## D. Risk Factors

***Risks Related to Our Business***

**Our financial results and near-term prospects are substantially dependent on DARZALEX. If our partner Janssen is unable to effectively maintain and grow sales of DARZALEX for its approved indications and to continue to expand its indications, our prospects for increased revenues and profitability will be adversely affected.**

In 2020, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of multiple myeloma ("**MM**"), accounted for 45% of our revenue, as compared to 92% in 2019, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. The decrease was mainly driven by the upfront payment of $672 million (DKK 4,398 million) related to the AbbVie collaboration that was allocated to license grants and recognized as revenue in June 2020. Excluding the one-time payment from AbbVie, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of MM, accounted for 79% of our revenue. Under our collaboration agreement regarding daratumumab, Janssen is currently fully responsible for developing and commercializing daratumumab and all costs associated therewith. Consequently, our revenue and resulting operating profit, if any, and near-term prospects are substantially dependent on the success of this collaboration and on Janssen's continued ability to effectively maintain and grow sales of daratumumab for its approved indications and to continue to expand its indications. Janssen has obtained marketing approval for DARZALEX for certain indications of frontline MM and relapsed/refractory, ("**R/R**"), MM in the United States, the European Union, Japan and in certain other countries. In addition, Janssen obtained marketing approval for the subcutaneous ("**SubQ**") formulation of daratumumab (daratumumab and hyaluronidase-fihj) in the U.S., where it is known as DARZALEX *FASPRO*, and in Europe, where it is known as DARZALEX SC. The SubQ formulation of daratumumab has also been approved in Japan. In the U.S. Janssen also obtained marketing approval for DARZALEX *FASPRO* for the treatment of light-chain ("**AL**") amyloidosis. Regulatory applications are currently pending with U.S. and European authorities based on the APOLLO study and with European and Japanese authorities based on the ANDROMEDA study. There can be no assurance that Janssen will be successful in obtaining additional approvals for DARZALEX or jurisdictions or in maintaining existing regulatory approvals. The FDA approval based on the ANDROMEDA study was granted as an accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). While DARZALEX product sales have grown over time, and our future plans assume that sales of DARZALEX will continue to increase, there can be no assurance that, even with the recent expansion to the prescribing label for DARZALEX in the United States and the European Union, DARZALEX sales will continue to grow or that Janssen will be able to maintain sales of DARZALEX at or near current levels. In particular, DARZALEX is subject to intense competition in the MM therapy market. There are numerous other products approved by the U.S. Food and Drug Administration (the "**FDA**") for the same indications as DARZALEX and the competition from these and other therapies is intensifying. We are also aware of numerous 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. In particular, Sanofi's isatuximab, a monoclonal antibody ("**mAb**") targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor ("**PI**"). If Janssen is unable to successfully compete with these other agents and technologies, DARZALEX sales could decline materially.

Janssen is also currently conducting clinical trials of daratumumab for the treatment of smoldering MM, ("**SMM**"), and additional indications of frontline MM and R/R MM, as well as certain other diseases in which CD38 is expressed, including AL amyloidosis, for which Janssen submitted a Biologics License Application ("**BLA**") to the FDA in September 2020, based on the Phase III ANDROMEDA study. This BLA was subsequently approved by the FDA in January 2021.

Although we are able to participate in the development strategy for daratumumab through regular meetings of the joint development and steering committee, we cannot control the amount and timing of resources that Janssen dedicates to the development and commercialization of daratumumab and our prospects for future milestone payments and royalties related to daratumumab depend on Janssen's decision to continue to conduct clinical trials of daratumumab for

expanded indications and to seek new regulatory approvals for daratumumab, and on the success of such studies and applications and to its active commercialization.

There can be no assurance that Janssen will complete the ongoing and planned studies of daratumumab, successfully or at all, or that Janssen will obtain and maintain the regulatory approvals necessary to market daratumumab for any additional indications. In particular, despite the FDA label expansion of daratumumab based on the ANDROMEDA study, there can be no assurance that additional marketing authorizations will be granted based on the ANDROMEDA study, that marketing approval will be granted based on the APOLLO study, that any of the other studies will be completed on the expected timeline or at all, or, if completed, that the final results of such studies will be positive. Negative or inconclusive results in these or other trials would negatively impact, or preclude altogether, Janssen's ability to obtain regulatory approvals for daratumumab in the proposed indications, which would limit the commercial potential of daratumumab. For example, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab for the treatment of patients with previously treated non-small-cell lung cancer, ("**NSCLC**"), was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in this arm of the study. Based on these findings, a Phase I study of daratumumab and Janssen's proprietary anti-PD-1 antibody for the treatment of patients with MM was also discontinued. Even if the results of Janssen's ongoing studies are positive, there can be no assurance that Janssen will apply for regulatory approval of the related indications and, if Janssen applies, that such applications will be successful, each of which would limit the commercial potential of daratumumab. Additionally, even if Janssen receives the required regulatory approvals to market daratumumab for any additional indications or in additional jurisdictions, Janssen may not be able to effectively commercialize daratumumab as a result of unfavorable pricing or reimbursement limitations, competition or other factors, or may choose not to prioritize daratumumab in its commercialization efforts.

In addition, 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 product 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 binding arbitration of two matters arising under the license agreement with Janssen relating to daratumumab. The arbitration is to settle whether Genmab is required to share in Janssen's royalty payments to Halozyme Therapeutics, Inc. ("**Halozyme**") for the Halozyme enzyme technology used in the SubQ formulation of daratumumab and 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 daratumumab. See "Item 8—Financial Information—Legal Proceedings".

Future prospects for daratumumab are also subject to the risks outlined below with respect to our other product candidates, including risks related to clinical studies, 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 as outlined below.

**Our future prospects for ofatumumab are dependent on our partner Novartis' ability to successfully expand ofatumumab's indications and to effectively commercialize it for its current indications and any new indications that may be approved, as well as on other external factors that could impact ofatumumab's future success.**

A SubQ formulation of ofatumumab has been approved for the treatment of certain relapsing forms of multiple sclerosis ("**RMS**") indications in the United States under the name Kesimpta. Under our collaboration agreement,

Novartis is fully responsible for development and commercialization of ofatumumab and all costs associated therewith. Consequently, the commercial success of ofatumumab is dependent on the success of this collaboration and the activities of Novartis. We cannot control the amount and timing of resources that Novartis dedicates to the development and commercialization of ofatumumab and our ability to obtain royalties related to ofatumumab depends on Novartis' decision to continue to study ofatumumab for new indications, to seek regulatory approvals for such indications and to effectively commercialize ofatumumab for new and existing indications, and on the success of such efforts. Kesimpta is also subject to competition in the RMS therapy market. There are numerous other products approved by the FDA for RMS, in particular Genentech's ocrelizumab, a mAb targeting CD20, which was approved as Ocrevus. Ocrevus was initially approved by the FDA in 2017 for relapsing or primary progressive forms of multiple sclerosis ("**MS**"). The current FDA approved indications for Ocrevus are RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults as well as primary progressive MS in adults. If Novartis is unable to successfully compete with this and other therapies, Kesimpta sales could be materially affected.

On January 22, 2018, Novartis announced that it would transition Arzerra in non-U.S. markets from commercial availability to limited availability through managed access programs or alternative solutions, where applicable and allowed by local regulations, due to increased availability of other treatments for chronic lymphocytic leukemia ("**CLL**") resulting in a low number of patients using Arzerra outside the United States. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. Subsequently, in August 2020 Genmab announced that Novartis planned to transition Arzerra to an oncology access program for CLL patients in the U.S. Genmab recognized $30 million lump sum from Novartis as payment for lost potential royalties. Ofatumumab is no longer in development for CLL. We expect Arzerra to remain commercially available for approved CLL indications in Japan.

**Our future prospects for teprotumumab are dependent on Horizon's ability to successfully expand teprotumumab's indications and to effectively commercialize it for its current indications and any new indications that may be approved, as well as on other external factors that could impact teprotumumab's future success.**

Teprotumumab has been approved for the treatment of thyroid eye disease ("**TED**") in the United States under the name TEPEZZA. The antibody 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. Under the terms of Genmab's agreement with Roche, Genmab will receive mid-single digit royalties on net sales of TEPEZZA. Horizon is fully responsible for development and commercialization of teprotumumab and all costs associated therewith. Consequently, the commercial success of teprotumumab is dependent on the success of the activities of Horizon. We cannot control the amount and timing of resources that Horizon dedicates to the development and commercialization of teprotumumab and our ability to obtain royalties related to teprotumumab depends on Horizon's decision to continue to study teprotumumab for new indications, to seek regulatory approvals for such indications and to effectively commercialize teprotumumab for new and existing indications, and on the success of such efforts.

**Biopharmaceutical product development involves a substantial degree of uncertainty. Our current product candidates are in various stages of development, and it is possible that none of our product candidates will become viable commercial products, on a timely basis or at all.**

Our clinical stage product candidates include eight proprietary product candidates, ongoing clinical studies for daratumumab, ofatumumab and teprotumumab by Janssen, Novartis and Horizon, respectively, and twelve additional product candidates being developed in collaboration with our partners. We also have approximately 20 proprietary and partnered product candidates in pre-clinical development. Other than amivantamab, in development by Janssen, tisotumab vedotin and epcoritamab, which are all currently in Phase III development, our current product candidates are in relatively early stages of development. All of our product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all.

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, we or our partners may not successfully develop any of our product candidates, or we or our partners may choose to discontinue the 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 partners' resources. It is possible that none of our current product candidates will ever obtain regulatory approval and, even if approved, such product candidates may never be effectively commercialized. 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 partners have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance. 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 partners' development program decision-making and resource prioritization decisions may not improve our results of operations or future growth prospects or enhance the value of the American depositary shares ("**ADSs**").

Additionally, our most advanced proprietary product candidate, tisotumab vedotin, is currently in Phase III development with a BLA submitted in January 2021, and we have not advanced any product candidates through late-stage clinical development ourselves. If we are unable to develop late-stage development capabilities, we will be required to continue to contract with third parties 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.

**We have no history of commercializing our marketed products. Building our commercialization capabilities will require significant investment of time and money. There can be no assurance that we will successfully set up our commercialization capabilities, or that we will successfully commercialize any of our product candidates in the future.**

We are currently building and expanding our commercialization capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our customers and shareholders. Our goal is to become a commercial-stage company with an initial focus on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seagen Inc. ("**Seagen**"). In October 2020, we and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin. Furthermore, in June 2020, we entered into a collaboration and license agreement with AbbVie Biotechnology Ltd. ("**AbbVie**"), pursuant to which we intend to jointly research, develop, manufacture and commercialize certain product candidates. The development of our commercialization capabilities will benefit from the experience gained with AbbVie's infrastructure, procedures and commercialization best practices in connection with this collaboration.

Our market based commercialization operations are currently being developed. 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 larger 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 set up commercialization capabilities will be successful.

Even if tisotumab vedotin or one of our other proprietary product candidates obtain 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. 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 the market price of our ADSs and our financial condition, results of operations and future growth prospects.

**Tisotumab vedotin may not obtain regulatory approval, on our expected timeline or at all, and, if it is approved, we may be unable to effectively commercialize it. We do not have sole control over the development and commercialization of tisotumab vedotin.**

Tisotumab vedotin is currently our most advanced proprietary product candidate, and our initial commercialization efforts are focused on setting up our commercialization capabilities to market tisotumab vedotin for the treatment of cervical cancer. We are developing tisotumab vedotin in collaboration with Seagen under an agreement in which the companies share all future costs and profits for the product on a 50:50 basis. Under our agreement, Seagen and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. However, there can be no assurance that tisotumab vedotin will obtain regulatory approval on our expected timeline or at all. We and Seagen conducted a potentially registrational Phase II clinical trial of tisotumab vedotin for the treatment of patients with recurrent and/or metastatic cervical cancer and reported very favorable topline results for this study in June 2020. A confirmatory Phase III study was subsequently announced in January 2021. There can be no assurance that the Phase III study will be completed, on the proposed timeline or at all, or that the results will be supportive of the Phase II clinical trial. A BLA submission was made to support a potential accelerated approval pathway with the U.S. FDA. There is no guarantee that we will obtain marketing approval or, if we obtain marketing approval, that we and Seagen will be able to successfully commercialize tisotumab vedotin. If we are unable to commercialize tisotumab vedotin for cervical cancer, we may lose a portion of our investment and may incur additional costs to refocus our efforts on other products or indications, which could have a negative impact on our business, financial condition, results of operations and future growth prospects.

In October 2020, we and Seagen entered into a joint commercialization agreement. Genmab will co-promote tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. In all other markets, if any, Seagen will be responsible for commercializing tisotumab vedotin and Genmab will receive royalties based on a percentage of aggregate net sales ranging from the mid-teens to the mid-twenties. The companies will continue the practice of joint decision-making on the worldwide development and commercialization strategy for tisotumab vedotin. If we and Seagen are unable to continue to agree on the development and commercialization strategies for tisotumab vedotin, such efforts may be delayed, or we may be required to take full responsibility for ongoing development and commercialization efforts, including the costs of such efforts. In addition, either party may opt out of co-development and profit-sharing in return for receiving milestone payments and royalties from the continuing party.

Furthermore, 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 in Seagen’s ADC development programs, including adverse effects resulting from the use of ADC technology in commercial settings or human clinical trials and/or the imposition of clinical holds on any trials for product candidates using this technology, could have a detrimental impact on the continued development of tisotumab vedotin, which could adversely affect our business, financial condition, results of operations and future growth prospects.

**Our research & development efforts may not succeed in generating a continued pipeline of products. Any failures or setbacks in our DuoBody platform or our other proprietary technologies could negatively affect our business and financial condition.**

Discovering and developing new products is a costly and uncertain process. Substantial resources are required in order to yield innovations. It is important for us to pursue early stage research and development in order to ensure a sustained portfolio of products.

This is in part driven by the productivity of our proprietary technologies. Many of our proprietary and partnered product candidates are created with, and dependent upon, our proprietary technologies, including our proprietary epcoritamab (DuoBody-CD3xCD20), DuoBody-CD40x4-1BB and DuoBody-PD-L1x4-1BB product candidates, which were created with our DuoBody technology, as well as several additional product candidates in clinical development by Janssen through our DuoBody collaboration, including amivantamab, our proprietary HexaBody-DR5/DR5 and HexaBody-CD38 product candidates, which were created with our HexaBody technology, and our proprietary DuoHexaBody-CD37 product candidate, which was created with our DuoHexaBody technology. Our DuoBody technology is also the basis of our collaborations with certain other partners, including Novo Nordisk and BioNTech and our HexaBody technology is the basis of our CD38 collaboration with Janssen. To date, no products based on any of these technologies have been approved for commercial sale in any jurisdiction. Any failures or setbacks with respect to our proprietary technologies, 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, as well as our ability to maintain and/or enter into new corporate collaborations regarding our technologies or otherwise, which would negatively affect our business and financial condition.

**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. For example, daratumumab has been approved in certain jurisdictions in combination with other products, including with (i) lenalidomide and dexamethasone (“**Rd**”), for the frontline treatment of transplant-ineligible MM patients and for the treatment of MM patients who have received at least one prior line of therapy; (ii) bortezomib and dexamethasone, (“**Vd**”), for the treatment of MM patients who have received at least one prior line of therapy; (iii) pomalidomide and dexamethasone, (“**Pd**”), for the treatment of MM patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor, (“**PI**”); (iv) bortezomib, melphalan and prednisone (“**VMP**”), for frontline treatment of transplant-ineligible MM patients; (v) bortezomib, thalidomide and dexamethasone (“**VTd**”), for frontline treatment of transplant-eligible MM; (vi) carfilzomib and dexamethasone (“**Kd**”), for the treatment of adult patients with relapsed/refractory MM who have received one to three previous lines of therapy and (vii) in combination with bortezomib, cyclophosphamide and dexamethasone (“**VCd**”), for the treatment of AL amyloidosis. In addition, daratumumab is currently under regulatory review in combination with other products, including (i) Pd, for the treatment of MM patients who have received at least two prior therapies, including lenalidomide and a PI and (ii) in Europe, in combination with VCd, for the treatment of AL amyloidosis. Daratumumab is also in Phase III clinical trials with (i) bortezomib, lenalidomide and dexamethasone (“**VRd**”) and VMP for frontline treatment of transplant-ineligible MM patients; and (ii) VRd and lenalidomide for frontline treatment of transplant-eligible MM patients. We and our partners are also testing other product candidates as combination treatments.

Approval of a product for the treatment of a disease indication in combination with other therapeutic products exposes us and our 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. For example, in May 2012, the FDA issued a safety announcement relating to the risk of second primary malignancies in patients with newly diagnosed MM that had received lenalidomide, marketed as Revlimid, and on July 18, 2013, Celgene, in consultation with the FDA, discontinued treatment with Revlimid in a Phase III trial for the treatment of previously untreated elderly patients with CLL due to an

imbalance observed in the number of deaths in patients treated with Revlimid versus patients treated with chlorambucil. 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. For example, in May 2019, Regeneron Pharmaceuticals Inc. reported that the combination of its bispecific mAb with a PD-1 inhibitor led to enhanced cytokine release syndrome in patients in a Phase I trial and was a potential cause of two patient fatalities in the study. In addition, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination treatment arm of the study.

**Partnerships are an important part of our strategy and we may not be able to continue our current partnerships or establish additional partnerships.**

We have entered into a number of different partnerships 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 partnerships and to enter into additional partnerships 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 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 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 partners with respect to the ownership of rights, royalty entitlements or other matters with respect to any technology or products developed with our partners or with respect to the interpretation of related agreements. Lengthy negotiations with potential new partners or disagreements between us and our partners 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 partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely limit the number of product candidates that we would be able to develop and commercialize, significantly increase our need for capital and/or place additional strain on management's time, any of which could materially harm our business, financial condition and results of operations. Furthermore, as discussed above, we cannot assure you that we would be able to establish the necessary internal product development and commercialization capabilities to develop and commercialize our product candidates ourselves in a timely matter or at all, or that any product development or commercialization activities we carry out would be successful.

**We rely on our partners' willingness and ability to devote resources to the development and commercialization of our products and product candidates and to otherwise support our business as contemplated in our partnership agreements, which may be terminated.**

We rely on our 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, we have granted Janssen worldwide exclusive rights to develop and commercialize daratumumab, have granted Novartis worldwide exclusive rights to develop and commercialize ofatumumab, and have also entered into partnerships with AbbVie, Seagen and BioNTech for certain of our proprietary product candidates. In addition, we have granted Janssen and Novo Nordisk certain rights to develop product candidates using our DuoBody technology platform. We have also created product candidates that have been out-licensed to Janssen, Roche, Bristol-Myers Squibb ("**BMS**"), ADC Therapeutics, Lundbeck and Amgen, and have entered into a research collaboration and exclusive license agreement with Immatics Biotechnologies GmbH, or Immatics, to discover and develop potential next-generation bispecific immunotherapies to target multiple cancer indications. We have also entered a research collaboration and license agreement with CureVac AG to develop differentiated mRNA-based antibody products and an exclusive license and option agreement with

Janssen to develop a next-generation CD38 product using our HexaBody technology platform. As part of our partnership with AbbVie we will also enter into a discovery research collaboration to select and develop up to four additional differentiated next-generation antibody-based product candidates, potentially across both solid tumors and hematological malignancies. If we do not realize the contemplated benefits from our collaborations, our business, financial condition and results of operations may be materially harmed.

In particular, the termination of our key partnerships could significantly delay the development and commercialization of our products and product candidates and impact our financial results and future prospects. Our licensing partners generally have the right to terminate our partnerships with notice at any time. For example, Janssen has the right to terminate our collaboration agreement concerning daratumumab with 150 days' written notice to us, Novartis has the right to terminate the co-development and collaboration agreement concerning ofatumumab at any time by providing nine months' prior written notice to us, and Seagen has the right to opt out of co-development and profit-sharing of tisotumab vedotin in return for receiving milestone payments and royalties from us. In particular, any disruption to our collaboration with Janssen or changes in Janssen's product development or business strategy for daratumumab could result in a material decline in our revenue. In addition, any failure by Janssen to perform its obligations under our agreement for any reason, including its obligations to make milestone payments or pay royalties, could have a material adverse effect on our financial performance. Our near-term prospects for product development and commercialization could also be significantly impacted by any disruption in, or termination of, our collaborations with Seagen and AbbVie for tisotumab vedotin and epcoritamab, respectively.

We also rely on our 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 partners subjects us to a number of additional risks, including the following:

- our 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 partners may devote to the development, commercialization, marketing and distribution of products or product candidates;
- our partners may not develop products generated using our antibody technology as expected;
- disputes between us and our 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;
- we may not receive milestone payments from our partners, at the expected time or at all, if our partners do not achieve future milestones or if we and our partners disagree about whether a milestone has been reached;
- with respect to collaborations under which we have an active role, we and our 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;
- our partners may delay, 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 partners may divert significant time and effort of our scientific staff and management team;

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

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

- business combinations, financial difficulties or significant changes in a partner's business strategy, including as a result of the COVID-19 pandemic, may adversely affect that 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 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.

**If our license agreements violate the competition provisions of the EC Treaty, then some terms of our key agreements may be unenforceable.**

Certain license agreements that we have entered into, or may enter into, will grant or may grant exclusive licenses of patents, patent applications and know-how and, therefore, might be found to be restrictive of competition under Article 81(1) of the EC Treaty. Article 81(1) prohibits agreements which restrict competition within the European Community and affect trade between member states. We determine on an agreement-by-agreement basis whether an existing exemption from the application of Article 81(1) applies to the agreement. If an exemption is not applicable, provisions of any license agreement which are restrictive of competition under Article 81(1), including those relating to the exclusivity of rights, may be unenforceable and we could lose the benefit of the rights granted under the provision and may be ordered to pay fines and damages to third parties.

**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. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA, the EMA and any other comparable regulatory authority, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of these product candidates.**

The FDA, the European Medicines Agency ("**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 partners must provide these regulatory authorities with data from pre-clinical studies 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. DARZALEX, Kesimpta and TEPEZZA are our only approved products. We cannot be certain that our or our 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 or reimbursement of approved products or validations or endorsements of treatment options. Such third parties may require additional data or studies for their determinations.

Pre-clinical studies and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays or failure. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years and require significant expenditures to complete the pre-clinical studies and clinical trials necessary to commercialize a product candidate, and delays or failures are inherently unpredictable and can occur at any stage. Topline or interim results of clinical trials do not necessarily predict final results, and success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the 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 partners will not face similar setbacks. If topline or interim data that we or our partners report differ from final results, if others, including regulatory authorities, disagree with our assumptions, calculations, conclusions, or analyses or interpret or weigh the data differently, or if subsequent studies are unsuccessful, we or our 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.

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. In addition, advancements or changes in the industry standards or techniques may impact the value and recognition of our and our partners' clinical data. Failure to adopt new industry standards may result in less comparable or useful study 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 partners to change the design of our clinical trials. For example, Janssen has selected minimal residual disease ("**MRD**"), an emerging efficacy endpoint in MM, as the primary endpoint in the Phase III CEPHEUS trial of daratumumab in combination with VRd for the treatment of frontline MM and in the Phase III AURIGA trial of daratumumab in combination with lenalidomide as maintenance treatment for MM patients who are MRD positive after frontline autologous stem cell transplant.

Although these trials include more conventional measures as secondary endpoints, such as progression free survival ("**PFS**") and overall survival ("**OS**"), this design may not be sufficient to obtain regulatory approval, and Janssen may be required to change the design of these trials or conduct additional trials to obtain regulatory approval for these indications. Similarly, limitations of MRD as an endpoint may result in a need for more comprehensive results. Changing the design of a clinical trial can be expensive and time-consuming. 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 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. In addition, 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 partners have the exclusive right to commercialize our product candidates.

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

- we or our 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;
- 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 study, by regulatory authorities or by us or our partners due to failure to meet clinical protocols, safety issues or adverse effects, failure to demonstrate product

efficacy, changes in clinical protocols or applicable regulatory requirements, lack of funding or other factors;

- investigators or other third parties could conduct clinical studies 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 studies on long-term tolerance could invalidate the use of our product;
- final results of studies may not confirm positive interim results or the results of earlier trials;
- results may not meet the level of statistical significance required by the FDA, the EMA or other relevant regulatory agencies to establish the safety and efficacy of our product candidates for continued trial or marketing approval;
- 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 partners or contract research organizations ("**CROs**"), may be unable or unwilling to perform under their contracts.

Furthermore, 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 studies 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 may be 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 commercialization of our product candidates may be delayed, and we may not be entitled to receive certain contractual payments, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

**Results of pre-clinical or early clinical trials may not be indicative of results obtained in later clinical trials, the timing and outcomes of which are always uncertain, and our product candidates may not successfully complete clinical trials on our expected timeline or at all.**

Even if we or our 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, the results of early stage clinical trials are based on a limited number of patients and may, upon further review, be revised or negated by regulatory authorities or by later-stage clinical results. Historically, industry-wide results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Industry-wide, a number of new drug and biologic candidates have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including emerging knowledge or changes in regulatory policy during the period of product development.

Clinical trials may not demonstrate statistically sufficient levels of safety and efficacy to obtain the requisite regulatory approvals. 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.

**We rely on third parties to conduct our clinical trials and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.**

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 partner is responsible for clinical development, we rely on such partners to conduct clinical trials. These partners may also hire CROs or other third parties to conduct clinical studies on our products and product candidates. The third parties with whom we and our 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. The FDA and regulatory authorities in Europe and other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices ("**cGCPs**"), for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. 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 studies or trials.

**We and our partners have conducted and intend to conduct additional clinical trials for selected products and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations due to the study design and conduct, trial population or for other reasons, or may require additional U.S.-based trials.**

We and our partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly 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. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with cGCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any clinical trials that we or our 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. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our and our partners' ability to conduct clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

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

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 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 study 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 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 partners' clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. We expect that we and our 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 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 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 partners' ability to advance the development of our product candidates.

**Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics, or to enter into successful commercial arrangements for such diagnostics, could harm our development strategy.**

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the product candidates we are developing. Through collaborations, we may develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics 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. We expect that we may develop companion diagnostics in collaboration with third parties and may be dependent on the scientific insights and sustained cooperation and effort of such partners in developing and obtaining approval for companion diagnostics. We and our partners may encounter difficulties in developing and obtaining approval for any companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by us or our partners to obtain regulatory approval of companion diagnostics could delay or prevent approval of our product candidates. In addition, we or our partners may encounter production difficulties that could constrain the supply of the companion diagnostics, and may experience difficulties gaining acceptance of the use of such companion diagnostics in the clinical community. Failure to gain market acceptance of such companion diagnostics could have an adverse effect on our or our partners' ability to successfully commercialize such product candidates. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we or our partners anticipate using in connection with development and commercialization of our product candidates, or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative companion diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

**We are subject to extensive and costly government regulation, and are required to obtain and maintain governmental approvals to commercialize our products.**

Product candidates employing our antibody technology are subject to extensive and rigorous government regulation. The FDA, the EMA and similar regulatory agencies in other countries regulate the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. The regulatory review and approval or licensing process is lengthy, expensive and uncertain and requires the submission of extensive pre-clinical and clinical data and supporting information for each indication to establish the product candidate's safety and efficacy. We or our partners may be unable to obtain regulatory approval on the basis of such data if the relevant regulatory authorities disagree with the design or implementation of the clinical trials, determine that the results of such trials do not meet the requisite level of statistical significance, disagree with our or our partners' interpretation of such data, determine that we or our partners have not demonstrated the safety and efficacy of the product candidate or that its benefits outweigh its risks or fail to approve the manufacturing processes or facilities for the product candidate. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, particularly as we move towards the commercial stage of our product candidates, we may be required to report some of these relationships to the FDA or other regulatory authorities, as well as to certain national registers or other applicable agencies. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. We have not

obtained regulatory approval for any of our proprietary product candidates and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Even if we or our partners are able to obtain approval for our products or product candidates, regulatory authorities may grant approval for fewer or more limited indications than requested, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

In addition, once a product obtains regulatory approval, numerous post-approval requirements apply, including periodic monitoring and reporting obligations, review of promotional material, reports on ongoing clinical trials and adverse events and inspections of manufacturing facilities. In addition, material changes to approved products, including any changes to the manufacturing process or labeling, require further review by the appropriate authorities before marketing. Approvals may also be withdrawn or revoked due to safety, effectiveness or potency concerns, including as a result of adverse events reported in patients or ongoing clinical trials, or failure to comply with cGMPs. In addition to revocation or withdrawal of approvals, we and our partners may be subject to warnings, fines, recalls, criminal prosecution or other sanctions if we fail to comply with regulatory requirements. If we or our partners are unable to obtain or maintain regulatory approvals for our products and product candidates, our business, financial condition, results of operations and future growth prospects will be negatively impacted and we or our partners may be subject to sanctions. In addition, even if our products are approved for marketing, we or our partners may be unable to market our products, successfully or at all, if we are unable to obtain favorable pricing for our products or if third-party payors do not agree to provide reimbursement for our products, at favorable rates or at all. See “—Risks Related to Government Regulation” below for more information about the regulatory risks we and our partners face.

**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 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 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.

**Reports of adverse or undesirable events or safety concerns involving daratumumab, ofatumumab, teprotumumab or our proprietary or partnered product candidates could delay or prevent us or our partners from obtaining or maintaining regulatory approvals, or could negatively impact sales and prospects of our products and product candidates.**

As with most biological drug products, use of our products and product candidates could be 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 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 could 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 partners’ clinical trials, regulatory processes, reputation and results.

Such adverse events or safety concerns involving our products or product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or could negatively impact patient enrollment in, or completion of,

clinical trials. For example, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination arm of the study. Based on these findings, a Phase I study of daratumumab and Janssen's proprietary anti-PD-1 antibody for the treatment of patients with MM was also terminated. In addition, in June 2018, a Phase I study of JNJ-63709178, one of the product candidates being developed by Janssen through our DuoBody collaboration was put on clinical hold due to the occurrence of a Grade 3 adverse event. This hold was subsequently lifted and the study is ongoing. However, there can be no assurance that this study will not be halted again or terminated in the future. The Phase I/II clinical trial for our HexaBody-DR5/DR5 product was put on a brief partial clinical hold for discussions with the U.S. FDA around liver toxicity. After the protocol was amended with additional provisions to mitigate liver toxicity risk the partial hold was lifted in October 2019 and enrollment of patients was re-opened. The study is currently recruiting, but there can be no assurance that this study will not be halted again in the future.

In addition, reports of adverse events or safety concerns involving our products or product candidates could result in regulatory authorities 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 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 could 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 could prevent us or our partners from developing, commercializing or maintaining market acceptance of daratumumab, ofatumumab, teprotumumab or the particular product candidate or could substantially increase commercialization costs, which 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 to distribute our products.

In addition, the reporting of adverse safety events involving daratumumab, ofatumumab or our product candidates, or public rumors about such events, could cause our stock price to decline or experience periods of volatility. There are no assurances that patients receiving daratumumab, ofatumumab, teprotumumab or our product candidates will not experience serious adverse events in the future.

**We have received Fast Track Designation ("FTD"), and Breakthrough Therapy Designation ("BTD"), for certain indications in the past and may seek FTD or BTD, or may seek to participate in other programs for expedited development or review, in the future. We may fail to obtain such designation and may not be eligible for participation in such programs, and even if received, such designations or programs may not lead to a faster development or regulatory review or approval process.**

If a product candidate is intended for the treatment of a serious or life-threatening disease or condition, and pre-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may apply for FTD from the FDA for such indication. Similarly, the FDA may grant BTD to expedite the development and review of products that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that

the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." In addition, the FDA or other regulatory bodies periodically introduce other programs for expedited review of applications, including the FDA's Real-Time Oncology Review ("**RTOR**"), Pilot Program, which is currently available for certain supplemental applications for already-approved cancer drugs, and the FDA's priority review designation. The RTOR Pilot Program allows the FDA to review data before the applicant formally submits its completed supplemental application, resulting in a more efficient review when the applicant submits the full supplemental application. Priority review is an FDA designation under which the FDA sets the target date for FDA action on a BLA or supplemental BLA ("**sBLA**") at six months after the FDA accepts the application for review, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition.

Although these designations and pilot programs are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant these designations or include product candidates within pilot programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even if we or our 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 denied based on study data, study design or other factors. See also "—We and our partners have conducted and intend to conduct additional clinical trials for selected products and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations due to the study design and conduct, trial population or for other reasons, or may require additional U.S.-based trials." See "Item 4.B—Business Overview—Government Regulation" for more information about BTD and FTD and other programs for expedited review.

Daratumumab has received BTD for three indications of R/R MM and FTD for one indication of R/R MM and teprotumumab has received BTD and FTD for the treatment of Graves' Orbitopathy (also known as thyroid eye disease). These products have been approved for each of the designated indications and these designations are not applicable to ongoing studies for daratumumab and teprotumumab in other indications. We or our partners may seek FTD or BTD or seek eligibility for other expedited review or approval programs for some or all of our other product candidates in the future, but we may never receive such designation or be accepted to such program, and, even if received or accepted, the development or regulatory review of our product candidates may not be expedited or benefited by such designation or program. In addition, such designation or acceptance to such program does not assure ultimate approval by the FDA or the applicable regulatory body.

**Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us or our partners to modify such programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.**

To help patients afford our products, certain of our partners have, and we may have in the future, patient assistance programs and we or our 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 or our partners' 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. For example, the Office of Inspector General of the U.S. Department of Health & Human Services ("**OIG**"), has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. If we, our 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 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 the OIG and other enforcement 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 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.

**We currently rely on a limited number of contract manufacturers to produce our product candidates for clinical trials and are currently negotiating arrangements for commercial scale production.**

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, Novartis for the manufacture of ofatumumab, Horizon is responsible for the manufacture of TEPEZZA, and Seagen will be responsible for the manufacturing of tisotumab vedotin. For the 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.

We are aware of only a limited number of companies on a worldwide basis who 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 study, which could result in loss if we terminate the study or need to make changes to the product.

**We and our manufacturing partners must obtain and maintain compliance with applicable laws and regulations, including cGMPs.**

Before commercializing 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 manufacture, 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 study materials in our pre-clinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of pre-clinical study or clinical trial materials could delay the completion of our pre-clinical studies and clinical trials, increase the costs associated with maintaining our pre-clinical study and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the studies and trials completely.

In addition, we have little 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 partners may not be able to obtain regulatory approval for or successfully commercialize such products, and we or our 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, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or earlier than we anticipate.**

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to antibody therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. 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. 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. 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. For example, Sanofi's isatuximab, a mAb targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. Genentech's ocrelizumab, a mAb targeting CD20, was approved as Ocrevus by the FDA initially in 2017 and is currently approved for RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. We are also aware of other companies that have or are developing technologies that may be competitive with ours, including bispecific, ADC, CAR modified T-cell ("**CAR-T**"), and ribonucleic acid ("**RNA**")-based, technologies. 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 4.B—Business Overview—Competition" below for more information about our competitors.

In addition, 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. 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. In addition, 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 in approving 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. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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, or 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 depend, 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 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.

**Our products may face increasing pricing and reimbursement pressure through government and third party decisions to reduce cost or limit physician choice. We may face increased competition from lower-cost products imported from other countries.**

The success of our currently commercialized products as well as that of our future potential product launches depends, in part, on the access, pricing and reimbursement environment. There is increasing pricing & reimbursement pressure in many countries that is manifested through government and third party price controls, increased public pressure on price increases, increasing cost containment and formulary restriction policies including but not limited to reference pricing, health technology assessment, pathways, contracting, as well as regulatory reform intended to limit health care provider and patient choice and/or reduce the cost of medicines.

Any products we or our 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, leading to reduced revenues and lower sales margins, 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. The ability of patients and other customers to obtain these lower-priced imports has grown significantly. Some of these foreign imports are illegal under current 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.

**Even if any of our product candidates receive marketing approval or if any of our marketed products receive marketing approval for additional indications, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.**

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 payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well-established in the medical community, and doctors may continue to rely on these treatments. If our products or product candidates do not achieve an adequate level of acceptance, our commercial opportunity may be limited and/or our revenues from sales of these products may be negatively impacted. The degree of market acceptance of our product candidates and new indications for our marketed products, if approved for commercial sale, will depend on a number of factors, including the price, efficacy, safety, convenience and ease of administration of such products, along with their competitive advantages vis-à-vis other therapies, designation as a first-, second- or third-line treatment and any labeling restrictions or warnings. The processes developed for safe administration and any changes to the standard of care for the targeted indications may also have an impact on market acceptance of such products. The willingness of the target patient population to try, and of physicians to prescribe, the product, as well as the availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors are also key factors that impact market acceptance of a new product. In addition, the strength of the sales, marketing and distribution support provided by us or our partners will play a key role in the effective commercialization of a new product.

**Our target patient population may be lower than our estimates and we may be unable to recoup our investment due to small patient population or restrictions to the approved indication of a product.**

Periodically, we and our partners make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party 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, all of which could materially adversely affect our business, financial condition, results of operations and future growth prospects.

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 candidate without obtaining regulatory approval for additional indications for such product candidates. In addition, we expect that we or our 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. For product candidates that prove to be sufficiently beneficial as second- or third-line therapies, we expect that we or our partners would seek approval of such products as a second-line therapy (with respect to products initially approved as third-line therapies) and/or as frontline therapies. However, such applications may require us or our partners to conduct additional clinical trials at significant cost and risk, and there can be no assurance that such clinical trials or regulatory applications would be successful. If we or our 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 may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to obtain this capital when needed may force us to delay, limit or terminate our product development efforts or other operations.**

We are currently advancing our proprietary product candidates through clinical development and are conducting pre-clinical studies with respect to other programs. Developing product candidates is expensive, time-intensive and risky, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we seek to advance our proprietary product candidates toward commercialization. In addition, we expect our general and administrative expenses to increase over the next few years as we continue to build and eventually

expand our commercialization capabilities in a number of jurisdictions. Although we believe that our existing revenue streams 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. 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 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.

**We expect to incur higher research and development costs and general and administrative expenses in future periods as we advance our proprietary product candidates through clinical development and expand our commercialization capabilities.**

We expect to incur higher research and development costs in future periods, including increasing costs for clinical trials and manufacturing as our proprietary product candidates advance in clinical development and as we increase the number of product candidates under active clinical development. Our ongoing research and development and, increasingly, pre-launch commercial activities will require substantial amounts of capital and may not ultimately be successful. Over the next several years, we expect that we will continue to incur substantial expenses, primarily as a result of activities related to the continued development of our clinical pipeline and the build-up of our late-stage development and commercialization capabilities. Our proprietary product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop into commercially viable products, if at all. Our commitment of resources to the research and continued development of our product candidates and the expansion of our pipeline will likely result in our operating expenses increasing and/or fluctuating as a result of such activities in future periods. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

We also expect our general and administrative expenses to increase over the next few years as we continue to build and eventually expand our commercialization capabilities in a number of jurisdictions. In addition, we expect the structure and composition of our staff and expenses to change as we focus on advancing our proprietary product candidates and develop our late-stage development and commercialization capabilities.

**We have revenues and expenses in foreign currencies and we have invested a part of our cash position in both Danish and foreign marketable securities and are therefore exposed to different kinds of financial risks including foreign exchange risk, changes in interest rates and credit risks.**

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, Novartis 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 Danish kroner 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 Danmarks Nationalbank 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 financial risks 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 adequate, 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, loss of any potential future revenue and a decline in the market price of our ADSs.

**Our internal computer systems, or those of our partners or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our business and product development.**

Our computer systems, including those hosted by third parties, and those of our partners and other contractors or consultants, may be vulnerable to cyber security breaches, computer viruses and unauthorized access, as well as damage or loss of data due to natural disasters, terrorism, war and telecommunication and electrical failures. Our vulnerability to such events may increase while employees work remotely during the COVID-19 pandemic and in the future. Employees may have to use their own devices without dedicated support and security, the number of devices used by employees and the amount of traffic on secured corporate networks can increase, and preventing unauthorized access to networks may be more challenging. These and other factors can be exploited to facilitate phishing, malware 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 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 you 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 investment.

**As a result of the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the Foreign Corrupt Practices Act.**

As a result of the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the Foreign Corrupt Practices Act ("**FCPA**"), which generally prohibits companies and their intermediaries from making or offering improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The FCPA generally also 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 amended written code of business conduct and other policies and procedures to assist us and our personnel in complying with the FCPA and other applicable anti-bribery laws. However, 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.

**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, as many jurisdictions have prohibited international travel and implemented social distancing, quarantine and similar measures for their residents to contain the spread of the coronavirus. COVID-19 is also expected to put a strain on the healthcare systems in the major countries where our partners sell our products and where we and they conduct our clinical trials. The COVID-19 pandemic may be prolonged and may have long-term impacts on the development, regulatory approval and commercialization of our product candidates and on sales of our approved products. The longer the pandemic continues, the more severe the impacts described below will be on our business. The extent, length and consequences of the pandemic are uncertain and impossible to predict. Genmab has established a COVID-19 response team, led by the Chief Executive Officer, which is closely monitoring the evolving situation and has developed and implemented precautionary measures, including remote working for the majority of Genmab employees with a small subset of employees on-site to maintain critical laboratory activities that cannot be done remotely. The response team issues regular updates to employees with guidance to help limit the impact of COVID-19 at our workplace and on our communities and ensure business continuity.

The continued spread of COVID-19 globally could adversely affect our and our 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 and travel restrictions and social distancing impede patient and staff mobility. This is expected to 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. As the COVID-19 pandemic and global measures to contain it are still developing, the

full extent of the impact of COVID-19 on the clinical development of our product pipeline cannot currently be determined, although such impact may be significant.

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 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 preclinical 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. For example, this could cause a delay in the approval by U.S. and European regulatory authorities of daratumumab based on the Phase III APOLLO study, a delay in the approval by European regulatory authorities of daratumumab for the treatment of AL amyloidosis based on data from the ANDROMEDA study and ofatumumab for the treatment of RMS based on data from the ASCLEPIOS studies and a delay in the approval by U.S. regulatory authorities of tisotumab vedotin for the treatment of cervical cancer based on data from the innovaTV 204 study.

Disruption in shipping and manufacturing may also negatively affect our supply chain, causing our 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 partners' clinical trials. 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 has dramatically restricted manufacturing capacity available for the production of TEPEZZA at Horizon's drug product contract manufacturer, Catalent. Prolonged disruption in the supply of TEPEZZA or other of our or our 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 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 continue to affect sales of DARZALEX for existing indications, which could reduce our royalty income 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.

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. 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 Kesimpta and TEPEZZA, by our partners and on our royalty and milestone income therefrom.

***Risks Related to Our Intellectual Property***

**Our ability to compete may decline if we or our partners are unable to or do not adequately protect intellectual property rights or if our intellectual property rights are inadequate for our products, product candidates or future products or product candidates.**

Our commercial success and viability depend in part on our and our 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 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 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 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 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 partners' pending or any future patent applications may not result in issued patents;
- any patents issued to us or our 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 partners' technologies, compositions and methods may not be patentable;
- others may design around our or our 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; or
- 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 partners' patents.

**Patent applications may be denied. Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in court. Patents issued to our partners may not entitle us to royalties on the products that they protect.**

Any or all of our or our partners' pending or any future patent applications may not result in issued patents. The determination of patentability by the relevant patent office is complex and may take several years, the breadth of allowed claims is uncertain, and the patent applications may ultimately be denied or result in issued patents with allowed claims that differ from those in the original application. 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 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 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.

In administrative and court actions, grounds for a patent validity challenge may include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness (lack of inventive step) and in some cases, lack of sufficiently teaching, or non-enablement of, the claimed invention. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the patent examiner during prosecution in the USPTO, the EPO or elsewhere, or made a misleading statement during prosecution in the USPTO. Third parties may also raise similar claims before administrative bodies in the USPTO or the EPO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner were unaware during prosecution.

Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been cited in every patent office. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technologies, products, product candidates, compositions and methods of use.

Patents issued to our partners may offer protection for sales of the relevant products by our partners against competition from biosimilars or otherwise, but we will only be entitled to royalties and other payments on those sales to the extent provided by the terms of the relevant agreements with our partners.

**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 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. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. 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 partners may have the right to terminate the license. Under the terms of some of the relevant agreements, our 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, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.**

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 partners or customers in our markets of interest, thus this could materially harm our business and negatively affect our position in the marketplace.

In addition, the standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. 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 costly litigation, and unfavorable outcomes could require us to pay damages or royalties and could limit our research and development activities or our ability to commercialize certain products.**

Even if we or our partners have or obtain patents covering our technologies, products, product candidates, compositions or uses, we or our 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 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 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 patent 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 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 partners' technologies, products, product candidates, compositions or their uses infringe or interfere with the patent rights of third parties, or that we or our 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. The basis of such litigation could be existing patents or patents that are granted in the future. If we or our partners were to face infringement claims or challenges by third parties, an adverse outcome could subject us or our 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 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. Litigation with third parties concerning alleged infringement of their intellectual property rights could require us and our partners to bear substantial costs and impose burdens on our and their management and personnel, even if we or our 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 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 partners to seek legal or administrative actions against third parties. We or our 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.

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

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, 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.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technologies. Competitors could purchase our products and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technologies, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technologies and know-how may incorporate such technologies and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technologies or know-how, and any such dispute may not be resolved in our favor. 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 and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and processes, our competitive position could be adversely affected, as could our business.

**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. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications due in several stages over the lifetime of patents or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. 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 less extensive 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. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings and legal actions to enforce our patent rights in the United States or in Europe and in foreign jurisdictions can be expensive, could result in substantial costs, and could divert management time and our efforts and attention from other aspects of our business. In addition, such proceedings or legal actions could put our patents at risk of being invalidated, found unenforceable or interpreted narrowly, could put our patent applications at risk of not being issued and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may or may not choose to pursue litigation or other actions against those that have infringed our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

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 adequate protection for our technologies, products, product candidates or compositions or uses thereof and the enforcement of intellectual property.

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.

**Third parties may challenge the inventorship of our patent filings and other intellectual property or may assert ownership or commercial rights to inventions we develop.**

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with our 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.

**Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products and processes.**

Recent patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, Leahy-Smith America Invents Act ("**Leahy-Smith Act**") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the United States patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had conceived or reduced to practice the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

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.

Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our partners fail to maintain the patents and patent applications

covering our products, product candidates, technologies or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

**Patent terms may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.**

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our products and product candidates are obtained, once the patent term has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or product candidates similar or identical to ours.

**Third parties may assert that our employees or consultants or we have wrongfully used or disclosed confidential information or misappropriated trade secrets, or claim ownership of what we regard as our own intellectual property.**

Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and could otherwise adversely impact our business.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

**Our collaboration and intellectual property agreements with our partners or other third parties may be interpreted differently by us and our 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 partners or other third parties. From time to time, we have discussions or disagreements with our partners or other third parties regarding the interpretation of our contracts with them. 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.

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

Our 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 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 candidate 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 payor 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 payors, such as U.S. government health care programs like Medicare and Medicaid, commercial insurance and managed healthcare organizations. These third party payors 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 payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors 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. The primary trend in the U.S. healthcare industry and elsewhere has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products and/or biosimilars. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations. Accordingly, in markets outside the United States, 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 payors. 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. For example, Medicare reimbursement under the Medicare Physician Fee Schedule is updated on an annual basis. The Medicare Access and CHIP Reauthorization Act of 2015 instituted a 0.5% payment update for July 2015 through the end of 2019, and a 0% payment update for 2020 through 2025, along with a merit-based incentive payment system beginning January 1, 2019, that will replace current incentive programs. For 2026 and subsequent years, the payment update will be either 0.75% or 0.25% depending on which Alternate Payment Model the physician participates.

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 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 payors 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.

**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 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. For example, the U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. 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 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, 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 regulated 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 studies or to conduct new studies 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. Certain approvals of DARZALEX and Arzerra in the European Union were initially granted on the basis of conditional marketing authorizations. Each of these conditions have been met.

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 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 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 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. We expect more rigorous coverage criteria in the future in the U.S. healthcare market and an additional downward pressure on the prices that we or our partners receive for approved products, which may trigger a similar reduction in payments from private payors. If we or our 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 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 by the former administration 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 legislation or executive action or the impact of potential legislation or executive action on us. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes 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 to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, 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 customers for our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

Furthermore, the former Trump Administration has taken several executive actions, including the issuance of a number of executive orders, which could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuing guidance, and reviewing and approving marketing applications. It is difficult to predict how these orders will be implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority, or whether they will be rescinded or replaced. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, we and our partners could be limited and/or delayed in obtaining new regulatory approvals or maintaining existing approvals, either of which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

**We are subject to various laws protecting the confidentiality of certain patient health information, and our failure to comply could result in penalties and reputational damage.**

Numerous countries in which we, our 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 patient health information. 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**"), which became applicable on May 25, 2018, introduced new data protection requirements in the European Economic Area (the 28 member states of the European Union plus Iceland, Liechtenstein and Norway), ("**EEA**"), and substantial fines for infringements of the data protection rules. For several EEA jurisdictions, the GDPR expanded significantly the jurisdictional reach of EEA data protection law by extending the law's application to the processing of personal data in connection with the offering of goods or services to data subjects located in the EEA and processing personal data in connection with monitoring the behavior of data subjects located in the EEA. The GDPR imposes several increased obligations and specific restrictions on controllers and processors processing personal data including, for example, additional requirements in relation to the information obligation, where applicable, higher standards for organizations to demonstrate compliance, such as obtainment of valid consent or assessment of another legal basis to justify the data processing activities, increased requirements pertaining to health data (including, in certain situations, where such data is key-coded), mandatory data breach notification requirements, appointment of a data protection officer where the core activities of the controller or the processor consist of processing of sensitive personal data (i.e., health data) on a large scale, additional mandatory requirements for the content of data processing agreements with service providers processing personal data, implementation of appropriate technical and organizational measures and expanded rights for individuals over their personal data. This could affect our and our partners or third-party contractors' ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, potentially leading to harm to our business and financial condition. If the measures implemented by us or our 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.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the EEA, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data), meaning that inconsistencies between different member states will still arise. EEA member states have their own regimes on medical confidentiality and national and EEA-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the EEA.

In addition to the GDPR, we, our 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.

**Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.**

As a biotechnology company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We, our partners and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, 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. We cannot guarantee that the safety procedures utilized by our 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, 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, which may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.**

Healthcare providers, such as physicians and others, play a primary role in the recommendation and prescription of our products. Our or our partners' arrangements with such persons and third-party payors and our general business operations will expose us or our 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 Health Insurance Portability and Accountability Act of 1996, as amended ("**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 be 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. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, 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 operations. If the physicians or other providers or entities

with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. For more information about these and other applicable regulations, see ''Business—Government Regulation'' below.

**Our employees and partners may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements, which could significantly harm our business.**

We are exposed to the risk of fraud or other misconduct of our employees and partners. Misconduct by our partners 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 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 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.

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

**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. Holders of ADSs have contractual ADS holder rights. The deposit agreement among us, the depositary and all persons directly or indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. ADS holders may only exercise voting rights with respect to the shares underlying their respective ADSs in accordance with the provisions of the deposit agreement, which provides that holders may vote the shares underlying their ADSs either by withdrawing the shares or by instructing the depositary to vote the shares or other deposited securities underlying their ADSs. However, holders may not know about the meeting sufficiently in advance to withdraw the shares and, even if they instruct the depositary to vote the shares underlying their ADSs, we cannot guarantee you that the depositary will vote in accordance with the holders' instructions. Please see the risk factor entitled "—Holders may not be able to exercise their right to vote the shares underlying their ADSs."

In addition to voting rights, holders' right to receive any dividends we declare on our shares, whether in the form of cash or bonus securities, is also more limited than that of our shareholders. For example, we may elect to offer subscription rights to our shareholders without offering such rights directly to ADS holders as such subscription rights will be offered to the depositary as shareholder. The depositary has substantial discretion as to what will happen with any offered subscription rights and may determine that it is not legal or reasonably practicable to make such rights available to ADS holders, in which case the depositary will endeavor to sell such rights and distribute the proceeds to ADS holders, which it may not be able to do at the then-current market price or at all. If the depositary is unable to distribute or sell such rights, they will lapse, and ADS holders will receive no value. 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.

**The trading price of our equity securities may be volatile due to factors beyond our control, and holders of the ADSs could incur substantial losses.**

The market prices of the ADSs and shares may be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for the ADSs and shares may be influenced by many factors, including, but not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- the release of new data from the clinical trials of our products and product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- currency fluctuations;
- price and volume fluctuations attributable to inconsistent trading volume levels of our ADSs;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies, products and product candidates;
- changes to coverage policies or reimbursement levels by commercial third party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- issuances or sales of our shares or ADSs by us, our insiders or our other shareholders or ADS holders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares or ADSs at a favorable price or at all, and may otherwise negatively affect the liquidity of the trading market for our ADSs. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of shares or ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit, the attention of our senior management would be diverted from the operation of our business, and we could incur significant liabilities, any one of which could have a material adverse effect on our business, financial condition and results of operations.

**If securities or industry analysts do not publish research or 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. We are currently followed by analysts, but there can be no assurance that these analysts will continue to follow us or that additional securities or industry analysts will commence coverage of us. If no or only limited securities or industry analysts cover our company, the trading price for the ADSs would be negatively impacted. 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 ceases coverage of our company or 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.

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

ADS holders 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 you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities. 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.

**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 you 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 you 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 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 any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

**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 Stock Market**"), 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. We will next make a determination with respect to our foreign private issuer status on June 30, 2021.

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. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly greater than the costs we incur as a foreign private issuer. 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. Such conversion and modifications would involve additional costs. 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.