D. Risk Factors

Summary

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 3.D. “Risk Factors” in this Annual Report on Form 20-F. 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 future prospects for amivantamab, marketed as RYBREVANT; ofatumumab, marketed as KESIMPTA; teclistamab, marketed as TECVAYLI; teprotumumab, marketed as Tepezza; and tisotumab vedotin, marketed as Tivdak, are dependent on our collaboration partners’ abilities to successfully expand the indications for these products, and to effectively commercialize them for their current indications and any new indications, and in current or new markets, as well as on other external factors that could impact the future success of such products.
- Biopharmaceutical product development involves a substantial degree of uncertainty.
- We have a very limited history of commercializing our marketed products.
- Collaborations continue to be an important part of our strategy and we may not be able to continue or optimize our current collaborations or establish additional collaborations.
- 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.
- We may not meet publicly announced product development objectives.
- We rely on third parties to conduct our clinical trials.
- The U.S. Food and Drug Administration (“**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.
- Any approval granted for our products or product candidates in the United States does not assure approval of such products in the European Union or other foreign jurisdictions.
- We may be affected by reports of adverse events or safety concerns relating to our products or product candidates.
- We rely on a limited number of contract manufacturers.
- Sales of our products and product candidates will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

- 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.

- The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.

- 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.

- We are subject to healthcare laws and regulations.

Risks Related to Our Business

Our financial results and near-term prospects are substantially dependent on the commercial success of DARZALEX.

In 2022, royalties and milestone payments from Janssen related to daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the United States and as DARZALEX SC in Europe for subcutaneous ("**SC**") administration) for certain indications of multiple myeloma ("**MM**") and light-chain ("**AL**") amyloidosis, accounted for 69% 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 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 of the last-to-expire relevant Genmab-owned patent (as defined in the agreement) covering daratumumab in such country. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026.

In September 2020, Genmab commenced a binding arbitration of two matters arising under its license agreement with Janssen relating to daratumumab. Under the license agreement, Genmab is, among other things, entitled to royalties from Janssen on net sales of daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the U.S. and as DARZALEX SC in Europe for SC administration). In April 2022, the arbitral tribunal issued an award in the binding arbitration of the two matters. Genmab did not seek a review of the award, and the award is now final. The first matter concerned the question as to whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement. As to that matter, the tribunal determined by majority opinion that Janssen's obligation to pay royalties to Genmab on sales of licensed product, in each applicable country, extends through the expiration or invalidation of the last-to-expire relevant Genmab-owned patent covering the product or use thereof, but not the relevant Janssen-owned patent. The relevant Genmab-owned issued U.S., European and Japanese patents will expire in the late

2020s and early 2030s. The second matter concerned the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for the Halozyme enzyme technology used in the SC formulation of daratumumab (marketed as DARZALEX *FASPRO* in the U.S.). The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SC daratumumab sales. As to that matter, the tribunal ruled by majority opinion that Janssen is permitted to continue reducing its royalty payments to Genmab as an offset against a share of Janssen's royalty payments made to Halozyme. On June 9, 2022, Genmab announced the commencement of a second arbitration under the daratumumab license agreement with Janssen. This second arbitration follows from the award in the prior arbitration, where the tribunal ruled in favor of Janssen on the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for its technology used in the daratumumab SC product. The tribunal based its ruling on the finding that DARZALEX *FASPRO* constitutes a new licensed product under the license agreement. In this second arbitration, Genmab is consequently seeking an award of $405 million plus interest in accrued milestone payments for DARZALEX *FASPRO* and a declaration that it is entitled to a new 13-year royalty term from the date of DARZALEX *FASPRO*'s first commercial sale. See "*Item 8 – Financial Information —Legal Proceedings*".

There can be no assurance that, even with the expansions to the prescribing label for DARZALEX in the United States and the European Union, 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 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, including Sanofi S.A. ("**Sanofi**")'s isatuximab. 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.

Our future prospects for amivantamab, marketed as RYBREVANT; ofatumumab, marketed as KESIMPTA; teclistamab, marketed as TECVAYLI; teprotumumab, marketed as Tepezza; and tisotumab vedotin, marketed as Tivdak, are dependent on our collaboration partners' abilities to successfully expand the indications for these products, and to effectively commercialize them for their current indications and any new indications, and in current or new markets, as well as on other external factors that could impact the future success of such products.

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

- Amivantamab – The two antibody libraries used to produce amivantamab were both generated by Genmab, but the antibody pair used to create amivantamab was selected in collaboration between Genmab and Janssen with subsequent development work and commercialization led by Janssen;

- Ofatumumab – Novartis is fully responsible for the development and commercialization of ofatumumab and all costs associated therewith;

- Teclistamab - The antibody for this product was created by Janssen by leveraging Genmab's DuoBody technology, and under our agreement with Janssen, the development and commercialization of the product is now being conducted by Janssen;

- Teprotumumab – The antibody for this product was created by Genmab, under a collaboration with Roche, and development and commercialization of the product is now being conducted by Horizon under a license from Roche; and

- Tisotumab Vedotin – This product is being developed in collaboration with Seagen Inc. ("**Seagen**"), and under our agreement, Seagen and Genmab are each responsible for leading commercialization activities in certain territories.

If we do not realize the anticipated benefits from these collaborations and others, 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.

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 our partnered products. 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 or significant changes in a collaboration partner's business strategy, including as a result of the COVID-19 pandemic, may adversely affect that collaboration partner's willingness or ability to continue to pursue our products or product candidates; 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.

Biopharmaceutical product development involves a substantial degree of uncertainty.

Our product pipeline currently includes nine proprietary product candidates, including ongoing clinical trials for tisotumab vedotin by us in collaboration with Seagen and for epcoritamab by us in collaboration with AbbVie. There are also ongoing clinical trials for daratumumab, amivantamab, and teclistamab by Janssen, ofatumumab by Novartis and teprotumumab by Horizon, and seven 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. For example, in September 2021, we decided that the data did not support the further development of HexaBody-DR5/DR5, and we and AbbVie Inc. ("**AbbVie**") decided to halt further development of DuoBody-CD3x5T4. In June 2022, AbbVie decided to discontinue co-development of DuoHexaBody-CD37 and upon expiry of the 180-day notice period on December 24, 2022, we became solely responsible for the further development of DuoHexaBody-CD37. 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 is developed using Seagen's proprietary antibody-drug conjugate ("**ADC**") technology in combination with our proprietary HuMax-TF antibody. Any failures or setbacks with respect to our proprietary technologies or Seagen'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 ourselves. Tisotumab vedotin received accelerated FDA approval in September 2021. We submitted a Biologics License Application ("**BLA**") for SC epcoritamab to the FDA in September 2022, which was accepted with Priority Review in November 2022 with a target action date of May 21, 2023, and a Japan New Drug Application ("**JNDA**") to the Ministry of Health, Labor and Welfare ("**MHLW**") in December 2022. Our collaboration partner, AbbVie, submitted a marketing authorization application ("**MAA**") to the European Medical Agency ("**EMA**") in October 2022, which was also validated in October 2022. If we are unable 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.

We have a very limited history of commercializing our marketed products.

We are currently building and expanding our commercialization capabilities 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 become a commercial-stage company with an initial focus on successfully commercializing tisotumab vedotin, marketed as Tivdak in the U.S. for the treatment of cervical cancer following the receipt of accelerated FDA approval in September 2021. We are developing tisotumab vedotin in collaboration with Seagen.

We continue to develop our market-based commercialization operations in the U.S. and Japan. Building comprehensive commercialization capabilities will require substantial investment of time and money and will require significant management focus and resources. We will be competing with pharmaceutical and biotechnology companies with established commercialization and marketing capabilities. 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 will 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.

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.

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.

Collaborations continue to be an important part of our strategy and we may not be able to continue or optimize our current collaborations or establish additional collaborations.

We have entered into a number of different collaborations for development, co-development, commercialization and co-commercialization of our products and product candidates, as well as for the in- and out-licensing of third-party technologies and our proprietary technologies. Our ability to continue our current collaborations and to enter into additional collaborations will depend in large part on whether we are able to successfully demonstrate our ability to select and develop product candidates and whether our antibody technology and other platform technologies are attractive formats for developing antibody therapeutic products. Existing or potential collaboration partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make collaboration with us less attractive to them. For example, if an existing collaboration partner purchases or is purchased by one of our competitors, that company could be less willing to continue its collaboration with us. Moreover, from time to time we have discussions, disagreements or disputes with our collaboration partners with respect to the ownership of rights, royalty entitlements or other matters with respect to any technology or products developed with our collaboration partners or with respect to the interpretation of related agreements, which may lead to delays in or termination of the research, development or commercialization of products and product candidates or affect the financial and non-financial rights and obligations under the related agreements. If we are not able to establish additional collaborations on terms that are favorable to us or if any significant number of our existing material collaborations are terminated and we cannot replace them, or if we are unable to favorably resolve disagreements or disputes with our collaboration partners, this could materially harm 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 trials 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' 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. It may take several years and require significant expenditures to complete the pre-clinical trials 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 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.

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, the price of our ADSs may be adversely affected.

We rely on third parties to conduct our clinical trials.

We do not currently have the ability to independently conduct clinical trials. With respect to our proprietary product candidates or any other product candidates for which we control the clinical development, we rely on third parties, such as CROs, to conduct clinical trials on our product candidates. For our out-licensed products and product candidates, or for any product candidates where our collaboration partner is responsible for clinical development, we rely on such collaboration partners to conduct clinical trials. These collaboration partners may also hire CROs or other third parties to conduct clinical trials on our products and product candidates. 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 our 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.

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 United States, including in the European Union where we are headquartered. Although the FDA may accept data from clinical trials conducted outside the United States, 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 United States, 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 United States. 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 the European Union or other foreign jurisdictions.

In order to market and sell our drugs in the European Union 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 United States generally includes all of the risks associated with obtaining FDA approval. In addition, many countries outside the United States 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 United

States 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 United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

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 our stock price to decline or experience periods of volatility.

We may fail to obtain designations for expedited development or review or such designations may not lead to a faster development or regulatory review.

Fast Track Designation ("**FTD**"), Breakthrough Therapy Designation ("**BTD**"), and pilot 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. See also "*—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.*" See "*Item 4 –Information on the Company —Government Regulation*" for more information about BTD and FTD and other programs for expedited review.

We rely on a limited number of contract manufacturers.

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, and teclistamab. Novartis is responsible for the manufacture of ofatumumab, Horizon is responsible for the manufacture of teprotumumab, and Seagen is responsible for the manufacturing of tisotumab vedotin. For the product candidates and products we are entirely responsible to manufacture, we currently rely primarily upon one single source third-party CMO, Lonza Group AG ("**Lonza**"), 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 ourselves and currently have no plans to build our own clinical or commercial scale manufacturing capabilities.

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 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 often 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 of 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.

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 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 United States, 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. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. However, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals of a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the ultimate impact of the BPCIA is subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to U.S. congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Additional jurisdictions outside of the United States have established abbreviated pathways for regulatory approval of

biological products that are biosimilar to reference products previously approved. For example, in the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. We are aware of many pharmaceutical and biotechnology and other companies that are actively engaged in research and development of biosimilars or interchangeable products.

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 United States and the European Union 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.

Sales of our products and product candidates 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.

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 expect to incur increased research and development expenses and selling, general and administrative expenses in future periods.

We are currently advancing our proprietary product candidates through clinical development and are conducting pre-clinical trials with respect to other programs. Developing product candidates is expensive, time-intensive and risky, and we expect our research and development expenses to increase over the next few years, particularly as we seek to advance our proprietary product candidates toward commercialization. We also expect our selling, general and administrative expenses to increase over the next few years as we seek to expand our commercialization capabilities in a number of jurisdictions. Such expenses may increase over time as a result of inflation and other factors.

We may need to raise additional capital to fund our existing operations, commercialize our products or expand our operations.

Although we believe that our existing revenue streams and our marketable securities will be sufficient to fund our current projects and commercialization activities, our operating plans may change as a result of a variety of factors, and we may need to seek additional funds sooner than planned through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. Further, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives which could benefit from additional capital.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if 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 United States 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, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Moreover, the terms of any financing may adversely affect the holdings or the rights of our ADS holders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs to decline. The sale of additional equity or convertible debt securities could be dilutive to our ADS holders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaboration partners or at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or proprietary product candidates or otherwise agree to terms unfavorable to us. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any proprietary product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, any of which could impair our business, financial condition, results of operations and future growth prospects.

Our collaboration and intellectual property agreements with our collaboration partners or other third parties may be interpreted differently by us and our collaboration partners or other third parties.

Certain provisions in our collaboration and intellectual property agreements, including the agreements governing our product or technology collaborations and in-licenses of third-party intellectual property or technology, may be interpreted differently by us and our collaboration partners or other third parties. From time to time, we have discussions or disagreements with our collaboration partners or other third parties regarding the interpretation of our contracts with them. Currently, an arbitration is ongoing against Janssen. See *"—Our financial results and near-term prospects are substantially dependent on the commercial success of DARZALEX."* The resolution of any contract interpretation disagreement or dispute could affect the scope of our rights to the relevant intellectual property or technology, or otherwise affect our financial (including with respect to reimbursements, fees, milestones and royalties) or non-financial rights and obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 and Roche (Horizon). 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.

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.

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 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 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.

We may acquire businesses or products, or form collaborations, in the future, and we may not realize the benefits of such acquisitions or collaborations.

Should attractive opportunities arise, we may acquire companies or technologies that facilitate our access to new medicines, 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 or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions on favorable terms and could be led to finance these acquisitions using cash and marketable securities that could otherwise be allocated to other purposes in the context of our existing operations, or issuances of equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders and adversely affect the market price of our ADSs. If we acquire or enter into collaborations with businesses with promising markets or technologies, 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 or collaborations. We cannot assure that we will achieve the expected synergies to justify any such transaction, which 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.

The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread worldwide and has been declared a global pandemic. COVID-19 has resulted in global business and economic disruption, including supply chain issues, and has put a strain on the healthcare systems in the major countries where our collaboration partners sell our products and where we and they conduct our clinical trials. The COVID-19 pandemic may have long-term impacts on the development, regulatory approval and commercialization of our product candidates and on sales of our approved products. As the pandemic evolves, there may be an impact on our business. The extent, length and consequences of the pandemic are uncertain and impossible to predict, and may be affected by the emergence, spread, infectiousness and severity of new virus variants of concern, the efficacy, availability and administration of vaccines and the development and administration of treatments. Genmab has a COVID-19 response team, led by the Chief Executive Officer, that monitors the situation and implements precautionary measures based on local recommendations, as necessary.

The continued spread of COVID-19 globally could adversely affect our and our collaboration partners' ability to recruit and retain patients and principal investigators, site staff and other resources for clinical trials, as hospitals and other healthcare providers prioritize resources toward the outbreak. This may result in delays or deferrals of affected clinical trials. Any changes in clinical trial practices and policies imposed by regulators in response to COVID-19 may

also contribute to such delays or deferrals or cause the costs of clinical trials to increase. The full extent of the impact of COVID-19 on the clinical development of our product pipeline cannot currently be determined.

COVID-19 may also affect our employees and the employees of our third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. Such employees may be unable to work as a result of sickness or becoming caregivers to sick family members or may be delayed or limited in their ability to work as a result of measures such as mandatory remote work or suspension of travel. This may, among other things, limit the CROs' ability to commence and conduct our or our collaboration partners' clinical trials, as well as to analyze the data from clinical trials that have been completed. Limitations on the work of our employees as a result of COVID-19 may also affect progress on our pre-clinical pipeline, as access to activities in our research laboratories may be partially or completely restricted.

Delay in presentation of data analysis, disruptions in the business of the FDA or other health authorities as a result of COVID-19 and related containment measures, or delays in necessary interactions with the FDA, other health authorities, local regulators, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, could result in delays of reviews and approvals, including with respect to our product candidates.

Disruption in shipping and manufacturing may also negatively affect our supply chain, causing our collaboration partners or producers of comparator drugs used in our clinical trials and their respective suppliers to be unable to produce and ship materials required for use in our clinical trials, in sufficient quantities or at all, leading to delay in, or termination of, our and our collaboration partners' clinical trials. For example, tocilizumab is a product used in certain clinical trials, including trials of epcoritamab and certain products in development by collaboration partners. In June 2021 the FDA approved an emergency use authorization for tocilizumab for the treatment of severe COVID-19 and in other countries tocilizumab use was prioritized for patients with severe COVID-19. Many hospitals therefore prioritized tocilizumab use for those patients with severe COVID-19 and for the other approved tocilizumab indications. Therefore, enrollment in clinical trials where tocilizumab was required as a rescue medication for cytokine release syndrome may have been impacted until hospitals could ensure sufficient supply to treat these patients. Supply chain disruption may also affect the manufacturing, shipment and commercialization of approved products. For example, on December 17, 2020, Horizon announced a short-term disruption in the supply of TEPEZZA due to government-mandated orders to produce COVID-19 vaccines, which dramatically restricted manufacturing capacity available for the production of TEPEZZA at Horizon's drug product CMO, Catalent, Inc. ("**Catalent**"), in the first quarter of 2021. Prolonged disruption in the supply of our or our collaboration partners' products, as a result of COVID-19 or otherwise, may have a material adverse effect on our business, financial condition, results of operation and cash flows.

Any delay in or disruption to clinical trials, regulatory submissions and regulatory approvals would jeopardize timelines for developing, receiving approval for, and subsequently commercializing our product candidates, or obtaining label expansion for our existing products, all of which would adversely affect our operations and financial performance.

COVID-19 impacted DARZALEX sales in 2020 and could in the future affect sales of DARZALEX for existing indications, which could reduce our royalty revenue pursuant to our collaboration with Janssen. Should the resources of healthcare systems worldwide, including in the United States and Europe, become more severely strained by their response to the pandemic or if such strain is prolonged, resources previously devoted to the diagnosis and treatment of MM may be redeployed to addressing COVID-19, resulting in fewer prescriptions and sales of DARZALEX. Additionally, many patients who currently receive DARZALEX are elderly and immunocompromised and, therefore, more susceptible to severe negative impacts from COVID-19. Such patients may be unable to travel to healthcare facilities to receive DARZALEX treatment as a result of mandatory or self-imposed restrictions on local travel or other social distancing measures. Should they contract COVID-19, they may become unable to continue with their DARZALEX treatment, and many such patients may die. Should treatment of current patients with DARZALEX be temporarily deferred or should such patients die, or should there be a delay or reduction in diagnoses of new MM patients and treatment prescriptions as healthcare resources are redeployed, demand for DARZALEX may be reduced. This would lead to a corresponding reduction in DARZALEX sales and a resulting decrease in our revenues from royalties under our collaboration with Janssen, which would adversely affect our financial performance. In addition, the

pandemic could result in delays in clinical development, regulatory approval and commercialization of DARZALEX for additional indications.

While global health authorities and global vaccination efforts alleviated some of the adverse impacts of the COVID-19 pandemic, the full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop, including with respect to new virus variants and vaccine administration. The factors discussed above, as well as other factors which are currently unforeseeable, may result in further and other unforeseen material adverse impacts on our business and financial performance, including on the sales of Tivdak, RYBREVANT, Kesimpta, TEPEZZA, and TECVAYLI, by our collaboration partners and on our royalty and milestone income therefrom.

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.

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 move toward further commercialization of products. Since 2019 Genmab has grown from 548 employees to 1,660 at the end of 2022. In 2019 there were 12 ongoing clinical trials for Genmab proprietary products, which are those owned at least 50% by Genmab. By the end of 2022 this number had more than doubled to 25, including multiple Phase III trials. Such growth has put significant demands on our management and infrastructure, including new operational and financial systems, as well as extending manufacturing and commercial outsource 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.

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 United States, 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 United States, 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 United States, 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 United States 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 United States 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 United States, 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 United States 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 United States, 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 United States 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 United States 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 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 United States 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 European Union, 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.

We may face difficulties from changes to current regulations and future legislation.

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 United States, the European Union 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 United States, 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 European Union, 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 European Union 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 European Union ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the European Union and United States, 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 United States. 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 United States, 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 will go 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.

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.

We are subject to 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 United States.

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, certain of our collaboration partners have, and we may implement in the future, patient assistance programs and 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 employees and collaboration partners may engage in misconduct or other improper activities.

We are exposed to the risk of fraud or other misconduct of 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 United States, 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 United States 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 our Ordinary Shares, ADSs and Foreign Private Issuer Status

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.

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 United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement. 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.

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 United States, substantially all of our assets are located outside the United States. The majority of our directors and senior management reside outside the United States. As a result, it may not be possible to effect service of process within the United States 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 United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a 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 senior management, or certain experts named herein who are residents of Denmark or countries other than 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 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 United States. 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 senior 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 will not be required to file such reports with the SEC as frequently or as promptly as U.S. public companies and will not be 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.

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. While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, we could lose our foreign private issuer status in the future. Our foreign private issuer status will next be determined as of June 30, 2023.

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. 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.

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%