European Medicines Agency ("**EMA**") or similar regulatory agencies at any time may also implement new standards or change their interpretation and enforcement of existing standards for manufacturing, packaging or testing of products.

Manufacturers of pharmaceutical and biologic products encounter difficulties in production, including difficulties with production yields, stability of the product candidate, quality control and assurance, shortages of qualified personnel, compliance with relevant regulations, production costs and development of advanced manufacturing techniques and process controls. If our manufacturer were to encounter any of these difficulties or otherwise fail to comply with its obligations to us or under applicable regulations, our ability to provide trial materials in our pre-clinical trials and clinical trials would be jeopardized. Any delay or interruption in the supply of pre-clinical trial or clinical trial materials could delay the completion of our pre-clinical trials and clinical trials, increase the costs associated with maintaining our pre-clinical trial and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, we lack direct control over our manufacturers' compliance with these regulations and standards and manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other regulatory requirements. The discovery of manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with cGMP or other requirements after approval of a product may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, fines or criminal sanctions. If the safety of any product supplied is compromised due to the manufacturers' failure to adhere to applicable laws or for other reasons, we or our collaboration partners may not be able to continue clinical trials

for our product candidates, obtain regulatory approval for or successfully commercialize our products, and we or our collaboration partners may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical trials, regulatory submissions, approvals or commercialization of our products and product candidates or entail higher costs or impair our reputation. No assurance is given that third-party manufacturers will be able to comply adequately with the applicable regulations.

Our employees and collaboration partners may engage in misconduct or other improper activities.

We are exposed to the risk of fraud or other misconduct by our employees and collaboration partners. Misconduct by our collaboration partners, vendors or suppliers could include intentional failures to comply with legal requirements or the requirements of the FDA, the EMA and other comparable regulatory authorities; failure to provide accurate information to applicable government authorities; failure to comply with fraud and abuse and other healthcare laws and regulations in the U.S., Denmark and other jurisdictions; failure to comply with the Foreign Corrupt Practices Act ("**FCPA**") and other applicable anti-bribery laws; failure to report financial information or data accurately; or failure to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, bribery and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Our collaboration agreements include provisions regarding regulatory compliance, but it is not always possible to identify and deter misconduct, and the precautions we and our collaboration partners take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Specifically, the FCPA prohibits companies and their intermediaries from making or offering improper payments to non-U.S. officials for the purpose of obtaining or retaining business, and requires companies listed on a U.S. stock exchange to maintain a system of adequate internal accounting controls and to make and keep books, records and accounts that accurately and fairly reflect transactions and dispositions of assets. Because of the predominance of government-sponsored health care systems around the world, many of our commercial relationships outside the U.S. are with governmental entities, and personnel of such entities may be considered non-U.S. officials for purposes of the FCPA. Violations of the FCPA and other applicable anti-bribery laws are punishable by criminal fines and imprisonment, civil penalties, disgorgement of profits, injunctions and debarment from government contracts as well as other remedial measures. We have adopted an updated written code of business conduct, an anti-corruption, anti-bribery policy, and other policies and procedures to assist us and our personnel in complying with the FCPA and other applicable anti-bribery laws, but there can be no assurance that such policies will be effective in preventing or deterring violations of the FCPA, whether intentional or not. Our personnel and others acting on our behalf could take actions that violate these requirements, which could adversely affect our reputation, business, financial condition and results of operations.

Risks Related to Product Development

Biopharmaceutical product development involves a substantial degree of uncertainty.

Our product pipeline currently includes nine proprietary products and product candidates. There are also ongoing clinical trials for daratumumab, amivantamab, teclistamab and talquetamab by Janssen, ofatumumab by Novartis and teprotumumab by Amgen, and five additional product candidates being developed by our collaboration partners. Many of our current product candidates are in relatively early stages of development, and all of our product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop them into commercially viable products, if at all.

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, we or our collaboration partners may not successfully develop any of our product candidates, or we or our collaboration partners may choose to discontinue the development or co-development of product candidates for a variety of reasons, including

due to safety, risk versus benefit profile, exclusivity, competitive landscape, commercialization potential, production limitations or prioritization of our or our collaboration partners' resources. In addition, our research programs may initially show promise in identifying potential product candidates yet fail to yield product candidates suitable for clinical development or commercialization. Likewise, we and our collaboration partners have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance. As one example among others, in September 2023, we decided to discontinue the program for DuoHexaBody-CD37 due to a strategic evaluation within the context of our portfolio. We may not have the resources to invest in all of our current product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates. Decision-making about which product candidates to prioritize involves inherent uncertainty, and our and our collaboration partners' development program decision-making and resource prioritization decisions may not improve our results of operations or future growth prospects.

Many of our proprietary and partnered product candidates are created with, and dependent upon, our proprietary technologies. In addition, tisotumab vedotin was developed using Pfizer's proprietary antibody-drug conjugate ("**ADC**") technology in combination with our proprietary TF antibody. Any failures or setbacks with respect to our proprietary technologies or Pfizer's ADC development programs, including adverse effects resulting from the use of these technologies in human clinical trials and/or the imposition of clinical holds on trials of any product candidates using our proprietary technologies, could have a detrimental impact on our clinical pipeline, and specifically on the commercialization of tisotumab vedotin.

Additionally, with the exception of tisotumab vedotin and epcoritamab we have not advanced any product candidates through late-stage clinical development. If we are unable to continue to develop late-stage development capabilities, we will be required to continue to contract with third parties via licensing and development agreements to complete the development of our proprietary product candidates, which we may not be able to do on a timely basis, on terms favorable to us, or at all, and the development of our proprietary product candidates could be delayed or terminated. Our failure to effectively advance our development programs could have a material adverse effect on our business, financial condition, results of operations and future growth prospects, and cause the market price of our ADSs to decline.

Furthermore, we may develop companion diagnostics, both during our clinical trials and in connection with the commercialization of our product candidates, which are subject to regulation by the FDA, the EMA, and comparable foreign regulatory authorities as companion diagnostic medical devices, and typically require separate regulatory approval prior to commercial use. Any delay or failure by us or our collaboration partners to obtain regulatory approval of companion diagnostics could harm our development strategy and/or delay or prevent approval of our product candidates, which may adversely affect our business, financial condition and results of operations.

Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.

The FDA, EMA, and comparable regulatory authorities in other jurisdictions must approve new product candidates before they can be marketed, promoted or sold in those territories. We or our collaboration partners must provide these regulatory authorities with data from pre-clinical and clinical trials that demonstrate that our product candidates are safe and effective for a specific indication before they can be approved for commercial distribution. We cannot be certain that our or our collaboration partners' pre-clinical or clinical trials for our product candidates will be successful or that any of our other proprietary or partnered product candidates will receive approval from the FDA, the EMA or any other regulatory authority. In addition, certain other third parties make decisions about products or product candidates based on results of clinical trials, including determinations relating to pricing, access or reimbursement of approved products or validations or endorsements of treatment options. Such third parties may require additional data or trials for their determinations.

Pre-clinical trials and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays or failure.

We may be required to revise our development plans and extend dose exploration as a result of FDA's Project Optimus, which requires the implementation of strategies for dose finding and dose optimization that leverage pre-clinical and clinical data in dose selection, including randomized evaluations of a range of doses in clinical trials. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval.

It may take several years and require significant expenditures to complete the pre-clinical and clinical trials necessary to commercialize a product candidate, and delays or failures are inherently unpredictable and can occur at any stage. Even if we or our collaboration partners obtain positive results from pre-clinical or early clinical trials, we or they may not achieve the same success in subsequent trials. In particular, the results of pre-clinical trials are based on animal, *in vitro* or other laboratory testing and may not be predictive of the safety or efficacy of our product candidates in humans. Similarly, topline or interim results of clinical trials do not necessarily predict final results. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after obtaining promising results in earlier trials, and we cannot be certain that we or our collaboration partners will not face similar setbacks. If topline or interim data that we or our collaboration partners report differ from final results, or if others, including regulatory authorities, disagree with our assumptions, calculations, conclusions, or analyses or interpret or weigh the data differently, or if subsequent trials are unsuccessful, we or our collaboration partners may be unable to obtain marketing approval for product candidates on a timely basis or at all, which could impact our reputation, business, financial condition, results of operations and future growth prospects.

Furthermore, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of the relevant product candidate as well as other product candidates employing the same technology, which could have a significant impact on our product pipeline and future growth prospects. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us and may require us or our collaboration partners to delay, reduce the scope of or eliminate one or more product development programs, which could have a material adverse effect on our business, financial position, results of operations and future growth prospects. Any delays in product development may allow our competitors to bring products to market before we do or shorten any periods during which we or our collaboration partners have the exclusive right to commercialize our product candidates. In addition, advancements or changes in the industry standards or techniques may impact the value and recognition of our and our collaboration partners' clinical data. Failure to adopt new industry standards may result in less comparable or useful trial results. Alternately, early adoption of emerging protocols or endpoints may result in data that is not recognized by certain regulatory bodies or industry professionals, or if such protocols are later found to be ineffective, may require us or our collaboration partners to change the design of our clinical trials.

In connection with clinical trials of our product candidates, we face a number of risks, including risks that:

- we or our collaboration partners may be unable to manufacture or obtain sufficient quantities of qualified materials for clinical trials or may be required to modify manufacturing processes;
- patient recruitment may be slower than expected and we may have difficulty accessing potential clinical trial sites;
- a product candidate may be ineffective, inferior to existing approved products for the same indications, unacceptably toxic or have unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- a clinical trial may be delayed, suspended or terminated by the institutional review board or ethics committee responsible for overseeing the clinical trial, by regulatory authorities or by us or our collaboration partners due to failure to meet clinical protocols, safety issues or adverse effects, failure to demonstrate product efficacy, changes in clinical protocols, may require additional dose finding and/or dose optimization, or applicable regulatory requirements, lack of funding or other factors;

- investigators or other third parties could conduct clinical trials on our products or product candidates that could lead to adverse events or results that could negatively impact the development, regulatory approval or marketability of such products;
- extension trials on long-term tolerance could invalidate the use of our product;
- clinical trials may not demonstrate statistically sufficient levels of safety and efficacy to obtain the requisite regulatory approvals;
- even if data is sufficient for regulatory approval, it may not be sufficient to secure pricing reimbursement or to secure validation of our products by key industry players, which could delay or prevent the commercial launch of a product; and
- our collaboration partners or CROs may be unable or unwilling to perform under their contracts.

The FDA may not accept data from trials we or our collaboration partners conduct outside the United States or may require additional U.S.-based trials as a condition of regulatory approval.

We and our collaboration partners have conducted, currently are conducting and intend in the future to conduct clinical trials outside the U.S., including in the EU where we are headquartered. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA, including with respect to compliance with cGCPs and applicability of the data to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. If the FDA does not accept the data from any clinical trials that we or our collaboration partners conduct outside the U.S., it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these product candidates for the proposed indications in the U.S. In other jurisdictions, for instance, in Japan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction.

We or our collaboration partners may encounter difficulties enrolling patients in our clinical trials.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We or our collaboration partners may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the trial population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and/or related technologies;
- clinicians’ and patients’ perceptions as to 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 ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our and our collaboration 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 patients available for our and our collaboration partners' clinical trials. We expect that we and our collaboration partners will conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our and our collaboration partners' clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to only use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any future clinical trial.

Even if we and our collaboration partners are able to enroll a sufficient number of patients in our clinical trials, delays in patient 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 collaboration partners' ability to advance the development of our product candidates.

Any approval granted for our products or product candidates in the United States does not assure approval of such products in Japan, the EU or other foreign jurisdictions.

In order to market and sell our drugs in Japan, the EU and other jurisdictions, we and our collaboration partners must obtain separate marketing approvals, and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, many countries outside the U.S. require that the drug be approved for reimbursement before the drug can be approved for sale in that country. We and our collaboration partners may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

We may fail to obtain designations for expedited development or review or such designations may not lead to a faster development or regulatory review. Acceptance into an expedited review program or receipt of accelerated approvals does not assure ultimate full regulatory approval.

Fast Track Designation ("**FTD**"), Breakthrough Therapy Designation ("**BTD**"), and the accelerated approval programs of the FDA and other regulatory authorities are intended to expedite the review and approval of drug candidates in certain circumstances. These designations and programs do not, however, ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion regarding whether or not to grant these designations or include product candidates within pilot programs, and, even if we or our collaboration partners believe a particular product candidate is eligible for these designations or programs, we cannot assure that such authority would agree. Even if we or our collaboration partners receive such designations or are eligible for inclusion in expedited review pilot programs in the future, we may not experience a faster development, review or approval process compared to conventional procedures. In addition, such designations or processing under such pilot programs may be withdrawn if the FDA or the relevant regulatory body no longer believes such product candidate meets the criteria for the designation or program. Furthermore, these designations and pilot programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted expedited review or BTD or FTD designation may be ultimately denied based on trial data, trial design or other factors, and even if our product candidates are accepted into such a program, this does not assure ultimate approval by the FDA or the applicable regulatory body. Any accelerated approval received for our products, such as the approvals for Tivdak and EPKINLY, is contingent on successful completion of diligently conducted post-marketing confirmatory trials, and accelerated approval may be withdrawn if post-marketing trials do not verify the product's benefit or demonstrate sufficient clinical benefit to justify associated risks, other

evidence demonstrates that the product is not safe or effective, or the FDA considers promotional materials relating to the product to be false or misleading. The terms and conditions of expedited development and review programs are subject to change as a result of regulatory developments, and any such changes may adversely affect our ability to secure or maintain accelerated approvals or BTD, FTD or similar designations from the FDA or another regulator. See "*Item 4 –Information on the Company —Government Regulation*" for more information about BTD, FTD and accelerated approval programs for expedited review.

Risks Related to Our Products

We may be affected by reports of adverse events or safety concerns relating to our products or product candidates.

As with most biological drug products, use of our products and product candidates is associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. In particular, many of our and our collaboration partners' clinical trials are conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and in some cases, our product candidates are used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients may suffer adverse medical events or die for reasons that may or may not be related to our product candidates. Reports of adverse events or safety concerns could have negative impacts on our or our collaboration partners' clinical trials, regulatory processes, reputation and results, whether or not actually shown to be related to our product candidates.

Reports of adverse events or safety concerns involving our products or product candidates have sometimes resulted and can in the future result in regulatory authorities interrupting, delaying or halting clinical trials (or otherwise negatively impacting patient enrollment in or completion of clinical trials), limiting, denying, withdrawing approval of or recalling such product for any or all indications, including the use of such product in its previously approved indications, or may require additional clinical trials, updates to the prescribing information, including boxed warnings, contraindications, or other labeling statements, implementation of a Risk Evaluation and Mitigation Strategy ("**REMS**") or the issuance of field alerts, warnings or other communications to physicians, pharmacies or patients. In certain cases, regulatory authorities may order us or our collaboration partners to conduct additional trials or to cease further development or commercialization of the product or product candidate entirely. Furthermore, actual or potential drug-related side effects can affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates. Reports of adverse events or safety concerns, or changes to regulatory approvals or labeling, may also have a significant impact on market acceptance of our products by patients and physicians or may trigger potential product liability claims, fines, injunctions or the imposition of civil or criminal penalties. Any of these events has the potential to prevent us or our collaboration partners from developing, commercializing or maintaining market acceptance of the relevant product or product candidate or to substantially increase commercialization costs, which in turn could significantly harm our business, financial condition, results of operations and future growth prospects.

Adverse events may also impact the sales of our products. We may be required to further update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a REMS, which could adversely affect the acceptance of our products in the market, make competition easier or make it more difficult or expensive for us or our collaboration partners to distribute our products. In addition, the reporting of adverse safety events involving our products or product candidates, or public rumors about such events, could cause the price of ADSs to decline or experience periods of volatility.

Several of our products and product candidates are used or proposed to be used in combination with other therapeutic products, which exposes us to risks related to those products.

Part of the clinical development strategy for certain of our product candidates, including daratumumab, is to seek to identify patients or patient subsets within a disease category whose treatment may benefit from our products in combination with other therapeutic products. Approval of a product for the treatment of a disease indication in combination with other therapeutic products exposes us and our collaboration partners to certain risks related to those other therapeutic products, including the risks that such products will become less competitive or obsolete or will be found to have safety concerns, which could potentially result in removal of such products from the market. Furthermore, seeking to heighten immune or other therapeutic responses through combination treatments carries an inherent risk that the combination may cause unexpected side effects or safety issues not observed in treatment with the individual products alone.

We may face product liability claims related to the use or misuse of our products or technologies.

Our business exposes us to potential product liability risks which are inherent in research and development, pre-clinical and clinical testing, manufacturing, marketing and use of antibody products. Product liability claims may be expensive to defend and may result in judgments against us which are potentially punitive. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials. Although we believe that our current coverage limits are appropriate, we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms. Any claims against us, regardless of their merit, could cause our business to suffer. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in decreased demand for our products, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals or labeling, marketing or promotional restrictions, exhaustion of any available insurance and our capital resources, the inability to commercialize any product or product candidate, damage to our reputation, loss of any potential future revenue and a decline in the market price of our ADSs.

Risks Related to Our Business

We face intense competition and rapid technological change.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties, including pharmaceutical companies, biotechnology companies, academic institutions and other research organizations, compete with us in developing various approaches to antibody therapy and other competing therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do, and earlier-stage companies may also prove to be significant competitors, especially through collaborative arrangements with larger collaboration partners. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs. In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same indications that our products and product candidates are designed for and being developed to treat. In addition, our DuoBody and other technology partners may develop compounds utilizing our technologies that may compete with product candidates that we are developing. See “*Item 4B– Business Overview—Competition*” below for more information about our competitors.

In the U.S., the Biologics Price Competition and Innovation Act of 2009 (“**BPCIA**”), created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” or “biosimilar” to or “interchangeable” with an FDA-approved biological product, which may be used by our competitors to receive approval for, and commercialize, product candidates that compete with our products with less effort and expense than would

otherwise be required, and any period of exclusivity for which our products qualify may be reduced to a shorter period than we expect due to regulatory action or otherwise. See "*Item 4B—Business Overview—Competition*" for more information on this regulatory pathway.

It is possible that our competitors will succeed in developing products and technologies that are more effective than our products and product candidates or that would render our technology obsolete or noncompetitive. It is also possible that our competitors will succeed in developing biosimilar or interchangeable products for our products or our product candidates. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding biosimilars and other cancer therapies continue to accelerate. We cannot predict to what extent the entry of biosimilars or other competing products will impact potential future sales of our products or our product candidates.

In addition, the pricing of our products depends, and the pricing of our products and product candidates, if and when approved for marketing, will depend, in part, on the pricing strategies adopted by our competitors. If we or our collaboration partners are forced to reduce the prices of our products, or if sales of our products fall due to competitive pricing, our revenue from milestone payments, sales or royalties related to such products will be negatively affected.

Any products we or our collaboration partners are able to commercialize in the U.S. and the EU may be subject to competition from lower-priced imports of those same products, as well as lower-priced imports of competing products from Eastern Europe, Canada, Mexico and other countries with government price controls or other market dynamics that, in each case, reduce prices of products leading to reduced revenues and lower sales margins. The ability of patients to obtain these lower-priced imports has grown significantly. Some of these foreign imports are illegal under current U.S. and European law. However, the volume of imports is now significant, due in part to the limited enforcement resources and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower-priced medicines. Parallel importation or importation of foreign products could adversely affect our future profitability. This impact potentially could become even greater if there is a further change in relevant protective legislation or if state or local governments take further steps to import products from abroad.

Our internal computer systems, or those of our collaboration partners, contractors or consultants, may fail or suffer cyber or other security breaches.

Our computer systems, including those hosted by third parties, and those of our collaboration partners, contractors or consultants, may be vulnerable to cyber security risks, such as computer viruses and unauthorized access, and natural disasters, terrorism, war and telecommunication and electrical failures, which can lead to damage, loss or leakage of business data or unavailability of computer systems. Our vulnerability to such events may increase while employees work remotely which results in additional cyber security threat profiles and an increase in the amount of traffic on secured remote corporate networks and preventing or detecting unauthorized access to internal networks may be more challenging. These and other factors, including the increased use of artificial intelligence within the biopharmaceutical industry, can be exploited to facilitate phishing, malware, ransomware or other attacks on our systems. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. In addition, any loss or disclosure of trade secrets, clinical data, personal data, or other proprietary information as a result of such disruption or breach could subject us to litigation or regulatory review and sanctions and may impact our reputation and our and our collaboration partners' ability to further develop and commercialize our products and product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and the market price of our ADSs.

Epidemics, pandemics, or other public health crises could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.

We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises), including the global outbreak of coronavirus and its variants (COVID-19). Health crises similar to COVID-19 may cause us to modify our business practices and take further actions as may be required by government authorities or as we determine are in the best interests of our patients, customers, employees, and collaboration partners. A health crisis could also result in the imposition of new mandates and prolonged restrictive

measures in order to control the spread of disease. Health crises could adversely impact sales of our products as well as our operations, including, among other things, our supply chain, third-party suppliers, sales and marketing, and clinical trial operations. They could also adversely affect global economic conditions generally. Any efforts we put in place to help mitigate the impact of health crises may not completely prevent our business from being adversely affected.

While governments across the world have substantially reopened their economies following restrictions implemented in connection with the COVID-19 pandemic, the extent to which health crises could impact the Company's future operations will depend on many factors which cannot be predicted with confidence, including the location, severity and duration of an outbreak, nature and length of government response measures in response thereto, availability and accessibility of vaccinations and treatments and the impact of disease variants. Any of these factors could adversely affect our business and financial results.

Climate change, or regulatory or market measures to address climate change, as well as man-made disasters or infrastructure failures, may materially adversely affect our financial condition and business operations.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our future operations from natural disasters and extreme weather conditions, such as hurricanes, tornadoes, earthquakes, wildfires or flooding. Similar risks could result from man-made disasters or failures, including power shortages, telecommunications or infrastructure failures, cybersecurity incidents or physical security breaches. Some potential impacts to our business include increased operating costs due to additional regulatory requirements, water limitations, disruptions to our supply chain from altered availability of goods and services and physical risks to our facilities, which may result in delays in the development of our product candidates or the interruption of our business operations for a substantial period of time. Being unable to fully use our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If these facilities are unable to operate, even for a short period of time, any or all of our research and development programs and our commercialization efforts may be harmed.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we or our collaboration partners are unable to or do not adequately protect intellectual property rights or if our intellectual property rights are inadequate.

Our commercial success and viability depend in part on our and our collaboration partners' ability to obtain and maintain adequate intellectual property protection in the U.S., Europe and other countries with respect to our existing products, product candidates and processes and related technologies owned by us and to successfully defend these rights against third-party challenges, successfully enforce these rights to prevent third-party infringement, as well as our ability to maintain adequate intellectual property protection for any future technologies and products. If we or our collaboration partners do not adequately protect our intellectual property, competitors may be able to use our technologies or products and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and significantly reduce our revenues and potential profits.

While we rely on a combination of patents, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements to protect the intellectual property related to our brands, products, product candidates and proprietary technologies, our strategy and future prospects are based, in particular, on our patent portfolio. We and our collaboration partners or licensees will best be able to protect our technologies, products and product candidates and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, effectively protected trade secrets, or other regulatory exclusivities, cover them. However, the process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position and other intellectual property rights of biopharmaceutical companies involve complex legal, administrative and factual questions, and the issuance, scope, validity and enforceability of patents cannot be predicted

with certainty. Also, intellectual property rights have limitations and do not necessarily address all potential threats to our competitive advantage. Our and our collaboration partners' ability to obtain patent protection for our or their technologies, products and product candidates is uncertain, and the degree of future protection afforded by such intellectual property rights is uncertain due to a number of factors, including, but not limited to:

- we or our collaboration partners may not have been the first to make or file patent applications for the inventions covered by pending patent applications or issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions and uses thereof;
- any or all of our or our collaboration partners' pending, or any future patent applications may not result in issued patents;
- any patents issued to us or our collaboration partners may not provide a basis for commercially viable products, or may not provide any competitive advantages in countries of significant business opportunity;
- third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the U.S. Patent and Trademark Office ("**USPTO**"), or oppositions in the European Patent Office ("**EPO**"), or observations or protests, or any similar actions in other patent administrative or court proceedings worldwide that challenge the validity, enforceability or scope of such patents, which may result in our patent claims being narrowed or invalidated which could limit our ability to prevent competitors from developing and marketing similar products;
- our or our collaboration partners' technologies, compositions and methods may not be patentable;
- others may design around our or our collaboration partners' patent claims to produce competitive products or uses which fall outside of the scope of our patents;
- third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology;
- patent terms may be inadequate to protect our competitive position on our technologies, products and product candidates for an adequate amount of time;
- the Supreme Court of the U.S., other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, or change the patent lifetime of, our or our collaboration partners' patents; and
- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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.

Patent applications may be denied or issued patents covering our products and product candidates could be found invalid or unenforceable.

Even if patents do successfully issue and even if such patents cover our technologies, products, product candidates, compositions and methods of use, third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the USPTO, third-party oppositions in the EPO or observations or protests, or similar

actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in our or our collaboration partners' patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products. Further, if we or our collaboration partners initiate legal proceedings against a third-party to enforce a patent covering our product, product candidate or technology, the defendant could counterclaim that the patent covering our product, product candidate or technology is invalid or unenforceable. In patent litigation in the U.S., certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products.

We currently rely on proprietary technology licensed from third parties and may rely on other third-party licensors in the future. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from these licensors or other third parties, we may not be able to continue developing and commercializing our products.

We currently in-license certain technology and intellectual property from third parties to be able to use such technology and intellectual property in our products and product candidates and to aid in our research activities. In the future we may in-license technology and intellectual property from additional licensors.

We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the technology and intellectual property we license from them. We have limited control over these activities or any other technology and intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the technology and intellectual property that is licensed to us.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to proceed without making use of the technologies, compositions or methods covered by such third-party intellectual property rights and may need to attempt to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible at a reasonable cost or at all. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources or greater clinical or commercialization capabilities than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates, products and related proprietary technologies. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license under third-party intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access the same technologies licensed to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

Our existing in-licenses impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors or collaboration partners may have the right to terminate the license. Under the terms of some of the relevant agreements, our collaboration partners also have the right to terminate the agreements at their discretion. In the event of termination of any of these agreements, we may not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property.

Competitors may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims on a country-by-country basis, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from continuing its activities on the grounds that our patent claims do not cover these activities. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products, which could materially harm our business and negatively affect sales of our products. Similarly, if we assert trademark or trade name infringement claims, a court may determine that the trademarks or trade names we have asserted are invalid or unenforceable, or that the party against whom we have asserted infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks or trade names, which we may need in order to build name recognition with potential collaboration partners or customers in our markets of interest, thus this could materially harm our business and negatively affect our position in the marketplace.

Further, even if we prevail against an infringer in a U.S. district court or foreign trial-level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in certain territories, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which securities analysts or investors could perceive to be negative. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Claims that our products or product candidates or their uses infringe the intellectual property rights of third parties could result in the need for third-party licenses with royalty payments or costly litigation with unfavorable outcomes.

Even if we or our collaboration partners have or obtain patents covering our technologies, products, product candidates, compositions or uses, we or our collaboration partners may still be barred from making, using, importing or selling or otherwise exploiting our products, product candidates or technologies because of the patent rights of others. Our competitors have filed, and in the future may file, patent applications covering technology, compositions or products and uses that are similar or identical to ours. There are many issued U.S., European and other worldwide patents relating to therapeutic drugs, and some of these may relate to compounds we or our collaboration partners intend to commercialize. Numerous worldwide patents and pending patent applications owned by others exist in the cancer field and may cover products or product candidates which we or our collaboration partners are developing. It is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products, product candidates and technologies. We cannot guarantee that our technologies, products, product candidates, compositions and their uses do not or will not infringe third-party patents or other intellectual property rights. Because patent applications usually take 18 months to publish and many years to issue, there may be currently pending applications with patent claims unknown to us or which will change over time and may later result in issued patents that purportedly cover our

technologies, products, product candidates or compositions and uses. These patent applications may have been filed earlier than or have priority over patent applications filed by us or our collaboration partners. We may be required to develop or obtain alternative technologies, review product design or, in the case of claims concerning registered trademarks, rename our products or product candidates.

Claims that our or our collaboration partners' technologies, products, product candidates, compositions or their uses infringe or interfere with the patent rights of third parties, or that we, our employees, our consultants or our collaboration partners have misappropriated third-party trade secrets, could result in costly litigation and could require substantial time and money to resolve, even if litigation were avoided. If we, our employees, our consultants or our collaboration partners were to face infringement claims or challenges by third parties, an adverse outcome could subject us or our collaboration partners to significant liabilities to such third parties. Litigation or threatened litigation could result in significant demands on the time and attention of our management team. A negative outcome could expose us or our collaboration partners to payment of costs, damages and other financial remedies, including in some jurisdictions, increased damages, such as treble damages and attorneys' fees, if we were found to have willfully infringed a patent, and equitable remedies such as restraining orders or injunctions. Litigation with third parties concerning alleged infringement of their intellectual property rights could require us and our collaboration partners to bear substantial costs and impose burdens on our and their management and personnel, even if we or our collaboration partners were to ultimately succeed in such proceedings. Costs of patent litigation and awards of damages in patent infringement cases can be significant, and equitable remedies such as temporary restraining orders and injunctions can negatively impact or prevent product development and commercialization. A negative outcome could also lead us or our collaboration partners to delay, curtail or cease the development and commercialization of some or all of our products and product candidates, or could cause us or our collaboration partners to seek legal or administrative actions against third parties. We or our collaboration partners may need to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms, or at all. Even if we are able to obtain licenses from a third-party to resolve a dispute, such settlement arrangements could involve substantial costs including one-time and/or ongoing royalty payments.

We may be unable to protect the confidentiality of our trade secrets and know-how.

In addition to seeking patent protection for our products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaboration partners, consultants, advisors, vendors, university and/or institutional researchers and other third parties. We also have entered or seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and once disclosed we may lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable and may be inadequate. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

We will not seek to protect our intellectual property rights or technologies 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.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Filing, prosecuting and defending patents on our technologies, products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and, therefore, we typically elect to seek protections in certain jurisdictions only. We may choose not to pursue or maintain protection for particular inventions, products or product candidates. In

addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products in a manner that exploits our technologies and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. or in Europe, and thus such protection may not be sufficient to prevent or stop infringing activities.

The requirements for patentability may differ from country to country, particularly in developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Also, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties if the patents are not being exploited within a certain time period. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country or region-by-region basis, which is an expensive and time-consuming process with uncertain outcomes. If we fail to timely file a patent application in a specific country or major market, we may be precluded from doing so at a later date.

In addition, changes in the law and legal decisions by courts in the U.S., Europe and foreign countries may affect our ability to obtain or maintain adequate protection for our technologies, products, product candidates or compositions or uses thereof and the enforcement of intellectual property, and may apply retroactively to affect the term and/or scope of our patents.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with our collaboration partners that provide for the ownership of intellectual property arising from our collaborations. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from collaboration. Disputes may arise with respect to ownership of the intellectual property developed pursuant to such collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business, financial condition, results of operations and future growth prospects.

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 license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition.

Our registered or unregistered trademarks and trade names 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 collaboration partners or customers in our markets of interest. If we do not own or control trademarks associated with our products, product candidates or technologies, we may not be in control of defending against any claims brought against those trademarks. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our business may be adversely affected.

In addition, any proprietary name we propose to use with any of our product candidates in the U.S. or other jurisdictions must be approved by the FDA, the EMA or other governmental authorities, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Related to Government Regulation

Government restrictions on pricing and reimbursement, as well as other healthcare payer cost-containment initiatives, may negatively impact our ability to generate revenue.

Sales of certain of our products and our product candidates, if and when approved for marketing, have and will depend, in part, on the extent to which our products will be covered by third-party payers, such as U.S. government health care programs like Medicare and Medicaid, commercial insurance and managed healthcare organizations. These third-party payers play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payers will decide with respect to coverage and reimbursement for our product candidates. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations. Therefore, the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits. Adoption of price controls, cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures could limit our net revenue and results.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payers. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product.

In addition, in certain jurisdictions, marketing approval for a product, or the ability to launch an approved product, is subject to determination of pricing and reimbursement levels. In such jurisdictions, even if we or our collaboration partners are able to obtain marketing approval for our products, commercialization of our products may be significantly delayed or prevented altogether if we are unable to secure reimbursement for our products, at competitive levels or at all.

Moreover, increasing efforts by governmental and third-party payers in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to 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, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products.

In addition, any products we or our collaboration partners are able to commercialize may be subject to competition from lower-priced imports of those same products, leading to reduced revenues and lower sales margins, as well as lower-priced imports of competing products from countries with government price controls or other market dynamics that, in each case, reduce prices of products.

Even if approved, our products will be subject to extensive post-approval regulation, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. For U.S. approvals, the holder of an approved Biologics License Application ("**BLA**") is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the BLA. In addition, the FDA strictly regulates the promotional claims that may be made about pharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. In addition, we or our collaboration partners may be subject to significant liability if physicians prescribe any of our products to patients in a manner that is inconsistent with the approved label and if we are found to have promoted off-label uses of such products. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. In addition, any regulatory approvals that we or our collaboration partners receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Sales, marketing and scientific/educational grant programs in the U.S. must comply with the U.S. Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the federal Anti-Kickback Statute, the Federal Food, Drug and Cosmetic Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veteran's Health Care Act, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Within the EU, once a marketing authorization is obtained, numerous post-approval requirements also apply. The requirements are promulgated by both EU regulations (such as reporting of adverse events, etc.) as well as national applicable regulations (related to, for example, prices and promotional material). In addition, as part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use ("**CHMP**"), to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that target the treatment, prevention, or medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products. The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete non-clinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied.

Other jurisdictions also impose certain post-approval requirements or may grant conditional marketing approvals. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, notices or warning letters, recall or seizure of products, total or partial suspension of production or changes to manufacturing processes, denial or withdrawal of pre-marketing product approvals, import controls, or refusal to allow us to enter into supply contracts, including government contracts, each of which could have a significant impact on our business, financial condition, results of operations, future growth prospects and reputation. In addition, even if we and our collaboration partners comply with FDA, EMA and other applicable requirements, new information regarding the safety or effectiveness of a product could lead the FDA, the EMA or other regulatory authorities to modify or withdraw a product approval. Any government investigation of alleged violations of law could also require us or our collaboration 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 and our collaboration partners' ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results could be adversely affected.

Future laws and regulations and changes to existing ones may have an adverse impact on our business.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products and product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S., the EU or in other countries. If we or our collaboration partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we and our collaboration partners are not able to maintain regulatory compliance, we or they may lose any marketing approval that we or they may have obtained, which could adversely impact our business and financial results.

In particular, since its enactment, there have been judicial and congressional challenges to certain aspects of the Affordable Care Act ("**ACA**") in the U.S., as well as efforts to repeal or replace certain aspects of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. There is currently uncertainty with respect to the impact any such repeal may have, and any resulting changes may take time to unfold, which could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any such action or the impact on us. For example, the Tax Cuts and Jobs Act, among other things, removed the penalties for not complying with the ACA's individual mandate to carry health insurance. There may be additional challenges and amendments to the ACA in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which, due to subsequent legislative amendments, will stay in effect through fiscal year 2031, with the exception of a temporary suspension from May 1, 2020 through March 30, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. The American Taxpayer Relief Act, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the U.S. government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on patients for our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

Furthermore, the Inflation Reduction Act of 2022 ("**IRA**") was signed into law on August 16, 2022. The IRA, among other things, (i) allows the U.S. Department of Health and Human Services to negotiate prices for certain single-source drugs and biologics covered under Medicare Part B and Part D, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law; and (ii) establishes rebates under Medicare to penalize drug price increases that outpace inflation. Negotiations will begin with ten high-cost drugs paid for by Medicare Part D, and the negotiated prices will take effect in 2026. The effect of the IRA on the biopharmaceutical industry is uncertain, and the IRA could have a material effect on our business and results of operations in the future.

We are subject to various laws protecting the confidentiality of certain data and personal information, including patient health information, and our actual or perceived failure to comply could result in penalties and reputational damage.

In the course of our operations, we collect, use, store, disclose, transfer and otherwise process an increasing volume of personal information, including from our employees and third parties with whom we conduct business. Numerous countries in which we, our collaboration partners and our third-party contractors, including CROs and CMOs, operate, manufacture and sell our products have, or are developing, laws protecting personal data and the individual's right to privacy as well as the confidentiality of certain personal data and patient health information (i.e., laws and regulations that address data privacy and security).

EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation ("**GDPR**") imposes a range of requirements relating to the collection, use, handling and protection of personal data. If the measures implemented by us or our collaboration partners or service providers in order to comply with the GDPR requirements are not considered sufficient to ensure the necessary compliance level, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity and a potential loss of business. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Relatedly, following the United Kingdom's ("**U.K.**") withdrawal from the European Economic Area ("**EEA**") and the EU, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into U.K. national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the U.K. and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk. If we do not comply with our obligations under the GDPR, we could be exposed to the fines discussed above. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Further, the Court of Justice of the EU ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the EU and U.S., was invalid and could no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the U.S. Alternative transfer mechanisms may be used while the authorities interpret the decisions and scope of the invalidated Privacy Shield, including the standard contractual clauses ("**SCCs**"); however, the SCCs have also been called into question in the same ruling that invalidated the Privacy Shield. At present, there are few if any viable alternatives to the SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaboration partners. We may also be subject to U.S. federal rules, regulations and guidance concerning data security, including guidance from the FDA. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended ("**HIPAA**"). Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity or business associate in a manner that is not authorized or permitted by HIPAA. In many cases, these laws and regulations apply not only to third-party transactions, but also to transfers of information between or among us, any affiliates and other parties with whom we conduct business. These laws, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may harm our business, financial condition and results of operations. The regulatory framework for data privacy and security

worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

Certain states have also adopted comparable privacy and data security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, the California Consumer Privacy Act ("**CCPA**") went into effect in 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act ("**CPRA**") will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In addition to HIPAA, the CCPA and the GDPR, we, our collaboration partners and our third-party contractors are subject to similar data privacy and confidentiality laws in other countries in which we or they operate or market our products. Such laws and regulations may also impose costly compliance obligations and potentially significant fines or other penalties for non-compliance.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations related to privacy and data security, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, may cause us to become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations.

We and our business arrangements with third parties are subject to fraud, abuse and other healthcare laws and regulations.

Healthcare providers, such as physicians and others, play a primary role in the recommendation and prescription of our products. Our or our collaboration partners' arrangements with such persons and third-party payers and our general business operations expose us or our collaboration partners to broadly applicable fraud and abuse regulations, as well as other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products. Restrictions under applicable U.S. federal and state and non-U.S. healthcare laws and regulations include, but are not limited to, the Anti-Kickback Statute, the Beneficiary Inducement Statute, the HIPAA federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, the federal transparency requirements under the Physician Payments Sunshine Act and analogous U.S. state laws. Rules and regulations covering many of the same matters are found in numerous other countries, including in Denmark, and may be more stringent or result in higher exposures than those in the U.S.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely continue to be time-consuming and costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, in which case we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits

and future earnings and curtailment of our operations, any of which could substantially disrupt our business. For more information about these and other applicable regulations, see ''*Item 4 – Information on the Company —Government Regulation*'' below.

Enhanced scrutiny of pharmaceutical manufacturer donations to and support of patient assistance programs offered by charitable foundations may affect us or our collaboration partners.

To help patients afford our products, we and our collaboration partners have implemented, and may implement or further expand in the future, patient assistance programs. We or our collaboration partners also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients in affording pharmaceuticals have become the subject of scrutiny. In recent years, some pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their patient assistance programs and support of independent charitable patient support foundations under a variety of U.S. federal and state laws. At least one insurer also has directed its network pharmacies to no longer accept manufacturer co-payment coupons for certain specialty drugs the insurer identified. Our collaboration partners' or own patient assistance programs and support of independent charitable foundations could become the target of similar litigation.

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. If we, our collaboration partners or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we or such collaboration partner could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from government authorities seeking information related to their patient assistance programs and support. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our collaboration partners, employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations.

We are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials, and the cost of compliance is substantial. Our business activities involve the controlled storage, use and disposal of hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials in our manufacturing process. We cannot guarantee that the safety procedures utilized by our collaboration partners and by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. In addition, European, U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, we may be held liable for any consequential damage and any resulting claims for damages, face an interruption of our commercialization efforts, research and development efforts and business operations, and cause environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products, which may exceed our financial resources and may materially adversely affect our business, financial condition, results of operations and future growth prospects and the value of our ADSs.

Risks Related to Our Ordinary Shares, ADSs and Foreign Private Issuer Status

If we lose our foreign private issuer status in the future, we would incur significant additional costs and expenses.

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. We currently qualify as a foreign private issuer, and will continue to qualify as a foreign private issuer until, as of June 30 of our most recent fiscal year, (i) more than 50% of our shares are directly or indirectly owned of record by U.S. residents, and (ii) either (x) the majority of our executive officers or directors are U.S. citizens or residents, (y) more than 50% of our assets are located in the U.S., or (z) our business is administered principally in the U.S. We estimate that as of the latest determination date, approximately 46% of our outstanding shares, or 30 million shares, were beneficially held by U.S. residents.

Our foreign private issuer status will next be determined as of June 30, 2024. There can be no assurance that we will not lose our foreign private issuer status in the future.

The regulatory and compliance costs to us under U.S. securities laws if we lose our foreign private issuer status would be significantly more than the costs we incur as a foreign private issuer, and we would need to devote significantly more financial, management and other resources to compliance with U.S. securities laws than we currently do, particularly in the year in which we lose our foreign private issuer status. If we lose our foreign private issuer status, we would be required to report as a U.S. domestic issuer and be subject to other U.S. securities laws applicable to U.S. domestic issuers. For example, as a U.S. domestic issuer, we would be required to file periodic reports and registration statements with the SEC on U.S. domestic issuer forms, which are more detailed and extensive in certain respects than the forms available to us as a foreign private issuer. We would also be required to prepare our financial statements in accordance with U.S. GAAP and modify certain of our policies to comply with corporate governance practices applicable to U.S. domestic issuers. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, which could also increase our costs.

ADS holders do not directly hold our shares.

Holders of our ADSs are not treated as our shareholders and do not have shareholder rights. Our depositary, Deutsche Bank Trust Company Americas, is the holder of the shares underlying our ADSs. The deposit agreement among us, the depositary, and all other persons directly and indirectly holding ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary.

Holders may not be able to exercise their right to vote the shares underlying their ADSs.

ADS holders do not hold our shares directly and may only exercise voting rights with respect to the shares underlying their respective ADSs in accordance with the provisions of the deposit agreement and not as a direct shareholder of the Company. In order to vote the shares underlying their ADSs, ADS holders may either withdraw the shares underlying their ADSs or instruct the depositary to vote the shares underlying such ADSs. However, holders may not know about the meeting far enough in advance to withdraw the underlying shares, and after such withdrawal, holders would no longer hold ADSs, but would instead hold the underlying shares directly.

The depositary will try, as far as practicable, to vote the shares underlying the ADSs as instructed by the ADS holders. In such an instance, if we ask for holders' instructions, the depositary, upon timely notice from us, will notify holders of the upcoming vote and arrange to deliver our voting materials to holders. We cannot guarantee that holders will receive the voting materials in time to ensure that holders will be able to instruct the depositary to vote their shares or to withdraw their shares so that they can vote such shares themselves. If the depositary does not receive timely voting instructions from holders, it may give a proxy to a person designated by us to vote the shares underlying their ADSs. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that holders may not be able to exercise any right to vote that they may have with respect to the underlying shares, and there may be nothing they can do if the

shares underlying their ADSs are not voted as they requested. In addition, the depositary is only required to notify holders of any particular vote if it receives timely notice from holders in advance of the scheduled meeting. Our articles of association permit, in the case of general meetings, notice to be delivered within a relatively short time span, in which case the depositary would not be required to provide holders with notice of and access to such vote.

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

Holders' ADSs, which will be evidenced by American depositary receipts ("**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 holders' 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 holders' right to cancel their ADSs and withdraw the underlying shares. Temporary delays in the cancellation of holders' ADSs and withdrawal of the underlying shares may arise because the depositary has closed its transfer 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, holders may not be able to cancel their ADSs and withdraw the underlying shares when the holders 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. For more information, see the description of our securities registered under Section 12 of the Exchange Act included as an exhibit to this Annual Report on Form 20-F.

ADS holders' rights to pursue claims against the depositary are limited by the terms of the deposit agreement.

The deposit agreement governing the ADSs provides that the depositary may, in its sole discretion, require that any dispute or difference arising from the relationship created by the deposit agreement be referred to and finally settled by an arbitration conducted under the terms described in the deposit agreement, although the arbitration provisions do not preclude the holder from pursuing claims under U.S. federal securities laws in federal courts. Furthermore, if a holder is unsuccessful in such arbitration, the holder may be responsible for the fees of the arbitrator and other costs in connection with such arbitration pursuant to the deposit agreement.

In addition, the deposit agreement provides that, subject to the depositary's right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have non-exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, 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 shares, the ADSs or the deposit agreement, including any claim under the U.S. 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 U.S. state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the U.S. federal securities laws has not been finally adjudicated by the U.S. 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. 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 potential holders consult legal counsel regarding the jury waiver provision before investing in the ADSs.

If any holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, a holder or beneficial owner 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 and/or the depositary. If a lawsuit is brought against us and/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 plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not enforced, to the extent a court action proceeds, it would proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of, or a disclaimer of liability under, the U.S. federal securities laws and the rules and regulations promulgated thereunder.

If securities or industry analysts publish inaccurate or unfavorable research about our business, the price of the ADSs and their trading volume could decline.

The trading market for the ADSs and shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our equity securities, publishes inaccurate or unfavorable research about our business or expresses a negative opinion regarding the performance of our securities, or if our clinical trial results or operating performance fail to meet analyst expectations, the price of the ADSs would likely decline. If one or more of these analysts fails to publish reports on us regularly, or downgrades our securities, demand for ADSs could decrease, which could cause the price of the ADSs and their trading volume to decline.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Denmark. Although our wholly owned subsidiary, Genmab US, Inc., has an office and laboratory space in the U.S., substantially all of our assets are located outside the U.S. The majority of our directors and Executive Management reside outside the U.S. As a result, it may not be possible to effect service of process within the U.S. upon such persons or to enforce judgments against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. securities laws.

The U.S. 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 U.S. court, whether or not predicated solely upon U.S. securities laws, would not be enforceable in Denmark. In order to obtain a judgment that is enforceable in Denmark, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim again with a court of competent jurisdiction in Denmark. The Danish court will not be bound by the judgment by the U.S. court, but the judgment may be submitted as evidence. It is up to the Danish court to assess the judgment by the U.S. court and decide if and to what extent the judgment should be followed. Danish courts are likely to deny claims for punitive damages and may grant a reduced amount of damages compared to U.S. courts.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws, against us or members of our Board of Directors or our Executive Management, or certain experts named herein who are residents of Denmark or countries other than the U.S.

We are a “foreign private issuer,” as defined in the SEC’s rules and regulations, and, consequently, we are not subject to all of the disclosure and corporate governance requirements applicable to public companies organized within the United States.

We are a “foreign private issuer,” as defined in the SEC’s rules and regulations, and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the U.S. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our directors and Executive Management are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently publish

annual and quarterly reports on our website pursuant to the rules of Nasdaq Copenhagen and expect to file such financial reports on an annual and quarterly basis with the SEC, we are not required to file such reports with the SEC as frequently or as promptly as U.S. public companies and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K that a U.S. domestic company would be required to file under the Exchange Act. Accordingly, there may be less publicly available information concerning our company than there would be if we were not a foreign private issuer. In addition, as a foreign private issuer and as permitted by the listing requirements of the Nasdaq Stock Market LLC ("**NASDAQ**"), we will comply with certain home country corporate governance practices rather than the corporate governance requirements of the Nasdaq Stock Market.

Risks Related to Tax Matters

If we are a passive foreign investment company for U.S. federal income tax purposes for any taxable year, U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences.

A non-U.S. corporation will be a passive foreign investment company ("**PFIC**") for U.S. federal income tax purposes for any taxable year if either (i) at least 75% of its gross income for such taxable year is "passive income" (as defined in the relevant provisions of the U.S. Internal Revenue Code of 1986, as amended ("**Code**") or (ii) at least 50% of the value of its assets (generally, based on an average of the quarterly values of the assets) during such year is attributable to assets that produce or are held for the production of passive income. Based on the current and anticipated value of our assets and the nature and composition of our income and assets, we do not expect to be a PFIC for U.S. federal income tax purposes for our current taxable year ending December 31, 2024, or in the foreseeable future. However, the determination of whether we are a PFIC or not according to the PFIC rules is made on an annual basis and will depend on the nature and composition of our income and assets and the value of our assets from time to time. Therefore, changes in the nature and composition of our income or assets or the value of our assets may cause us to become a PFIC. The determination of the value of our assets (including goodwill not reflected on our balance sheet) may be based, in part, on the total market value of our shares and ADSs, which is subject to change and may be volatile.

If we are a PFIC for any taxable year during which a U.S. person holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. person. See *"Item 10.E—Taxation—Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."*

Changes in Danish, U.S. or other foreign tax laws or compliance requirements, or the practical interpretation and administration thereof, could have a material adverse effect on our business, financial condition and results of operations.

We are affected by various Danish, U.S. and foreign taxes, including direct and indirect taxes imposed on our global activities, such as corporate income, withholding, customs, excise/energy, value added, sales, environmental and other taxes. Significant judgment is required in determining our provisions for taxes and there are many transactions and calculations where the ultimate tax determination is uncertain.

Changes in Danish or foreign direct or indirect tax laws or compliance requirements, including the practical interpretation and administration thereof, including in respect to market practices, or otherwise, could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. As the tax landscape is evolving and our business model is evolving, Danish, U.S., or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our subsidiaries pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority