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

FORM 20-F

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

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

OR

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

Date of event requiring this shell company report:

Commission File number: 001-38976

Genmab A/S
(Exact name of Registrant as specified in its charter)

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

The Kingdom of Denmark
(Jurisdiction of incorporation or organization)

Kalvebod Brygge 43
1560 Copenhagen V
Denmark
(Address of principal executive offices)

Anthony Pagano
Executive Vice President and Chief Financial Officer
Genmab A/S
Kalvebod Brygge 43
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Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol	Name of each exchange on which registered
American Depositary Shares, each representing one-tenth of one ordinary share	GMAB	The NASDAQ Stock Market LLC
Ordinary shares, nominal value DKK 1 per share	GMAB	The NASDAQ Stock Market LLC*

* Not for trading, but only in connection with the registration of the American Depositary Shares on The NASDAQ Stock Market LLC.

Securities registered or to be registered pursuant to Section 12(g) of the Act. **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

65,718,456 Ordinary Shares (including shares underlying American Depositary Shares)

42,750,240 American Depositary Shares

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

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

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

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

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

☐ US GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other

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

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

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INTRODUCTION

In this Annual Report on Form 20-F the terms the "Company", "Genmab", "we", "us", "our" and the "Group" refer to the parent company Genmab A/S together with its consolidated subsidiaries. The term "Genmab A/S" is used when addressing issues specifically related to this legal entity.

Pursuant to Rule 12b-23 of the Securities Exchange Act of 1934, as amended (the **"Exchange Act"**), we incorporate information for certain items of this Annual Report on Form 20-F by reference to certain pages of the Genmab A/S statutory Annual Report 2021 (the **"Annual Report 2021"**), included as Exhibit 99.1(a) to Form 6-K furnished to the U.S. Securities and Exchange Commission (the "**SEC**") on February 16, 2022 and by reference to certain pages of the Genmab A/S statutory Annual Report 2020 (the "**Annual Report 2020**"), included as Exhibit 99.1(a) to Form 6-K furnished to the SEC on February 23, 2021. Therefore, the information in this Annual Report on Form 20-F should be read in conjunction with the incorporated portions of the Annual Report 2021 and the Annual Report 2020. Items not contained or not specifically referenced to within the Annual Report 2021 or the Annual Report 2020 should not be deemed to be part of this Annual Report on Form 20-F.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding sales and net sales, clinical development, regulatory approvals and commercialization of daratumumab, amivantamab, ofatumumab and teprotumumab by Janssen Biotech, Inc ("**Janssen**"), Novartis International AG ("**Novartis**") and Horizon Therapeutics plc ("**Horizon**"), respectively;

- our expectations regarding sales, clinical development, regulatory approval and commercialization of tisotumab vedotin and our other proprietary and partnered product candidates;

- our expectations with regard to our ability to create and develop additional product candidates and to submit investigational new drug ("**IND**") applications and/or clinical trial applications ("**CTAs**") for our preclinical product candidates;

- our receipt of future milestone payments and royalties from our partners, and the expected timing of such payments;

- our estimates and expectations regarding the potential market size and the size of the patient populations for our products and product candidates;

- our expectations regarding the potential advantages of our products and product candidates over existing therapies or therapies currently in development;

- our expectations regarding the potential advantages of our proprietary technologies over existing antibody technologies and the prospects for our ongoing and future technology collaborations;

- our plans to expand our translational research platform and the potential benefits of such platform;
- our expectations with regard to the willingness and ability of our current and future partners to pursue the development, approval and commercialization of our products and product candidates;
- our and our partners' product discovery, development and commercialization plans with respect to our products and product candidates and our proprietary technologies;
- our potential to enter into new collaborations;
- our and our partners' ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals for our products and product candidates;
- our ability to identify, and to negotiate contracts with, suitable contract manufacturing organizations ("**CMOs**") and the ability of such CMOs to manufacture sufficient quantities of our products and product candidates for clinical trials or commercialization in compliance with current good manufacturing practices ("**cGMPs**") (as defined herein);
- our ability to identify, and to negotiate contracts with, suitable contract research organizations ("**CROs**") and the ability of such CROs to conduct clinical trials on our product candidates in compliance with current good clinical practices ("**cGCPs**") (as defined herein);
- the commercialization and market acceptance of our products and product candidates;
- our plans to continue to build our commercialization capabilities and to commercialize tisotumab vedotin or other proprietary product candidates in-house;
- the pricing of and reimbursement for our approved products;
- the implementation of our business model and strategic plans for our business, products, product candidates and technologies;
- our ability to operate our business without violating applicable laws and regulations;
- our and our partners' ability to operate our businesses without infringing the intellectual property rights and proprietary technology of third parties;
- the scope of protection we and our partners are able to establish and maintain for intellectual property rights covering our products, product candidates and technologies;
- our analysis of potential patent infringement claims and our or our partners' rights with respect to such claims;
- estimates of our future expenses and revenue;

- our expectations regarding regulatory developments in the United States, the European Union, Japan and other jurisdictions;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain suitably qualified employees and key personnel, particularly for our commercialization efforts;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing therapies and technologies.

The forward-looking statements contained herein involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements.

You should understand that many important factors, in addition to those discussed or incorporated by reference in this report, could cause our results to differ materially from those expressed in the forward-looking statements. Potential factors that could affect our results include, in addition to others not described in this report, those described under "Item 3.D—Risk Factors." These are factors that we think could cause our actual results to differ materially from expected results.

Forward looking statements speak only as of the date on which they are made, and we undertake no obligation to update any forward-looking statements or other information contained in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports on Form 6-K furnished or filed with the SEC. Please also see the cautionary discussion of risks and uncertainties under "Item 3.D—Risk Factors." This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We maintain our books and records in Danish kroner and report under International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board ("**IASB**"). None of the audited consolidated financial statements (the "**Audited Financial Statements**") included in our Annual Report 2021 and incorporated by reference into this Annual Report on Form 20-F were prepared in accordance with accounting principles generally accepted in the United States. We use the symbol "$" to refer to the U.S. dollar, "DKK" to refer to the Danish kroner and the symbol "€" to refer to the Euro herein. While our financial results disclosed herein are presented in Danish kroner, certain amounts paid or payable to or by us under certain of our collaborations are presented in the currencies in which payments under such collaborations are denominated.

All references to "shares" in this Annual Report on Form 20-F refer to ordinary shares of Genmab A/S with a nominal value of DKK 1 per share.

This Annual Report on Form 20-F includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this Annual Report on Form 20-F appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

This Annual Report on Form 20-F contains estimates, projections and other information concerning our industry, our business and the markets for our products and product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 3. D —Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Forward-Looking Statements" above.

ENFORCEABILITY OF CIVIL LIABILITIES

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

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

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

PART I

ITEM 1 IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2 OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3 KEY INFORMATION

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 3.D. "Risk Factors" in this Annual Report on Form 20-F. You should carefully consider these risks and uncertainties when investing in our ordinary shares or American depositary shares ("**ADSs**"). The principal risks and uncertainties affecting our business include the following:

- Our financial results and near-term prospects are substantially dependent on 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 and the markets in which it is approved and launched, or if our arbitration with Janssen is resolved in a manner adverse to us, our revenues and profitability will be adversely affected.

- Our future prospects for amivantamab are dependent on our partner Janssen's ability to successfully expand amivantamab's indications and the markets in which it is approved and launched, and to effectively commercialize it for its current indication and any new indications that may be approved as well as on other external factors that could impact amivantamab's future success.

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

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

- 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.

- We have a very limited history of commercializing our marketed products. Continuing to build our commercialization capabilities requires significant investment, time and management focus, and we are subject to potential market level challenges including competition and market access limitations. There can be no assurance that we will successfully expand our commercialization capabilities, or that we will successfully commercialize any of our product candidates in the future.

- We do not have sole control over the commercialization of tisotumab vedotin and we may be unable to effectively commercialize it.

- Our research and 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, or the proprietary technologies of our partners on which we rely, could negatively affect our business and financial condition.

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

- 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.

- 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 on a timely basis or at all.

- 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 U.S. Food and Drug Administration ("**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 as a condition of regulatory approval.

- Reports of adverse or undesirable events or safety concerns 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.

- 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.

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

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

- Our business and operations have experienced rapid growth as we have started to transform into a fully-integrated biotech, which could lead to adverse business impacts if such continued growth is not carefully managed.

- 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.

- 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.

- 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.

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

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

- 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.

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 and the markets in which it is approved and launched, or if our arbitration with Janssen is resolved in a manner adverse to us, our revenues and profitability will be adversely affected.

In 2021, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of multiple myeloma ("**MM**") and light-chain ("**AL**") amyloidosis, accounted for 77% of our revenue, as compared to 45% in 2020, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. Janssen is currently fully responsible for developing and commercializing daratumumab and all costs associated therewith. Consequently, our revenue and resulting operating profit and near-term prospects are substantially dependent on the success of this collaboration and on Janssen's continued ability to maintain and grow sales of daratumumab for its approved indications and to continue to expand its indications. There can be no assurance that Janssen will be successful in obtaining additional approvals for DARZALEX or additional jurisdictions or in maintaining existing regulatory approvals. The FDA approval based on the ANDROMEDA study in AL amyloidosis 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). There can be no assurance that, even with the recent expansions to the prescribing label for DARZALEX in the United States and the European Union, DARZALEX sales will remain at or near current levels or will continue to grow. In particular, DARZALEX is subject to intense competition in the MM therapy market. In addition to numerous other FDA approved treatments for the same indications, we are also aware of several additional investigational agents and technologies that are currently being studied for the treatment of MM, any of which may compete with DARZALEX in the future. In particular, Sanofi's isatuximab, a monoclonal antibody ("**mAb**") targeting CD38, was approved as SARCLISA by the FDA in March 2020 and in Europe in June 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor ("**PI**"). In March 2021 SARCLISA was approved by the FDA in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed or refractory MM who have received one to three prior lines of therapy. If Janssen is unable to successfully compete with these or other agents and technologies, DARZALEX sales could decline materially.

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.

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. 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. 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. 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 subcutaneous ("**SC**") 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*". If this arbitration is resolved in a manner that is adverse to us, our revenues and profitability will be adversely affected.

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.

Our future prospects for amivantamab are dependent on our partner Janssen's ability to successfully expand amivantamab's indications and to effectively commercialize it for its current indication and any new indications that may be approved and the markets in which it is approved and launched, as well as on other external factors that could impact amivantamab's future success.

Amivantamab has been approved in the United States and the European Union under the name RYBREVANT for the treatment of certain adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor ("**EGFR**") exon 20 insertion mutations. The two antibody libraries used to produce amivantamab were both generated by Genmab. The antibody pair used to create amivantamab was selected in collaboration between Genmab and Janssen with subsequent development work led by Janssen. Under the terms of Genmab's agreement with Janssen, Genmab has begun to receive royalties on net sales of RYBREVANT. Janssen is fully responsible for development and commercialization of amivantamab and all costs associated therewith. Consequently, the commercial success of amivantamab is dependent on the success of the activities of Janssen. We cannot control the amount and timing of resources that Janssen dedicates to the development and commercialization of amivantamab and our ability to obtain royalties related to amivantamab depends on Janssen's decision to continue to study amivantamab for new indications, to seek regulatory approvals for such indications and to effectively commercialize amivantamab for new and existing indications, and on the success of such efforts. Future prospects for RYBREVANT are also subject to the risk of potential competition in NSCLC. If Janssen is unable to successfully compete with other therapies, RYBREVANT's sales could be materially affected.

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

A SC formulation of ofatumumab has been approved for the treatment of certain relapsing forms of multiple sclerosis ("**RMS**") indications in the United States, the European Union and Japan under the name Kesimpta. Under our collaboration agreement, Novartis is fully responsible for the 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 intense competition in the RMS therapy market. There are numerous other products approved by the FDA for RMS, in particular Genentech Inc.'s (a subsidiary of the Roche Group, "**Genentech**") 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.

Our future prospects for teprotumumab are dependent on Horizon's ability to successfully expand teprotumumab's indications and the markets in which it is approved and launched, 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. Future prospects for TEPEZZA are also subject to the risk of potential competition in TED. If Horizon is unable to successfully compete with other therapies, TEPEZZA's sales could be materially affected.

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 currently includes seven proprietary product candidates including ongoing clinical studies for tisotumab vedotin, ongoing clinical studies for daratumumab and amivantamab by Janssen, ofatumumab by Novartis and teprotumumab by Horizon, and 10 additional product candidates being developed in collaboration with our partners. We also have approximately 20 proprietary and partnered product candidates in preclinical development. Other than teclistamab, in development by Janssen, inclacumab in development by Global Blood Therapeutics under an exclusive worldwide licensing agreement with Roche, Mim8, in development by Novo Nordisk, 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. For example, in September 2021, we and AbbVie Biotechnology Ltd. ("**AbbVie**") decided to stop the further development of DuoBody-CD3x5T4 and we decided to stop the further development of HexaBody-DR5/DR5, as clinical data was not supportive of continued development. 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 preclinical 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.

Additionally, with the exception of tisotumab vedotin, which received accelerated FDA approval in September 2021, 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 via licensing and development agreements to complete the development of our proprietary product candidates, which we may not be able to do on a timely basis, on terms favorable to us, or at all, and the development of our proprietary product candidates could be delayed or terminated. Our failure to effectively advance our development programs could have a material adverse effect on our business, financial condition, results of operations and future growth prospects, and cause the market price of our ADSs to decline.

We have a very limited history of commercializing our marketed products. Continuing to build our commercialization capabilities requires significant investment, time and management focus, and we are subject to potential market level challenges including competition and market access limitations. There can be no assurance that we will successfully expand 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 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 successfully commercializing tisotumab vedotin, marketed as Tivdak in the U.S, for the treatment of cervical cancer following the receipt of accelerated FDA approval in September 2021. We are developing tisotumab vedotin in collaboration with Seagen Inc. ("**Seagen**").

Our market-based commercialization operations continue to be 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 build and expand comprehensive commercialization capabilities will be successful.

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

We do not have sole control over the commercialization of tisotumab vedotin and we may be unable to effectively commercialize it.

Our initial commercialization efforts are focused on building our commercialization capabilities to market tisotumab vedotin for the treatment of cervical cancer, following receipt of accelerated approval for tisotumab vedotin from the FDA as Tivdak in September 2021. We developed tisotumab vedotin in collaboration with Seagen. Under our agreement, Seagen and Genmab are each responsible for leading tisotumab vedotin commercialization activities in certain territories. There is no guarantee that we and Seagen will be able to successfully commercialize tisotumab

vedotin. If we are unable to commercialize tisotumab vedotin for cervical cancer to the extent we anticipated, on the timeline we anticipated or at all, a portion of our investment may not realize gains and we may incur additional costs to refocus our efforts on other products or indications. This 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 with respect to certain markets. 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 otherwise compromised, 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.

Our research and 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, or the proprietary technologies of our partners on which we rely, 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, DuoBody-PD-L1x4-1BB and DuoBody-CD3xB7H4 product candidates, which were created with our DuoBody technology, as well as several additional product candidates in clinical development and marketed by Janssen through our DuoBody collaboration, including amivantamab, approved in certain territories as RYBREVANT, and teclistamab. Our proprietary HexaBody-CD38 product candidate was created with our HexaBody technology, and our proprietary DuoHexaBody-CD37 product candidate 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 SE (“**BioNTech**”) and our HexaBody technology is the basis of our CD38 collaboration with Janssen. 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.

In addition, tisotumab vedotin is developed using Seagen’s proprietary antibody-drug conjugate (“**ADC**”) technology in combination with our proprietary HuMax-TF antibody. Any failures or setbacks 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 commercialization of tisotumab vedotin, which could adversely affect our business, financial condition, results of operations and future growth prospects.

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

Part of the clinical development strategy for certain of our product candidates, including daratumumab, is to seek to identify patients or patient subsets within a disease category whose treatment may benefit from our products in combination with other therapeutic products. 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 ("**R/R**") 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. 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 chronic lymphocytic leukemia (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. ("**Regeneron**") 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.

Partnerships continue to be an important part of our strategy and we may not be able to continue or optimize 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.

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, have entered into partnerships with AbbVie, Seagen and BioNTech for certain of our proprietary product candidates, and have entered into 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 any 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 Treaty Establishing the European Community ("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 preclinical 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. Tivdak, DARZALEX, RYBREVANT, 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, access or reimbursement of approved products or validations or endorsements of treatment options. Such third parties may require additional data or studies for their determinations.

Preclinical 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 preclinical 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 preclinical 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 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 is outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the timeframes we expect, or at all, the 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 preclinical 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 preclinical or early clinical trials, we or they may not achieve the same success in subsequent trials. In particular, the results of preclinical 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 preclinical 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 preclinical 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 on a timely basis or at all.

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 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 as a condition of regulatory approval.

We and our partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, including in the European Union where we are headquartered. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. 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. 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 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 preclinical 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. 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. 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, civil or administrative actions, 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 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 is associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. In particular, many of our and our 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 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, whether or not actually shown to be related to our product candidates.

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

In addition, reports of adverse events or safety concerns involving our products or product candidates can 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. As an example, the prescribing information for Tivdak includes a boxed warning for ocular toxicity, including the need for an ophthalmic exam at baseline, prior to each dose, and as clinically indicated. Patients must adhere to premedication and required eye care before, during and after infusion. 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 can affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates. Reports of adverse events or safety concerns, or changes to regulatory approvals or labeling, may also have a significant impact on market acceptance of our products by patients and physicians or may trigger potential product liability claims, fines, injunctions or the imposition of civil or criminal penalties. Any of these events has the potential to prevent us or our partners from developing, commercializing or maintaining market acceptance of the relevant product or product candidate or to substantially increase commercialization costs, which in turn could significantly harm our business, financial condition, results of operations and future growth prospects.

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

We may fail to obtain Fast Track Designation ("FTD"), Breakthrough Therapy Designation ("BTD") or other designations for expedited development or review that we may apply for in the future. Even if received, such designations or programs may not lead to a faster development or regulatory review or approval process.

FTD, BTD and pilot programs of the FDA and other regulatory authorities are intended to expedite the review and approval of drug candidates in certain circumstances. These designations and programs do not, however, ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion 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 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 as a condition for regulatory approval*." See "*Item 4 –Information on the Company —Government Regulation*" for more information about BTD and FTD and other programs for expedited review.

While daratumumab and amivantamab have received BTD or FTD for certain indications in the past, these designations are not applicable to ongoing studies for daratumumab and amivantamab 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 scrutiny of pharmaceutical manufacturer donations to and support of patient assistance programs offered by charitable foundations may require us or our partners or us 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 implement 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 partners' or own patient assistance programs and support of independent charitable foundations could become the target of similar litigation.

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. If we, our 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 government authorities seeking information related to their patient assistance programs and support. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our 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 and amivantamab, Novartis is responsible for the manufacture of ofatumumab, Horizon is responsible for the manufacture of teprotumumab, and Seagen is responsible for the manufacturing of tisotumab vedotin. For the products we are entirely responsible to manufacture, we currently rely primarily upon one single source third-party CMO, Lonza Group AG ("**Lonza**"), to manufacture and supply large quantities of our product candidates. We expect to negotiate contracts for commercial production on a product-by-product basis for products that we choose to commercialize ourselves and currently have no plans to build our own clinical or commercial scale manufacturing capabilities.

We are aware of only a limited number of companies on a worldwide basis 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.

In order to commercialize new pharmaceutical and biologic products, manufacturers must comply with the laws and regulations, including drug and biologic cGMPs, of the applicable governmental authorities. Compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturing facilities are also subject to pre-approval and ongoing periodic inspection by applicable governmental agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our technology. The FDA, the EMA or similar regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for 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 preclinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of preclinical study or clinical trial materials could delay the completion of our preclinical studies and clinical trials, increase the costs associated with maintaining our preclinical 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 lack direct control over our manufacturers' compliance with these regulations and standards and manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other regulatory requirements. The discovery of manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with cGMP or other requirements after approval of a product may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, fines or criminal sanctions. If the safety of any product supplied is compromised due to the manufacturers' failure to adhere to applicable laws or for other reasons, we or our 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 and other competing therapies. 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, preclinical 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 and by the EC in June 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 4B– 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 ("**MA**") 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 depends, and the pricing of our products and product candidates, if and when approved for marketing, will depend, in part, on the pricing strategies adopted by our competitors. If we or our 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 and reimbursement pressure in many countries that is manifested through government and third-party price controls, increased public pressure on price and 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 sources and internally generated analysis and use such estimates in making decisions regarding product development strategy, including determining indications on which to focus in preclinical 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 preclinical 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 selling, 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 selling, 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 selling, 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 DKK as our reporting currency.

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

If we fail to manage our 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, preclinical and clinical testing, manufacturing, marketing and use of antibody products. Product liability claims may be expensive to defend and may result in judgments against us which are potentially punitive. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials. Although we believe that our current coverage limits are appropriate we cannot be certain that the insurance policies will be sufficient to cover all claims that may be made against us. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms. Any claims against us, regardless of their merit, could cause our business to suffer. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in decreased demand for our products, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals or labeling, marketing or promotional restrictions, exhaustion of any available insurance and our capital resources, the inability to commercialize any product or product candidate, 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 cyber or other 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 risks, such as computer viruses and unauthorized access, and natural disasters, terrorism, war and telecommunication and electrical failures, which can lead to damage, loss or leakage of business data or unavailability of computer systems. Our vulnerability to such events may increase while employees work remotely during the COVID-19 pandemic which results in additional cyber security threat profiles and an increase

in the amount of traffic on secured remote corporate networks and preventing or detecting unauthorized access to internal networks may be more challenging. These and other factors can be exploited to facilitate phishing, malware, ransomware or other attacks on our systems. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. In addition, any loss or disclosure of trade secrets, clinical data or other proprietary information as a result of such disruption or breach could subject us to litigation or regulatory review and sanctions and may impact our reputation and our and our partners' ability to further develop and commercialize our products and product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and the market price of our ADSs.

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

Should attractive opportunities arise, we may acquire companies or technologies that facilitate our access to new medicines, research projects or geographical areas, or that enable us to achieve synergies with our existing operations. However, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions on favorable terms and could be led to finance these acquisitions using cash and marketable securities that could otherwise be allocated to other purposes in the context of our existing operations, or issuances of equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders and adversely affect the market price of our ADSs. If we acquire or enter into collaborations with businesses with promising markets or technologies, we may not be able to realize the benefits of such acquisitions or collaborations, including if we are unable to successfully integrate them with our existing operations and company culture, or if we encounter difficulties in developing, manufacturing and marketing any new products resulting from such acquisitions or collaborations. We cannot assure that we will achieve the expected synergies to justify any such transaction, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors' ability to realize on their 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 updated written code of business conduct, an anti-corruption, anti-bribery policy, and other policies and procedures to assist us and our personnel in complying with the FCPA and other applicable anti-bribery laws. 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, including supply chain issues, and has 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 have long-term impacts on the development, regulatory approval and commercialization of our product candidates and on sales of our approved products. As the pandemic continues, there may be an impact on

our business. The extent, length and consequences of the pandemic are uncertain and impossible to predict, and may be affected by the emergence, spread, infectiousness and severity of new virus variants of concern, the efficacy, availability and administration of vaccines and the development and administration of treatments. Genmab has an established COVID-19 response team, led by the Chief Executive Officer, that monitors the situation and has developed and implemented precautionary measures, including on-site testing where possible or remote working for Genmab employees where possible, based on local recommendations.

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. This may continue 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. 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.

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. For example, tocilizumab is a product used in certain clinical studies, including studies of epcoritamab and certain products in development by partners. In June 2021 the FDA approved an emergency use authorization for tocilizumab for the treatment of severe COVID-19 and in other countries tocilizumab use was prioritized for patients with severe COVID-19. Many hospitals therefore prioritized tocilizumab use for those patients with severe COVID-19 and for the other approved tociliczumab indications. Therefore enrollment in clinical trials where tocilizumab was required as a rescue medication for cytokine release syndrome may have been impacted until hospitals could ensure sufficient supply to treat these patients. Supply chain disruption may also affect the manufacturing, shipment and commercialization of approved products. For example, on December 17, 2020, Horizon announced a short-term disruption in the supply of TEPEZZA due to government-mandated orders to produce COVID-19 vaccines, which dramatically restricted manufacturing capacity available for the production of TEPEZZA at Horizon's drug product contract manufacturer, Catalent, in the first quarter of 2021. Prolonged disruption in the supply 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 in or disruption to clinical trials, regulatory submissions and regulatory approvals would jeopardize timelines for developing, receiving approval for, and subsequently commercializing our product candidates, or obtaining label expansion for our existing products, all of which would adversely affect our operations and financial performance.

COVID-19 impacted DARZALEX sales in 2020 and could in the future affect sales of DARZALEX for existing indications, which could reduce our royalty revenue pursuant to our collaboration with Janssen. Should the resources of healthcare systems worldwide, including in the United States and Europe, become more severely strained by their response to the pandemic or if such strain is prolonged, resources previously devoted to the diagnosis and treatment of

MM may be redeployed to addressing COVID-19, resulting in fewer prescriptions and sales of DARZALEX. Additionally, many patients who currently receive DARZALEX are elderly and immunocompromised and, therefore, more susceptible to severe negative impacts from COVID-19. Such patients may be unable to travel to healthcare facilities to receive DARZALEX treatment as a result of mandatory or self-imposed restrictions on local travel or other social distancing measures. Should they contract COVID-19, they may become unable to continue with their DARZALEX treatment, and many such patients may die. Should treatment of current patients with DARZALEX be temporarily deferred or should such patients die, or should there be a delay or reduction in diagnoses of new MM patients and treatment prescriptions as healthcare resources are redeployed, demand for DARZALEX may be reduced. This would lead to a corresponding reduction in DARZALEX sales and a resulting decrease in our revenues from royalties under our collaboration with Janssen, which would adversely affect our financial performance. In addition, the pandemic could result in delays in clinical development, regulatory approval and commercialization of DARZALEX for additional indications.

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

Climate change, or regulatory or market measures to address climate change, may materially adversely affect our financial condition and business operations.

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

Our business and operations have experienced rapid growth as we have started to transform into a fully-integrated biotech, which could lead to adverse business impacts if such continued growth is not carefully managed.

We have experienced rapid growth over the last several years, and we anticipate further growth as our pipeline advances, and we move toward further commercialization of products. Since 2019 Genmab has grown from 548 employees to 1,212 at the end of 2021. In 2019 there were 12 ongoing clinical trials for Genmab proprietary products, including those owned at least 50% by the company. By the end of 2021 this number had almost doubled to 23, including multiple Phase III trials. Such growth has put significant demands on our management and infrastructure, including new operational and financial systems, as well as extending manufacturing and commercial outsource arrangements. Our success will depend in part upon our ability to manage this growth effectively, including by maintaining our collaborative culture. As we continue to grow, we must continuously improve our operational, financial and management controls and our reporting systems and procedures. We must ensure that our policies and procedures evolve to reflect our dynamic operating model and implementation of financial systems. We must also continue to effectively retain existing employees and to attract, hire, train and retain new employees. Any failure to expand these areas and implement appropriate procedures and controls in an efficient manner and at a pace consistent with our business objectives could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we or our 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 prior 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.

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 an MA 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 MAs 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 MA, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional MA. 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 MA 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 MAs 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 MA 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 MA have been satisfied.

Other jurisdictions also impose certain post-approval requirements or may grant conditional marketing approvals. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, notices or warning letters, recall or seizure of products, total or partial suspension of production or changes to manufacturing processes, denial or withdrawal of pre-marketing product approvals, import controls, or refusal to allow us to enter into supply contracts, including government contracts, each of which could have a significant impact on our business, financial condition, results of operations, future growth prospects and reputation. In addition, even if we and our 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 to repeal or replace certain aspects of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. There is currently uncertainty with respect to the impact any such repeal may have and any resulting changes may take time to unfold, which could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any such action or the impact on us. For example, the Tax Cuts and Jobs Act, among other things, removed the penalties for not complying with the ACA's individual mandate to carry health insurance. There may be additional challenges and amendments to the ACA in the future.

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

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

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

EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation ("**GDPR**"), which became applicable on May 25, 2018, introduced new data protection requirements in the European Economic Area (the 27 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.

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

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

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

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

In addition to HIPAA, the CCPA and the GDPR, we, our 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.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations related to privacy and data security, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, 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 HIPAA federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, the federal transparency requirements under the Physician Payments Sunshine Act and analogous U.S.

state laws. Rules and regulations covering many of the same matters are found in numerous other countries, including in Denmark, and may be more stringent or result in higher exposures than those in the United States.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely continue to be time-consuming and costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 ‘‘*Item 4 – Information on the Company —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, vendors or suppliers could include intentional failures to comply with legal requirements or the requirements of the FDA, the EMA and other comparable regulatory authorities; failure to provide accurate information to applicable government authorities; failure to comply with fraud and abuse and other healthcare laws and regulations in the United States, Denmark and other jurisdictions; failure to comply with the 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 on Form 20-F.

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 the holders owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities. For more information, see the description of our securities registered under Section 12 of the Exchange Act included as an exhibit to this Annual Report on Form 20-F.

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

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

In addition, the deposit agreement provides that, subject to the depositary's right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have non-exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

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

If any holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, a holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

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

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

We are incorporated under the laws of Denmark. Although our wholly owned subsidiary, Genmab US, Inc., has an office and laboratory space in the United States, substantially all of our assets are located outside the United States. The

majority of our directors and senior management reside outside the United States. As a result, it may not be possible to effect service of process within the United States upon such persons or to enforce judgments against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. securities laws.

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a U.S. court, whether or not predicated solely upon U.S. securities laws, would not be enforceable in Denmark.

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

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce 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, 2022.

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.

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

A non-U.S. corporation will be a passive foreign investment company ("**PFIC**"), for U.S. federal income tax purposes for any taxable year if either (i) at least 75% of its gross income for such taxable year is "passive income" (as defined in the relevant provisions of the U.S. Internal Revenue Code of 1986, as amended ("**Code**") or (ii) at least 50% of the value of its assets (generally, based on an average of the quarterly values of the assets) during such year is attributable to assets that produce or are held for the production of passive income. Based on the current and anticipated value of our assets and the nature and composition of our income and assets, we do not expect to be a PFIC for U.S. federal income tax purposes for our current taxable year ending December 31, 2021 or in the foreseeable future. However, the determination of whether or not we are a PFIC according to the PFIC rules is made on an annual basis and will depend on the nature and composition of our income and assets and the value of our assets from time to time. Therefore, changes in the nature and composition of our income or assets or the value of our assets may cause us to become a PFIC. The determination of the value of our assets (including goodwill not reflected on our balance sheet) may be based, in part, on the total market value of our shares and ADSs, which is subject to change and may be volatile.

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

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

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

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

ITEM 4 INFORMATION ON THE COMPANY

A. History and Development of the Company

We were incorporated on June 11, 1998 as a private limited liability company ("**Anpartsselskab**", or "**ApS**") under Danish law as a shelf company and are registered with the Danish Business Authority (Erhvervsstyrelsen) in Copenhagen, Denmark under registration number (CVR) no. 21023884. Our name was changed to Genmab ApS on November 17, 1998 and we commenced operations in February 1999. On May 31, 1999, we were converted into a public limited liability company ("**Aktieselskab**", or "**A/S**") and changed our name to Genmab A/S.

Our shares are listed on Nasdaq Copenhagen under the symbol “GMAB”. Our American Depositary Shares (“**ADSs**”) are listed on the Nasdaq Global Select Market (“**NASDAQ**”) in the United States under the symbol “GMAB”.

Legal name:	Genmab A/S
Commercial name:	Genmab
Domicile:	Kalvebod Brygge 43, 1560 Copenhagen V, Denmark
Tel:	+45 70 20 27 28
Website:	www.genmab.com (The contents of this website are not incorporated by reference into this Annual Report on Form 20-F.)
Date of incorporation:	June 11, 1998
Legal form of the Company:	A Danish public limited liability company
Legislation under which the Company operates:	Danish law
Country of incorporation:	Denmark

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

B. BUSINESS OVERVIEW

We are an international biotechnology company with a core purpose to improve the lives of patients by creating and developing innovative antibody therapeutics. Our vision to transform cancer treatment has driven our passionate, innovative and collaborative teams to invent four next-generation antibody technology platforms that play a key role in building our product pipeline, fueling multiple differentiated cancer treatments that make an impact on people’s lives. Our proprietary pipeline, where we are responsible for at least 50% of development, includes bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. We currently have approximately 20 proprietary and partnered programs in preclinical development and seven product candidates in clinical development, including one approved product, Tivdak, developed in collaboration with Seagen. Tivdak was granted accelerated approval by the FDA for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tivdak is the first and only FDA approved ADC in this indication.

In addition to a broad pipeline of differentiated product candidates, our portfolio includes four approved products created by Genmab or that incorporate Genmab’s innovations that are being developed and marketed by others; daratumumab, marketed by Janssen as DARZALEX (IV formulation) and DARZALEX *FASPRO* or DARZALEX SC (SC formulation), approved in the U.S., Europe, Japan and certain other territories for the treatment of certain indications of MM and AL amyloidosis, amivantamab, marketed in the U.S., Europe and certain other territories as RYBREVANT for the treatment of certain adult patients with locally-advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, SC ofatumumab, marketed in the U.S., Europe, Japan and certain other territories as Kesimpta by Novartis for the treatment of RMS, and teprotumumab, marketed in the U.S. as TEPEZZA by Horizon for the treatment of TED.

Our strong pipeline of novel antibody-based product candidates for the treatment of solid tumors and hematological cancers is designed to address unmet medical needs and improve treatment outcomes for cancer patients. Our goal in building our pipeline is to retain at least 50% of product rights in selected programs and in geographic areas where we believe we will be able to maximize their value; we consider such products to be “our own” proprietary products. We currently have seven proprietary product candidates in clinical development: tisotumab vedotin, epcoritamab, DuoBody-PD-L1x4-1BB (GEN1046), DuoBody-CD40x4-1BB (GEN1042), DuoHexaBody-CD37 (GEN3009), HexaBody-CD38 (GEN3014) and DuoBody-CD3xB7H4 (GEN1047). It was determined in September 2021 that two additional clinical stage product candidates, HexaBody-DR5xDR5 (GEN1029) and DuoBody-CD3x5T4 (GEN1044), would not advance further in development. In addition to our proprietary clinical product candidates our partners, through collaboration agreements with us, have multiple products or product candidates in clinical development including ongoing label expansion studies for daratumumab, amivantamab, ofatumumab and teprotumumab. Our portfolio also includes four proprietary antibody technology platforms: (i) our DuoBody platform, which can be used for the creation and

development of bispecific antibodies; (ii) our HexaBody platform, which can be used to increase the potential potency of antibodies through hexamerization; (iii) our DuoHexaBody platform, which enhances the potential potency of bispecific antibodies through hexamerization; and (iv) our HexElect platform, which combines two HexaBody molecules to maximize potential potency while minimizing potential toxicity by more selective binding to desired target cells. Antibody products created with these technologies may be used in a wide variety of indications including cancer and autoimmune, central nervous system and infectious diseases. These platforms play a key role in building our product pipeline, enhancing our partnerships and generating revenue. We selectively enter into collaborations with other biotechnology and pharmaceutical companies that build our network in the biotechnology space and give us access to complementary novel technologies or products that move us closer to achieving our vision and fulfilling our core purpose.

The following charts summarize the disease indications and most advanced development status of products or product candidates in development by Genmab or by partners who are leveraging Genmab's innovation and technology. All Genmab owned ≥50% products and product candidates in ongoing clinical development are included in the chart below.

Genmab's Proprietary[1] Products

Product	Target	Developed By	Disease Indications	Most Advanced Development Phase (Preclinical / 1 / 1/2 / 2 / 3 / Approved)
Tivdak (tisotumab vedotin-tftv)	TF	Co-development Genmab / Seagen	Cervical cancer[2]	✓
Tisotumab vedotin			Ovarian cancer	
			Solid tumors	
Epcoritamab	CD3, CD20	Co-development Genmab / AbbVie	Relapsed/refractory diffuse large B-cell lymphoma (DLBCL)	
			B-cell non-Hodgkin lymphoma (NHL)	
			B-cell NHL (combo)	
			Relapsed/refractory chronic lymphocytic leukemia (CLL) & Richter's Syndrome	
DuoBody-PD-L1x4-1BB (GEN1046)	PD-L1, 4-1BB	Co-development Genmab / BioNTech	Non-small cell lung cancer (NSCLC)	
			Solid tumors	
DuoBody-CD40x4-1BB (GEN1042)	CD40, 4-1BB	Co-development Genmab / BioNTech	Solid tumors	
DuoHexaBody-CD37 (GEN3009)	CD37	Co-development Genmab / AbbVie	Hematologic malignancies	
HexaBody-CD38 (GEN3014)	CD38	Genmab[3]	Hematologic malignancies	
DuoBody-CD3xB7H4 (GEN1047)	CD3, B7H4	Genmab	Solid tumors	

Products and product candidates created by Genmab or created using Genmab's DuoBody bispecific antibody technology are being developed by partners in programs that run from Phase I development to approved medicines. The tables in this section include those therapies that have been approved as well as clinical stage products in Phase II development or later.

Programs Incorporating Genmab's Innovations and Technology[4]

Approved Medicines

Product	Developed & Marketed By	Disease Indications	Most Advanced Development Phase
			Preclinical / 1 / 1/2 / 2 / 3 / Approved
DARZALEX (daratumumab) & **DARZALEX *FASPRO*** (daratumumab and hyaluronidase-fihj)	Janssen Biotech Inc. (Tiered royalties to Genmab on net global sales)	Multiple myeloma (MM)[2]	✓
		AL Amyloidosis[2]	✓
Daratumumab		Non-MM blood cancers	
Kesimpta (ofatumumab)	Novartis (Royalties to Genmab on net global sales)	Relapsing multiple sclerosis[2]	✓
TEPEZZA (teprotumumab-trbw)	Horizon Therapeutics (under sublicense from Roche, royalties to Genmab on net global sales)	Thyroid eye disease[2]	✓
RYBREVANT (amivantamab-vmjw)	Janssen (Royalties to Genmab on net sales)	NSCLC	✓
Amivantamab		Advanced or metastatic gastric or esophageal cancer	

≥Phase II Clinical Stage Programs

Product	Technology	Developed By	Disease Indications	Most Advanced Development Phase
				Preclinical / 1 / 1/2 / 2 / 3 / Approved
Teclistamab (JNJ-64007957)	DuoBody	Janssen	Relapsed or refractory MM	**(BLA submitted)**
Inclacumab	UltiMAb	Global Blood Therapeutics	Vaso-occlusive crises (VOC) in sickle cell disease	
Mim8	DuoBody	Novo Nordisk	Hemophilia A	
Talquetamab (JNJ-64407564)	DuoBody	Janssen	Relapsed or refractory MM	
Camidanlumab tesirine (ADCT-301)	UltiMAb	ADC Therapeutics	Relapsed /refractory Hodgkin lymphoma	
PRV-015 (AMG 714)	UltiMAb	Provention Bio	Celiac disease	
Lu AF82422	UltiMAb	Lundbeck	Multiple system atrophy	

[1]Products or product candidates where Genmab has ≥50% ownership. Certain products in co-development, partners as indicated.
[2]See local country prescribing information for precise indications and safety information.
[3]Genmab is developing HexaBody-CD38 in an exclusive worldwide license and option agreement with Janssen.
[4]Products created by Genmab or that incorporate Genmab's innovation and technology, that are under development and where relevant commercialized by a third-party.

Our Business Strategy

Key elements of our strategy to achieve our vision and fulfill our core purpose include:

- ***Recurring revenue streams from collaborations.***
    - DARZALEX: Janssen is seeking to extend the commercial reach of daratumumab through label expansion. We will continue to contribute to the development strategy for daratumumab through a joint development and steering committee with Janssen.

- RYBREVANT: Janssen is investigating the use of amivantamab for the treatment of NSCLC. In May 2021, Janssen received approval from the FDA for amivantamab for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. In December 2021 the EC granted Janssen a conditional MA for amivantamab for the treatment of adult patients with advanced NSCLC with activating EGFR exon 20 insertion mutations, after failure of platinum-based therapy. Amivantamab is the first product created using Genmab's proprietary DuoBody technology platform to receive regulatory approval.

- Kesimpta: Novartis is investigating the use of ofatumumab for the treatment of RMS. In August 2020, Novartis received approval from the FDA for ofatumumab in RMS. Novartis was granted an MA for the treatment of RMS by the EC in March 2021.

- TEPEZZA: Horizon is investigating the use of teprotumumab for the treatment of TED and diffuse cutaneous systemic sclerosis. In January 2020, Horizon received approval from the FDA for teprotumumab in TED.

- ***Actively advance and expand our proprietary product pipeline.*** We are actively advancing our promising proprietary product candidates through development and seek to expand our proprietary product pipeline by developing new products in-house and by partnering selectively. In 2021 the first Phase III study of epcoritamab was initiated. We are developing epcoritamab in collaboration with AbbVie.

- ***Strengthen our product portfolio with strategic collaborations and potential acquisitions.*** We enter into strategic product and technology collaborations to build our network in the biotechnology space and to strengthen our portfolio with complementary technologies or products. We monitor for potential acquisitions that would advance our overall strategy.

- ***Leverage our proprietary technology platforms.*** Our leading proprietary antibody technology platforms play a key role in building our product pipeline, enhancing our partnerships and generating revenue. Multiple new product candidates are currently being developed by us and our partners using our technology platforms, including proprietary product candidates created with our DuoBody and HexaBody technologies. We actively seek partners interested in developing potential antibody therapeutics using our technologies.

- ***Build our translational research capabilities.*** Leveraging our expertise in antibody technologies and product development, we are expanding our translational research capabilities with the goal of building a library of antibody therapeutics that can be tailored to patients.

- ***Build our commercialization capabilities.*** We are currently building and expanding our commercialization capabilities to allow us to bring our own products to market for the indications and in the geographies we determine would create value for our customers and shareholders. Our initial focus for commercialization will be in the U.S. and in Japan. Our first product on the market is Tivdak, which received accelerated approval by the FDA in September 2021. Tivdak is being co-developed by Genmab and Seagen. Under a joint commercialization agreement, Genmab will co-promote Tivdak in the U.S. and lead commercial operational activities in Japan.

Our Products and Product Candidates

Daratumumab (DARZALEX)

Our lead product, daratumumab, marketed as DARZALEX for the treatment of certain MM and AL amyloidosis indications, is a human IgG1k mAb that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of MM cells and is also expressed by AL amyloidosis. It triggers a person's own immune system to attack cancer cells, resulting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through

immunomodulatory effects, in addition to direct tumor cell death via apoptosis, or programmed cell death. When first approved by the FDA in 2015 for intravenous ("**IV**") administration, it was the first human CD38-targeting mAb to reach the market and the first mAb to receive FDA approval to treat MM. DARZALEX is also the first and only SC CD38-directed antibody approved for the treatment of certain MM indications and the first and only approved therapy for AL amyloidosis. DARZALEX is commercialized by Janssen, under an exclusive development, manufacturing and commercialization agreement, which we entered into in 2012.

MM is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells. The 5-year survival rate for MM patients is estimated at 55.6% in the United States, based on 2011–2017 data from the National Cancer Institute Surveillance, Epidemiology, and End Results ("**SEER**"). The American Cancer Society estimated that approximately 34,920 people in the United States were newly diagnosed with MM in 2021 and approximately 12,410 people died from the disease. The World Health Organization ("**WHO**") estimated that approximately 176,404 people worldwide were newly diagnosed with MM in 2020 and 117,077 people died from the disease. AL amyloidosis is a very rare disease caused by the buildup of an abnormal protein called amyloid, which is made by plasma cells, in the tissues or organs. Approximately 4,000 new cases are diagnosed annually in the U.S.

The warnings and precautions for DARZALEX include infusion reactions, interference with serological testing and interference with determination of complete response. The most frequently reported adverse reactions (incidence ≥20%) in clinical trials were: infusion reactions, neutropenia, thrombocytopenia, fatigue, nausea, diarrhea, constipation, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy and upper respiratory tract infection. The warnings and precautions for DARZALEX *FASPRO* include hypersensitivity and other administration reactions and cardiac toxicity in patients with AL amyloidosis. The most frequently reported adverse reaction (incidence ≥20%) in clinical trials of DARZALEX *FASPRO* monotherapy in patients with MM was upper respiratory tract infection. The most frequently reported adverse reactions (incidence ≥20%) in clinical trials in patients with AL amyloidosis were: upper respiratory tract infection, diarrhea, peripheral edema, constipation, fatigue, peripheral sensory neuropathy, nausea, insomnia, dyspnea and cough.

Existing Marketing Approvals

Janssen has obtained regulatory approvals for DARZALEX, IV and SC formulations, in the jurisdictions set forth in the table below, as well as in certain other countries.

DARZALEX is indicated for the treatment of adult patients as either IV (daratumumab) or SC (daratumumab and hyaluronidase-fihj) administration:

Jurisdiction	Approval	Key Underlying Clinical Trial(s)
United States:		
Relapsed / Refractory MM		
IV: November 2015	Monotherapy for patients who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent	IV: SIRIUS (MMY2002)
SC: May 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: November 2016	In combination with Rd or Vd, for patients who have received at least one prior therapy	CASTOR (MMY3004); POLLUX (MMY3003)
SC: May 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: June 2017	In combination with Pd for patients who have received at least two prior therapies, including lenalidomide and a PI	IV: EQUULEUS (MMY1001)
SC: July 2021		SC: APOLLO (MMY3013)
IV: August 2020	In combination with Kd for patients with RRMM who have received one to three previous lines of therapy	IV: CANDOR
SC: December 2021		SC: PLEIADES (MMY2040)
Frontline MM		
IV: May 2018	In combination with VMP for newly diagnosed patients who are ineligible for autologous stem cell transplant ("**ASCT**")	IV: ALCYONE (MMY3007)
SC: May 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: June 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	IV: MAIA (MMY3008)
SC: May 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: September 2019	In combination with VTd for newly diagnosed patients who are eligible for ASCT	IV & SC: CASSIOPEIA (MMY3006)
SC: January 2021		
Split Dosing Regimen		
IV: February 2019	Option to split first infusion over two consecutive days	IV: EQUULEUS (MMY1001)
AL Amyloidosis		
SC: June 2021	In combination with VCd for newly diagnosed patients	SC: ANDROMEDA (AMY3001)
European Union:		
Relapsed / Refractory MM		
IV: April 2016	Monotherapy for patients whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy	IV: SIRIUS (MMY2002)
SC: June 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: February 2017	In combination with Rd or Vd for patients who have received at least one prior therapy	IV: CASTOR (MMY3004); POLLUX (MMY3003)
SC: June 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: May 2021	In combination with Kd for patients with RRMM who have received one to three previous lines of therapy	IV: CANDOR
SC: June 2021	In combination with Pd for patients who have received at least two prior therapies, including lenalidomide and a PI	SC: APOLLO (MMY3013)
Frontline MM		
IV: July 2018	In combination with VMP for newly diagnosed patients who are ineligible for ASCT	IV: ALCYONE (MMY3007)
SC: June 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)

IV: November 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	IV: MAIA (MMY3008)
SC: June 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
IV: January 2020	In combination with VTd for newly diagnosed patients who are eligible for ASCT	IV: CASSIOPEIA (MMY3006)
SC: June 2020		SC: COLUMBA (MMY3012)/ PLEIADES (MMY2040)
Split Dosing Regimen		
IV: December 2018	Option to split first infusion over two consecutive days	IV: EQUULEUS (MMY1001)
AL Amyloidosis		
SC: June 2021	In combination with VCd for newly diagnosed patients	SC: ANDROMEDA (AMY3001)
Japan:		
Relapsed / Refractory MM		
IV: September 2017	In combination with Rd or Vd	IV: CASTOR (MMY3004); POLLUX (MMY3003)
SC: March 2021		SC: COLUMBA (MMY3012)
IV: November 2020	In combination with Kd for patients with RRMM who have received one to three previous lines of therapy	IV: CANDOR
SC: December 2021	In combination with Pd for patients who have received at least two prior therapies, including lenalidomide and a PI	SC: APOLLO (MMY3013)
Frontline MM		
IV: August 2019	In combination with VMP for newly diagnosed patients ineligible for ASCT	IV: ALCYONE (MMY3007)
SC: March 2021		SC: COLUMBA (MMY3012)
IV: December 2019	In combination with Rd for newly diagnosed patients who are ineligible for ASCT	IV: MAIA (MMY3008)
SC: March 2021		SC: COLUMBA (MMY3012)
AL Amyloidosis		
SC: August 2021	In combination with VCd for newly diagnosed patients	SC: ANDROMEDA (AMY3001)

PI = proteasome inhibitor; Rd = lenalidomide and dexamethasone; Vd = bortezomib and dexamethasone; VMP = bortezomib, melphalan and prednisone; VTd = bortezomib, thalidomide and dexamethasone; ASCT = autologous stem cell transplant; Pd = pomalidomide and dexamethasone; Kd = carfilzomib and dexamethasone; VCd = bortezomib, cyclophosphamide and dexamethasone

Development Status

Beyond the current labeled indications, Janssen is conducting additional clinical studies for daratumumab, including multiple Phase III studies for the treatment of various stages of MM, including smoldering MM ("**SMM**"), frontline MM and R/R MM, with daratumumab alone or in combination with other therapies. The majority of these Phase III studies are utilizing the SC formulation of daratumumab.

Key Ongoing Trials

Janssen's comprehensive clinical development program for daratumumab also includes the following ongoing clinical trials:

Daratumumab for High Risk SMM

Janssen is currently conducting several clinical trials to assess whether earlier treatment with daratumumab could be used for patients with high-risk SMM to delay progression to MM, compared with active monitoring. The Phase II 123-patient, randomized, multicenter, open-label CENTAURUS (SMM2001) study is assessing three dose schedules of daratumumab for the treatment of patients with high-risk or intermediate-risk SMM who had a confirmed diagnosis of high-risk or intermediate-risk SMM for <5 years. Initial efficacy data from the CENTAURUS study was reported in December 2018 and it was determined that dose intensity was associated with efficacy. The safety profile of

daratumumab monotherapy in SMM remained consistent with other single-agent daratumumab studies, and no new safety signals were observed with longer follow-up.

Janssen used CENTAURUS data to set the dose schedule for the Phase III randomized, open-label, multicenter AQUILA (SMM3001) study, which is designed to assess the efficacy of daratumumab by SC injection in delaying the progression from SMM to MM in high-risk SMM patients. The AQUILA study recruited patients (≥18 y) who have had a confirmed diagnosis of SMM for ≤5 years, have factors indicating a high risk of progression, and have an Eastern Cooperative Oncology Group performance status of ≤1, which refers to impact of the disease on the patient's daily living abilities. The primary endpoint is PFS as assessed by an independent review committee. Secondary endpoints include time to biochemical or diagnostic (SLiM-CRAB) progression, overall response rate ("**ORR**"), CR rate, duration of and time to response, time to first-line treatment for MM, PFS on first-line treatment for MM, incidence of MM with adverse prognostic features and OS. Disease will be evaluated per International Myeloma Working Group response criteria. The study completed enrollment in May 2019 and is currently ongoing.

Daratumumab for Frontline Treatment for Transplant Eligible Patients

Janssen is conducting the following Phase III trials for frontline treatment of transplant eligible MM patients:

The Phase III PERSEUS (MMY3014) study is currently ongoing to evaluate the SC formulation of daratumumab in combination with VRd compared to VRd alone in approximately 690 participants with previously untreated MM. The primary endpoint of the study is PFS from randomization to the date of disease progression or death. Secondary endpoints include MRD-negative rate, ORR, PFS on next line of therapy, OS, time to and duration of response, health-related quality of life, pharmacokinetics, immunogenicity, stem cell yield after mobilization and time to engraftment post-ASCT. The PERSEUS trial completed enrollment in November 2019 and is currently ongoing.

Janssen also announced the Phase III randomized, open-label AURIGA (MMY3021) trial to evaluate SC daratumumab in combination with lenalidomide as maintenance treatment in approximately 214 patients with newly diagnosed MM who are MRD positive after frontline ASCT and have no prior anti-CD38 exposure, compared with maintenance treatment by lenalidomide alone. The trial is currently recruiting.

Daratumumab for Frontline Treatment for Non-Transplant Eligible Patients

Janssen is conducting the following Phase III trials for frontline treatment of non-transplant eligible MM patients:

The Phase III CEPHEUS (MMY3019) study is evaluating the SC formulation of daratumumab in combination with bortezomib, lenalidomide and dexamethasone, or VRd, compared to VRd alone in approximately 395 participants with frontline MM for whom hematopoietic stem cell transplant is not planned as initial therapy. The primary endpoint of the study is the percentage of participants with negative MRD status, measured after randomization and prior to PD or subsequent anti-MM therapy. Secondary endpoints include PFS, CR, MRD-negativity rate at one year, ORR, VGPR, PFS on the next line of therapy, DoR, health-related quality of life, pharmacokinetics, immunogenicity, and OS. The CEPHEUS trial completed enrollment in September 2019 and is currently ongoing.

Amivantamab

Amivantamab, created using Genmab's DuoBody technology platform is a fully human bispecific antibody that targets EGFR and Met, two validated cancer targets. The two antibody libraries used to produce amivantamab were both generated by Genmab. In collaboration with Janssen, the antibody pair used to create amivantamab was selected. Janssen is responsible for the development and commercialization of amivantamab and is currently investigating the use of amivantamab in various NSCLC indications. In May 2021, Janssen received approval from the FDA for amivantamab, as RYBREVANT, for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. RYBREVANT has also been approved in the EU and other markets. These are the first regulatory approvals for a therapy that was created using Genmab's proprietary DuoBody bispecific technology platform.

Amivantamab for the Treatment of Non-small Cell Lung Cancer

NSCLC makes up 80% to 85% of all lung cancers, which is one of the most common cancers worldwide. One of the most common mutations in NSCLC is alterations in EGFR, which is a receptor tyrosine kinase that supports cell growth and division. EGFR mutations are found in 10% to 15% of patients with NSCLC and EGFR exon 20 insertion mutations are the third most prevalent activating EGFR mutation. Patients with this profile have a real-world five-year overall survival rate of 8% in the frontline setting. Amivantamab is the first fully-human bispecific antibody approved for the treatment of patients with NSCLC with EGFR exon 20 insertion mutations.

In May 2021 the FDA approved the use of amivantamab, marketed as RYBREVANT for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Subsequently in December 2021 the EC granted Janssen a conditional MA for the treatment of adult patients with advanced NSCLC with activating EGFR exon 20 insertion mutations, after failure of platinum-based therapy. The approvals were based on data from the Phase I CHRYSALIS study.

Key Ongoing Trials in NSCLC

Janssen's clinical development program for amivantamab also includes the following ongoing Phase III clinical trials:

The Phase III PAPILLON study is a randomized, open-label study of the combination of amivantamab and carboplatin-pemetrexed therapy compared with carboplatin-pemetrexed in patients with EGFR exon 20 insertion mutated locally advanced or metastatic NSCLC. The estimated enrollment in the study is 300 patients and the study is currently recruiting.

The Phase III MARIPOSA study is a randomized study of amivantamab and lazertinib combination therapy versus osimertinib versus lazertinib as first-line treatment in patients with EGFR-mutated locally advanced or metastatic NSCLC. The estimated enrollment in the study is 1,000 patients and the study is currently recruiting.

The Phase III MARIPOSA-2 study is a randomized, open-label study of amivantamab and lazertinib in combination with platinum-based chemotherapy compared with platinum-based chemotherapy in patients with EGFR-mutated locally advanced or metastatic NSCLC after osimertinib failure. The estimated enrollment in the study is 500 patients and the study is currently recruiting.

Additional Trials of Interest

A Phase Ib study to assess the safety and pharmacokinetics of the SC formulation of amivantamab in advanced solid malignancies is currently recruiting with anticipated enrollment of 176 patients.

A Phase II open-label study of amivantamab in patients with previously treated advanced or metastatic gastric or esophageal cancer is recruiting with anticipated enrollment of 60 patients.

Ofatumumab

Ofatumumab is a human IgG1k mAb that targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops. The CD20 molecule is found on the surface of B-cells, the type of cell which is believed to trigger the inflammatory process that leads to MS. The CD20 molecule is not shed from the cell surface and is not internalized following antibody binding. The antigen-binding fragment ("**Fab**") domain of ofatumumab binds to the CD20 molecule and the fragment crystallizable ("**Fc**") domain mediates immune effector functions to result in B-cell lysis *in vitro*. Ofatumumab directs the body's immune system to fight normal and cancerous B-cells. Data suggest that possible mechanisms of cell lysis include complement-dependent cytotoxicity ("**CDC**"), and antibody-dependent, cell-mediated cytotoxicity ("**ADCC**"). Novartis is responsible for the development and commercialization of

ofatumumab in all potential indications and is currently investigating and commercializing a SC formulation of ofatumumab for the treatment of RMS.

Kesimpta for the Treatment of Relapsing Multiple Sclerosis

MS is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage of the brain, optic nerves and spinal cord. MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss. MS affects approximately 2.3 million people worldwide. It is often characterized into the following forms: primary progressive MS ("**PPMS**") and RMS, which includes relapsing-remitting MS ("**RRMS**") and secondary progressive MS ("**SPMS**"). Approximately 85% of patients initially present with RRMS. There is currently no cure for MS. Treatment typically focuses on speeding recovery from attacks, slowing the progression of the disease and managing MS. Ofatumumab is the first fully human anti-CD20 monoclonal antibody administered with a monthly 20 mg SC dosing regimen in clinical trials.

In August 2020 the FDA approved the use of Kesimpta injection for SC use, for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In March 2021 the EC granted Novartis an MA for the use of Kesimpta in the treatment of RMS in adults with active disease defined by clinical or imaging features. Kesimpta was also approved in Japan in March 2021. The approvals were based on data from the Phase III ASCLEPIOS I & II and Phase II APLIOS trials. The approval in Japan was also based on the Phase II COMB157G1301 study.

Key Ongoing Trials in RMS

Novartis' clinical development program for ofatumumab also includes the following ongoing Phase III clinical trials:

The Phase III OLIKOS study is a single arm study evaluating the continued efficacy, safety and tolerability of ofatumumab in patients with RMS who are transitioning from a CD20 mAb therapy. The estimated enrollment in the study is 100 patients and the study is currently recruiting.

The Phase III ALITHIOS study is evaluating the long-term safety, tolerability and effectiveness study of ofatumumab in patients with RMS. The purpose of this study is to collect long-term safety, tolerability, effectiveness and health outcomes data in eligible subjects who have participated in a Novartis ofatumumab clinical MS study. The estimated enrollment for this single group assignment study is 2010 participants and the study is currently recruiting.

The Phase III ARTIOS study is an open-label study to evaluate the effectiveness of treatment with ofatumumab in patients transitioning from commonly used oral MS therapies - fingolimod or dimethyl fumarate, due to breakthrough disease. The anticipated enrollment for this study is 550 patients and the study is currently recruiting.

The Phase III STHENOS study is an open-label, rater-blind randomized multi-center parallel-arm active-comparator study to assess the efficacy and tolerability of ofatumumab 20mg SC monthly versus first line physician's choice standard of care disease modifying therapy in the treatment of newly diagnosed RMS. The anticipated enrollment for this study is 236 patients and the study is currently recruiting.

The Phase III NEOS study is a two-year, randomized, three-arm, double-blind, non-inferiority study comparing the efficacy and safety of ofatumumab and Siponimod versus fingolimod in pediatric patients with MS followed by an open-label extension. The anticipated enrollment for this study is 180 patients and the study is currently recruiting.

Teprotumumab

Teprotumumab is a human monoclonal antibody that targets the Insulin-like Growth Factor 1 Receptor (IGF-1R), a well-validated target. Teprotumumab 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. Horizon is developing and manufacturing teprotumumab for the treatment of TED and investigating teprotumumab for the treatment of diffuse

cutaneous systemic sclerosis. In February 2019, Horizon reported positive topline results from the Phase III confirmatory OPTIC study of teprotumumab in the treatment of active TED. The study met its primary endpoint showing more patients treated with teprotumumab compared with placebo had a meaningful improvement in proptosis, or bulging of the eye, as 82.9% of patients treated with teprotumumab compared to 9.5% of placebo patients achieved the primary endpoint of a 3mm or more reduction in proptosis ($p<0.001$). The safety profile of teprotumumab in OPTIC was similar to that seen in the Phase II study with no new safety observations. The drop-out rate was <5% and balanced across placebo and treatment arms. There were no deaths during the study and a total of three serious adverse events: in the placebo arm, one patient had a visual field defect and received orbital decompression surgery and discontinued study; in the teprotumumab arm, one patient had pneumothorax (considered not related to study drug) and another had an infusion reaction that led to discontinuation of study drug. The vast majority of treatment-emergent adverse events were mild to moderate in intensity and no other adverse events resulted in discontinuation. Horizon submitted a BLA to the FDA in July 2019. The FDA granted priority review to the BLA in September 2019 and teprotumumab was subsequently approved as TEPEZZA in January 2020.

Tisotumab Vedotin

Tisotumab vedotin is an ADC created to target tissue factor ("**TF**"), a protein involved in tumor signaling and angiogenesis. TF is a transmembrane protein that is the main physiological initiator of coagulation and is involved in angiogenesis, cell adhesion, motility and cell survival. TF is expressed on many solid tumors, including cervical, ovarian, pancreatic, prostate and bladder tumors. The presence of TF is associated with poor prognosis. Based on its high expression on many solid tumors and its rapid internalization, we believe that TF is a suitable target for an ADC approach. Tisotumab vedotin combines our human mAb that binds to TF and Seagen's ADC technology that utilizes a cleavable linker and the cytotoxic drug monomethyl auristatin E. ADCs are mAbs that are linked to cytotoxic or cell-killing agents. Seagen's ADC technology utilizes mAbs that internalize within target cells after binding to a specified cell-surface receptor. Enzymes present inside the cell catalyze the release of the cytotoxic agent from the mAb, which then results in the desired activity, specific killing of the target cell. We are developing tisotumab vedotin in collaboration with Seagen.

Tivdak for the Treatment of Cervical Cancer

SEER estimated that 14,480 women would be diagnosed with cervical cancer in the United States in 2021, and that 4,290 would die from cervical cancer. Up to 16% of women initially present with metastatic cervical cancer, and those who present with earlier-stage disease may experience recurrence following treatment. Among women who present with earlier stage disease, 15%-61% will go on to develop metastatic cervical cancer, most commonly within the first two years following completion of therapy. The 5-year survival rate for women in the U.S. and Japan with recurrent or metastatic cervical cancer is only 17.6% and 19.5%, respectively.

In September 2021 the FDA granted Genmab and Seagen accelerated approval for Tivdak, the first and only approved ADC for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tivdak was approved under the FDA's Accelerated Approval Program based on tumor response and the durability of the response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. The approval was based on the innovaTV 204 study in 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based chemotherapy regimen.

Key Ongoing Trials

We and Seagen are currently evaluating tisotumab vedotin for the treatment of cervical cancer and other solid tumors in six clinical studies: innovaTV 204, innovaTV 205, innovaTV 206, innovaTV 207, innovaTV 208 and innovaTV 301.

innovaTV 204 is a single arm, multicenter, international, potentially registrational Phase II trial in patients with cervical cancer who have relapsed or progressed on or after platinum-containing chemotherapy and who have received or are ineligible for bevacizumab, with enrollment of 102 patients. The primary endpoint of the study was ORR as

assessed by an independent review committee. The trial also assessed DoR, PFS, OS and safety. Favorable topline results were announced in July 2020; results from the trial showed a 24% confirmed ORR by independent central review (95% Confidence Interval: 15.9% - 33.3%) with a median DOR of 8.3 months. The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia, epistaxis (nose bleeds), nausea, conjunctivitis, fatigue and dry eye. The data was featured in a late-breaking proffered paper oral presentation at the European Society for Medical Oncology ("**ESMO**") Virtual Congress 2020 in September. Based on this data, a BLA was submitted in February 2021 to support a potential accelerated approval pathway with the FDA. Subsequently, in September 2021, the FDA granted accelerated approval to tisotumab vedotin, as Tivdak, based on this study.

innovaTV 205 is a Phase I/II study of tisotumab vedotin as monotherapy or in combination with other therapies in subjects with recurrent or stage IVB cervical cancer and innovaTV 206 is a Phase I/II open label, single arm study of tisotumab vedotin monotherapy for patients in Japan with advanced solid malignancies. The first patient in the innovaTV 206 study was dosed in March 2019 with an expansion phase of tisotumab vedotin as monotherapy initiated in August 2019. In December 2019 the innovaTV 205 study was updated to include an arm with weekly dosing of tisotumab vedotin monotherapy. Interim data from two cohorts of the study was presented at the ESMO Virtual Congress 2021 as part of a featured mini oral presentation. The study is currently ongoing.

Beyond recurrent and/or metastatic cervical cancer, we believe there may be opportunities for tisotumab vedotin in earlier lines of cervical cancer and in other solid tumors that express TF. In 2018, we and Seagen announced innovaTV 207 and innovaTV 208, Phase II studies to assess, respectively, the activity, safety and tolerability of tisotumab vedotin for the treatment of selected solid tumors and the efficacy of tisotumab vedotin for platinum-resistant ovarian cancer. The innovaTV 207 study is currently recruiting while the innovaTV 208 study is active but no longer recruiting.

The first Phase III study of tisotumab vedotin was announced in January 2021. The open-label, randomized, global trial of tisotumab vedotin versus chemotherapy is enrolling approximately 482 patients with recurrent or metastatic cervical cancer who have received one or two prior lines of systemic therapy for their recurrent or metastatic disease. Eligible patients will be randomized to receive either tisotumab vedotin 2.0 mg/kg every three weeks or investigator's choice of chemotherapy. The primary endpoint of the study is overall survival. This global study is sponsored by Seagen in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups and the Gynecologic Oncology Group. The study is designed to confirm the potential of tisotumab vedotin as monotherapy for patients with metastatic and or recurrent cervical cancer. The study is currently recruiting.

Epcoritamab

Epcoritamab is a proprietary bispecific antibody therapeutic candidate created using our proprietary DuoBody technology. Epcoritamab is designed to target CD3, which is expressed on all T-cell subtypes and is part of the T-cell receptor, and CD20, a clinically well-validated therapeutic target. CD20 is expressed in a majority of B-cell malignancies, including CLL, diffuse large B-cell lymphoma ("**DLBCL**"), follicular lymphoma ("**FL**") and mantle cell lymphoma ("**MCL**"). In a number of laboratory models, epcoritamab has shown high potency in killing CD20+ tumors and induced potent tumor cell lysis across a panel of B-cell tumor lines. We are developing epcoritamab in collaboration with AbbVie.

Epcoritamab for the Treatment of B-cell malignancies

DLBCL is the most common type of non-Hodgkin lymphoma ("**NHL**") in the United States and worldwide. It is an aggressive form of NHL with relative 5-year survival rates of 63.9%, based on 2011-2017 SEER data. Prevalence is anticipated to increase, driven by growth in aging populations. DLBCL affects B-lymphocytes and can develop in the lymph nodes or in other organs, and may be either localized or generalized. The prognosis for relapsed or refractory DLBCL patients is poor, especially for those with high-risk factors, and for most patients with refractory DLBCL there are no curative treatment options. We and AbbVie are currently evaluating SC epcoritamab for the treatment of B-cell malignancies including DLBCL and CLL in five clinical studies: GCT3013-01 or EPCORE NHL-1, GCT3013-02 or EPCORE NHL-2, GCT3013-03 or EPCORE CLL-1, GCT3013-04 or EPCORE NHL-3 and GCT3013-05 or EPCORE DLBCL-1. Additional studies, including Phase III studies, are planned.

The first patient was dosed in the Phase I/II GCT3013-01, or EPCORE-NHL-1 safety and efficacy study of epcoritamab for the treatment of B-cell malignancies in July 2018, with initial dose-escalation data presented in December 2019. Updated dose-escalation data was presented at the American Society of Hematology ("**ASH**") annual meetings in December 2020 and 2021, and published in *The Lancet*, concluding that epcoritamab demonstrates a consistent and favorable safety profile, with no grade ≥3 CRS events and limited neurotoxicity, in support of outpatient administration. Emerging data shows that, with longer follow-up, epcoritamab presents substantial single-agent efficacy, including CR in heavily pretreated patients with FL, MCL, and DLBCL. The first expansion cohort was initiated in July 2020 and the trial is currently recruiting. A similar trial, GCT3013-04 or EPCORE NHL-3 is currently recruiting patients in Japan.

GCT3013-03, or EPCORE CLL-1, is a Phase I/II open-label, multi-center safety and efficacy study of epcoritamab in relapsed/refractory CLL and Richter's Syndrome. The trial includes two parts, a dose escalation phase (phase Ib) and an expansion phase (phase II). The dose escalation phase is currently recruiting, with preliminary results presented at ASH 2021.

GCT3013-05, or EPCOR DLBCL-1, is the first Phase III study of epcoritamab. The purpose of the open-label, randomized, multi-center trial is to evaluate the efficacy of epcoritamab compared to investigator's choice of chemotherapy in patients with relapsed, refractory DLBCL who have failed or are ineligible for ASCT. Estimated enrollment into the trial is 480 patients and the study is currently enrolling. The first patient was dosed in this study in January 2021.

DuoBody-PD-L1x4-1BB (GEN1046)

DuoBody-PD-L1x4-1BB is a bispecific antibody designed to target PD-L1 and 4-1BB to block the inhibitory PD-1/PD-L1 axis and simultaneously activate essential co-stimulatory activity via 4-1BB using an inert Fc backbone. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF receptor super-family and is expressed predominantly on activated T-cells. In preclinical settings, DuoBody-PD-L1x4-1BB promoted conditional T-cell activation in a tumor-specific manner by simultaneous activation and release of the key inhibitory brake. Preclinical studies also indicated a release of T-cell inhibition through the PD-1/PD-L1 axis, including in the absence of 4-1BB, strong co-stimulation via the agonistic activity of 4-1BB and T-cell clonal expansion. We are developing DuoBody-PD-L1x4-1BB for the treatment of solid cancers in collaboration with BioNTech using our proprietary DuoBody technology platform and PD-L1 antibody and BioNTech's 4-1BB antibody. A Phase I/II study of DuoBody-PD-L1x4-1BB for the treatment of malignant solid tumors was initiated in May 2019 with the first expansion cohort initiated in the first quarter of 2020. Preliminary clinical data was presented at the Society for Immunotherapy of Cancer ("**SITC**") Annual Meeting in November 2020. The study is currently recruiting. A Phase II study of DuoBody-PD-L1x4-1BB was initiated in November 2021. The multicenter, randomized, open-label study will evaluate DuoBody-PD-L1x4-1BB as monotherapy and in combination with pembrolizumab as treatment for patients with relapsed / refractory metastatic NSCLC after treatment with standard of care therapy with an immune checkpoint inhibitor.

DuoBody-CD40x4-1BB (GEN1042)

DuoBody-CD40x4-1BB is a bispecific antibody designed to conditionally activate both CD40-expressing antigen-presenting cells and 4-1BB-expressing T-cells using an inert DuoBody format. In preclinical settings, as presented at European Association for Cancer Immunotherapy Annual meeting in May 2019, the CD40- and 4-1BB-specific Fab arms of DuoBody-CD40x4-1BB bound to primary human CD40-expressing CD20+ B cells and activated 4-1BB-expressing CD3+ T cells. DuoBody-CD40x4-1BB dose-dependently induced CD40 signaling only upon CD40 binding and simultaneous binding to 4-1BB expressing cells and induced 4-1BB signaling only upon 4-1BB binding and simultaneous binding to CD40-expressing cells. DuoBody-CD40x4-1BB was also shown to conditionally increase proliferation of activated T cells in the presence of CD40-expressing cells *in vitro*. DuoBody-CD40x4-1BB induced T-cell proliferation upon crosslinking of CD40- and 4-1BB-expressing cells and the binding of only the CD40 arm or the 4-1BB arm had no effect on T-cell proliferation. In addition, DuoBody-CD40x4-1BB did not induce proliferation of T cells that had not been activated by polyclonal or antigen-specific T-cell receptor triggering. In the context of cancer, DuoBody-CD40x4-1BB can enhance anti-tumor immunity by (re-)activating tumor-specific T cells, either

intratumorally or in the tumor-draining lymph nodes. Conditional agonist activity is a unique mechanism of action, distinguishing DuoBody-CD40x4-1BB from agonistic monoclonal antibodies targeting CD40 or 4-1BB. It therefore represents a novel therapeutic agent with potential for treatment of solid tumors.

We are developing DuoBody-CD40x4-1BB for the treatment of solid cancers in collaboration with BioNTech using Genmab's proprietary DuoBody technology platform and BioNTech's CD40 and 4-1BB antibodies. The first patient was dosed in the first-in-human Phase I/II study of DuoBody-CD40x4-1BB for the treatment of malignant solid tumors in September 2019. Preliminary dose-escalation data was presented at the SITC Annual Meeting in November 2021. In September 2021 the study was updated to include multiple expansion cohorts in combination and in additional indications. These include DuoBody-CD40x4-1BB in combination with pembrolizumab in first-line NSCLC, in first-line head and neck squamous cell carcinoma and in first-line melanoma and in combination with pembrolizumab and chemotherapy in first-line head and neck squamous cell carcinoma and in first-line pancreatic ductal adenocarcinoma. The study is currently recruiting.

DuoHexaBody-CD37 (GEN3009)

DuoHexaBody-CD37 is a bispecific IgG1, created with our propriety DuoHexaBody technology platform that targets two non-overlapping CD37 epitopes. CD37 is a tetraspanin membrane protein abundantly expressed on normal and malignant B cells and represents a promising target for the treatment of B-cell malignancies. With DuoHexaBody-CD37 we aimed to generate CD37-specific antibodies with superior CDC activity. CDC is an efficient effector mechanism employed by multiple existing antibody therapeutics. In preclinical settings DuoHexaBody-CD37 has been shown to induce potent *in vivo* and *in vitro* anti-tumor activity. As presented at ASH in December 2018, DuoHexaBody-CD37 induced superior CDC activity compared to single HexaBody molecules or the combination thereof in CLL cells ex vivo. In addition, the potency of DuoHexaBody-CD37 was superior to standard-of-care CD20 antibodies *ex vivo*. The encouraging preclinical models suggest DuoHexaBody-CD37 is a promising candidate for clinical development in B-cell malignancies. In March 2020, we initiated a Phase I/II clinical trial of DuoHexaBody-CD37 for the treatment of hematologic malignancies. In December 2021 an arm was added to the study investigating DuoHexaBody-CD37 in combination with epcoritamab. The study is currently recruiting. We are developing DuoHexaBody-CD37 in collaboration with AbbVie.

HexaBody-CD38 (GEN3014)

HexaBody-CD38 is a novel human CD38 monoclonal antibody product incorporating our HexaBody technology. In preclinical models of hematological malignancies, as presented at ASH in December 2019, HexaBody-CD38 demonstrates enhanced CDC and shows potent anti-tumor activity. HexaBody-CD38 carries the E430G mutation that facilitates the natural process of antibody hexamer formation through intermolecular Fc-Fc interactions after antigen binding at the cell surface. Enhanced IgG hexamer formation increases binding of the hexavalent complement component C1q, thereby potentiating or unlocking antibody-mediated CDC. HexaBody-CD38 induced highly potent CDC *in vitro* in cell lines derived from hematological malignancies including MM, B cell lymphoma and acute myeloid leukemia ("**AML**"), inducing CDC in seventeen out of twenty-eight tumor cell lines that were not sensitive to daratumumab (<50% tumor cell lysis), including cell lines with low expression of CD38 or high expression of the complement inhibitory protein CD59. HexaBody-CD38 did not induce lysis of normal human B cells, T cells or erythrocytes, and induced minimal lysis of normal human NK cells. In addition, HexaBody-CD38 was consistently more potent than daratumumab in samples from daratumumab-naïve patients (newly diagnosed or relapsed/refractory to standard-of-care, including chemotherapy or high dose chemotherapy followed by ASCT, immunomodulatory drugs and proteasome inhibitors).

In June 2019, Genmab entered into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38. See below for additional details about this agreement. We submitted an IND to the FDA for HexaBody-CD38 in October 2020. In March 2021 we initiated a Phase I/II clinical trial of HexaBody-CD38 for the treatment of hematologic malignancies. The study is currently recruiting.

DuoBody-CD3xB7H4 (GEN1047)

DuoBody-CD3xB7H4 is a bispecific antibody created with our proprietary DuoBody technology platform. B7H4 is an immune checkpoint protein expressed on malignant cells in various solid cancers including breast, ovarian and lung cancer. The first preclinical presentation of DuoBody-CD3xB7H4 was made at the SITC Annual Meeting in November 2021. In preclinical studies, DuoBody-CD3xB7H4 induced T-cell mediated cytotoxicity of B7H4-positive tumor cells. DuoBody-CD3xB7H4 is being developed as a therapeutic agent for the treatment of solid cancer indications known to express B7H4. We submitted an IND to the FDA for DuoBody-CD3xB7H4 in July 2021. In January 2022 the first patient was dosed in the first-in-human Phase I/II clinical trial of DuoBody-CD3xB7H4 for the treatment of solid tumors. The study is currently recruiting.

DuoBody-CD3x5T4 (GEN1044)

DuoBody-CD3x5T4 is a CD3 bispecific, Fc-silenced IgG1 antibody with the capacity to crosslink T cells with 5T4-expressing tumor cells. In September 2021 we, along with AbbVie, decided that the data did not support the further development of DuoBody-CD3x5T4. The maximum tolerated dose was reached at a dose level that is below the one expected to be active.

HexaBody-DR5/DR5 (GEN1029)

HexaBody-DR5/DR5 is a proprietary antibody therapeutic candidate created with our proprietary HexaBody technology and DR5antibodies acquired from IDD Biotech. HexaBody-DR5/DR5 consists of two non-competing HexaBody molecules that are designed to target two distinct epitopes on death receptor 5, or "**DR5**", a cell surface receptor that mediates a process called programmed cell death. Increased expression of DR5 has been reported in several types of tumors. HexaBody-DR5/DR5 was the first HexaBody molecule to enter the clinic. In 2018, we initiated a Phase I/II clinical trial of HexaBody-DR5/DR5, GCT1029-01, for the treatment of solid tumors, with the first patient dosed in May 2018.

In September 2021 we decided that the data did not support the further development of HexaBody-DR5/DR5. Preliminary activity was shown, but the narrow therapeutic index does not support further development.

Preclinical Programs

In addition to our marketed products and clinical product candidates, we have approximately 20 active in-house and partnered preclinical programs.

Partnered Candidates

Our partners currently have multiple product candidates in clinical development through collaboration agreements with us. These include several bispecific antibodies being developed by Janssen using our proprietary DuoBody technology, which are being tested to treat NSCLC, solid tumors and certain MM indications. Additional products are being developed in partnership with Bristol-Myers Squibb ("**BMS**"), ADC Therapeutics, Lundbeck, Provention Bio, Global Blood Therapeutics and Novo Nordisk. In June 2021 teclistamab, in development with Janssen for certain MM indications, received BTD from the FDA. In December 2021 Janssen submitted a BLA to the FDA for teclistamab for the treatment of relapsed or refractory multiple myeloma. In January 2022 Janssen submitted a marketing authorization application ("**MAA**"), for teclistamab for the same indication. A Phase III study of teclistamab in combination with SC daratumumab in patients with relapsed or refractory MM was announced in October 2021 and is currently recruiting.

Our Technology Platforms

DuoBody Platform

The DuoBody platform is our innovative proprietary platform for the creation and development of bispecific antibodies. Bispecific antibodies bind to two different epitopes (or "docking" sites) either on the same, or on different

targets (also known as dual-targeting). We believe that dual-targeting may improve binding specificity and enhance therapeutic efficacy or bring two different cells together (for example engaging a T-cell to kill a tumor cell). Bispecific antibodies generated with our DuoBody platform can be used for the development of potential therapeutics for cancer, hemophilia and autoimmune, infectious, cardiovascular and central nervous system diseases. DuoBody molecules are designed to combine the benefits of bispecificity with the strengths of conventional antibodies, which may allow DuoBody molecules to be administered and dosed in the same way as other antibody therapeutics. Based on a proof-of-concept study, we believe that our DuoBody platform generates bispecific antibodies via a versatile and broadly applicable process which has the potential to be easily performed at high throughput, at standard bench, as well as on a commercial manufacturing scale. We use the DuoBody platform to create our own bispecific antibody programs and we actively seek partners interested in developing antibody therapeutics using our DuoBody technology. We have a number of commercial partners for the DuoBody technology, including Janssen, BioNTech, AbbVie and Novo Nordisk. See "—Product and Technology Collaborations—Collaborations and Other Agreements for our Partnered Products" for more information about our current licenses and collaborations.

A number of our proprietary bispecific antibodies created with the DuoBody technology are in clinical development. In addition, Janssen has progressed a number of product candidates into clinical development through our DuoBody partnership, including amivantamab, which has been approved in the U.S., Europe and certain other markets and teclistamab, for which a BLA was filed with the FDA in December 2021 and an MAA filed with the EMA in January 2022.

HexaBody Platform

Our HexaBody platform is a proprietary technology that is designed to increase the potency of antibodies. The HexaBody platform is designed to build on natural biology to strengthen the natural killing ability of antibodies while retaining regular structure and specificity. The HexaBody technology allows for the creation of potentially potent therapeutics by inducing antibody hexamer formation (clusters of six antibodies) after binding to their target antigen on the cell surface. We have used the HexaBody platform to generate antibodies with an enhanced complement-mediated killing design, allowing antibodies with limited or absent killing capacity to be transformed into potent, cytotoxic antibodies. In addition to complement-mediated killing, the clustering of membrane receptors by the HexaBody platform may lead to subsequent outside-in signaling. The HexaBody technology creates opportunities to explore new product candidates, to repurpose drug candidates unsuccessful in previous clinical trials due to insufficient potency and may provide a useful strategy in product life cycle management. We believe that the HexaBody technology is broadly applicable and may be combined with other antibody technologies. The technology has the potential to enhance antibody therapeutics for a broad range of applications in cancer and infectious diseases.

HexaBody-DR5/DR5 is our first proprietary antibody created with HexaBody technology to reach clinical development, though in September 2021 we decided that the data did not support the further development of HexaBody-DR5/DR5. In June 2019, we entered into an exclusive license and option agreement with Janssen to collaborate exclusively on a next-generation CD38 antibody product incorporating our proprietary HexaBody technology. The IND for HexaBody-CD38 was submitted to the FDA in October 2020 and the first CTA, in Denmark, was submitted in November 2020. The first patient was dosed with HexaBody-CD38 in March 2021.

DuoHexaBody Platform

The DuoHexaBody platform is a novel proprietary technology that combines the dual targeting design of our DuoBody technology with the potential enhanced potency of our HexaBody technology, creating bispecific antibodies with a target-mediated enhanced hexamerization design. DuoHexaBody-CD37 is currently our only proprietary bispecific antibody created with DuoHexaBody technology. An IND for DuoHexaBody-CD37 was submitted to the FDA in November 2019 and the first patient was treated with DuoHexaBody-CD37 in March 2020.

HexElect Platform

The HexElect platform is a novel proprietary technology that combines two different HexaBody molecules in order to selectively hit only those cells that express both targets by making the activity of complexes of HexaBody molecules

dependent on their binding to two different targets on the same cell. The HexElect platform maximizes potency while minimizing potential toxicity, potentially leading to more potent and safer products.

Manufacturing

We do not currently manufacture the drug products ourselves that we need to conduct our clinical trials, and we therefore rely on our partners or CMOs to supply drug product for our IND-enabling studies, clinical trials and process validation batches and related activities for BLA and other regulatory submissions, and we expect to rely on such partners or CMOs for production of commercial supply of our products in the future. Manufacturing clinical products is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our vendors are required to comply with cGMP regulations, which are regulatory requirements enforced by the FDA, the EMA and other regulatory bodies to assure proper design, monitoring and control of manufacturing processes and facilities for human pharmaceuticals.

We have no involvement with the manufacturing process for our partnered approved products, DARZALEX and RYBREVANT, handled by Janssen, Kesimpta, by Novartis and TEPEZZA handled by Horizon, under the applicable agreements. Currently, the majority of the drug products required for our clinical trials and preclinical studies are manufactured by Lonza. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including fill and finish, shipping and storage of drug products and our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. Although we rely on our cGMP manufacturers and suppliers, we have personnel with substantial manufacturing and production experience to oversee our relationships with such manufacturers and suppliers.

We believe our CMOs are, and any future CMOs will be, capable of producing sufficient quantities of drug product to support our currently planned commercialization, clinical trials and preclinical studies. We also believe that there are a number of alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of commercial products and drug product for our planned clinical trials and preclinical studies. However, should our CMOs not be able to provide sufficient quantities of commercial products or drug product for our planned commercialization, clinical trials or preclinical studies, we would be required to seek other CMOs to provide this drug product, potentially resulting in a delay in such trials or delivery of our commercialized products.

Commercialization Strategy

Our partnered approved products are DARZALEX and RYBREVANT marketed by Janssen, Kesimpta marketed by Novartis and TEPEZZA marketed by Horizon, under worldwide license agreements with us, or in the case of TEPEZZA, under a sublicense from Roche. We receive royalties from Janssen, Novartis and Roche based on net sales of DARZALEX, RYBREVANT, Kesimpta and TEPEZZA, but we are not involved with commercialization activities or strategy.

We are currently building and expanding our commercial capabilities to allow us to market our own products for the indications and in the geographies we determine would be most effective to create value for our shareholders. Genmab became a commercial-stage company to support the launch of Tivdak for the treatment of cervical cancer. We are developing and co-promoting tisotumab vedotin in the U.S. in collaboration with Seagen. In October 2020, Genmab 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. We view Japan as a promising commercial opportunity where modest commercial and medical affairs infrastructure has the potential to become a high-value investment. Given the low rate of cancer screening and human papillomavirus vaccinations in Japan, we believe that cervical cancer presents a significant unmet medical need in the Japanese medical market.

In June 2020, Genmab and AbbVie entered into a broad collaboration agreement to jointly develop and commercialize epcoritamab, DuoHexaBody-CD37 and DuoBody-CD3x5T4. For epcoritamab, the companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Genmab will be the principal for net sales in the U.S. and Japan and receive tiered royalties between 22% and 26% on remaining global net sales. For DuoHexaBody-CD37 and any product candidates developed as a result of the companies' discovery research collaboration, Genmab and AbbVie will share responsibilities for global development and commercialization in the U.S. and Japan, while AbbVie will be responsible for further global commercialization with Genmab having a right to opt-in to co-commercialize in the remaining territories. In September 2021 we, along with AbbVie, decided that the data did not support the further development of DuoBody-CD3x5T4.

Moving forward, we may choose to commercialize new products independently, or we may rely on our partners to do so in whole or in part. This will be determined on a product-by-product or indication-by-indication basis in each proposed market and will depend on the agreements we have with our partners and our assessment of the most effective commercialization plan to benefit patients and create value for our shareholders.

Competition

The biotechnology and pharmaceutical industries generally, and the cancer drug sector specifically, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and a strong emphasis on intellectual property. While we believe that our product candidates and our knowledge and experience provide us with competitive advantages, we face substantial potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing our product candidates.

Below is a description of competition in certain of our products and product candidates.

With respect to daratumumab, there are numerous other FDA-approved drugs for the treatment of MM, including immunomodulating agents such as BMS's Revlimid and Pomalyst®, PIs such as Janssen and Takeda's Velcade®, Amgen's Kyprolis®, and Takeda's Ninlaro®, histone deacetylase inhibitors such as Novartis' Farydak® and mAbs such as BMS' Empliciti®. Several of these drugs are used in combination with chemotherapy and corticosteroids. The competition daratumumab faces from these and other therapies is intensifying. Additionally, isatuximab, a CD38 antibody developed by Sanofi, was approved as SARCLISA by the FDA in March 2020 and the EC in June 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. The IKEMA trial of isatuximab + Kd in second line MM met its primary endpoint of improving PFS in May 2020 and the indication was approved by the FDA in March 2021. We are also aware of numerous additional investigational agents that are currently being studied. If any of these investigational agents are successful, they may compete with daratumumab in the future. Data have also been presented on several developing technologies and related potential products, including bispecific antibodies, ADCs and CAR-Ts that may compete with daratumumab in the future.

In August 2020 and March 2021 respectively, the FDA and the EC approved SC ofatumumab for the treatment of RMS in adults. Competition in the MS market is intense. There are numerous FDA-approved drugs for the treatment of the various forms of MS, including Biogen Inc.'s Tecfidera®, Novartis' GILENYA®, Sanofi's AUBAGIO® and several

mAbs such as Genentech's OCREVUS® (a CD20 antibody), Sanofi's LEMTRADA® and Biogen's TYSABRI®; glatiramer acetate-based therapies such as Teva Pharmaceutical Industries Limited's COPAXONE® and Sandoz's Glatopa®; and interferon-beta-based therapies such as Biogen's AVONEX® and PLEGRIDY®, Bayer AG's BETASERON®/Betaferon®, Novartis' EXTAVIA®, and Merck KGaA's Rebif®. A number of companies are also working to develop additional potential treatments for MS that may in the future further intensify the competition in the MS market, such as TG Therapeutics's ublituximab, currently under review with the FDA, BMS's Ozanimod and Novartis' Siponimod, which are currently being evaluated in Phase III clinical trials. Potential future sales may also be negatively impacted by the introduction of generics, prodrugs of existing therapeutics or biosimilars of existing products and other technologies.

With respect to tisotumab vedotin, we are aware of other companies that currently have products in development for the treatment of late-stage cervical cancer, which could be competitive with tisotumab vedotin, including checkpoint inhibitors from Agenus Inc., BMS, Merck, Roche, and Innovent Biologics, Inc. as well as other drugs in development from other companies. In June 2018 the FDA granted Merck's Keytruda, a PD-1 inhibitor, accelerated approval as monotherapy for patients with recurrent or metastatic cervical cancer. The FDA granted regular approval for this indication in October 2021, at the same time approving Keytruda in combination with chemotherapy, with or without bevacizumab, for patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test.

We are similarly aware, with respect to epcoritamab, of a number of other companies that have bispecific CD3xCD20-targeted product candidates in development for the treatment of B-cell malignancies, which could be competitive with epcoritamab including ADC Therapeutics Zynlonta, MorphoSys' Monjuvi, Regeneron's odronextamab, Roche's mosunetuzumab, which has BTD and for which a regulatory approval is anticipated in 2022, and glofitamab, Xencor's plamotamab and IGM biosciences' IGM 2323. We are also aware that there are a number of various CD20 and CD19 antibodies, immunomodulators, ADCs, tyrosine kinase inhibitors and CAR-T therapies that are either approved or in development for non-Hodgkin's lymphomas. In addition, in June 2019 Roche received accelerated approval in the U.S. for Polivy, a first-in-class anti-CD79b ADC, in combination with bendamustine and rituximab for adults with R/R DLBCL who have received at least two prior therapies. In August 2021 Roche announced that the Phase III POLARIX trial met its primary endpoint. The positive readout of POLARIX meets the post-marketing requirement to convert the accelerated approval into a full approval, potentially raising the bar for other drugs, including epcoritamab, to enter the R/R DLBCL space. It is also expected that the data will be submitted to health authorities globally with the potential for first-line approval in 2022.

With respect to DuoBody-PD-L1x4-1BB, we are aware of a number of other companies that have bispecific PD-L1x4-1BB products in development for the treatment of solid cancers including Merus and Incyte's MCLA-145, Elpiscience and Inhibrix's INBRX-105, Numab and Cstone Pharmaceuticals NM21-1480, Pieris's PRS-344, F-Star's FS222 and Macrogenics's PD-L1xCD137 DART.

In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our products and product candidates are designed and being developed to treat. We are also aware of other companies that have or are developing technologies that may be competitive with ours, including bispecific antibody, CAR-T and RNA-based technologies. In addition, our DuoBody and other technology partners may develop compounds utilizing our technology that may compete with product candidates that we are developing.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 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. This pathway allows competitors to reference the FDA's prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. 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. Data 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. In the European Union, the European Commission has granted MAs 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 companies, as well as 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 technologies that are more effective than our products or our 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.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our products, product candidates and technology platforms;
- license or acquire additional technology;
- complete clinical trials which position our products for regulatory and commercial success;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- establish efficient manufacturing processes and supply chain;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to our business, including the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

Product and Technology Collaborations

Collaborations for our Marketed Products

Janssen Daratumumab License and Development Agreement

In August 2012, we entered into a global license, development and commercialization agreement with Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, granting Janssen an exclusive, sublicensable license to certain of our patents, know-how and materials, owned by or licensed to us, to research, develop, make, offer and sell worldwide certain licensed products containing the human mAb denoted “daratumumab,” also known as HuMax-CD38

and DARZALEX. With respect to the licensed technology, we have given up the ability to develop or commercialize other products with affinity to the CD38 antigen target. We recorded an upfront license fee of $55.0 million and Johnson & Johnson Development Corporation invested DKK 475.2 million (approximately $80.0 million at the date of the agreement) to subscribe for 5.4 million newly issued shares of Genmab at a price of DKK 88 per share. Janssen is fully responsible for developing and commercializing the licensed products and all costs associated therewith.

Under this agreement, we could be entitled to up to approximately $1,015 million in development, regulatory and sales milestones, in addition to tiered double-digit royalties between 12% and 20% of net sales. As of December 31, 2021, Genmab has recorded $910 million in milestone payments from Janssen and could be entitled to receive up to $105 million in further payments if certain additional milestones are met. In 2019, sales milestones of $100 million and $150 million upon net sales reaching $2.5 billion and $3.0 billion in a calendar year, respectively, as calculated on the basis of the license agreement terms, were achieved. No further sales milestones are due under the license agreement. The following royalty tiers apply for net sales in a calendar year: 12% on net sales up to and including $750 million; 13% on net sales above $750 million and up to and including $1.5 billion; 16% on net sales above $1.5 billion and up to and including $2.0 billion; 18% on net sales above $2.0 billion and up to and including $3.0 billion; and 20% on net sales exceeding $3.0 billion.

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 daratumumab do not begin to expire until March 2026.

Janssen may fully or partially terminate the agreement at any time upon 150 days' prior written notice to us. Upon Janssen's termination of the agreement, we are granted an exclusive, perpetual, sublicensable license under any intellectual property controlled by Janssen or its affiliates to the extent necessary to make, have made, import, use, offer to sell or sell the terminated licensed product in such territory where the license has been terminated. If certain milestones have been met by Janssen prior to the termination, then we must pay royalties to Janssen for 10 years from our first commercial sale of a licensed product.

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 for the Halozyme enzyme technology used in the SC 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.

Novartis Ofatumumab Collaboration

In December 2006, we entered into a co-development and collaboration agreement with GlaxoSmithKline ("**GSK**"), pursuant to which GSK obtained exclusive, worldwide rights to develop and commercialize ofatumumab. This agreement was subsequently amended in 2010. In 2015, GSK transferred the ofatumumab collaboration for oncology and autoimmune diseases to Novartis. Novartis is now responsible for the development and commercialization of ofatumumab in all potential indications. Novartis is fully responsible for all costs associated with developing and commercializing ofatumumab. Under the current agreement with Novartis, we are entitled to royalties of 20% of worldwide net sales of ofatumumab for intravenous treatments and 10% of worldwide net sales of ofatumumab for non-intravenous treatments, as well as certain potential regulatory and sales milestones, of which only certain sales milestones remain. Novartis is currently investigating a SC formulation of ofatumumab for the treatment of RMS and has obtained approval for this indication in the U.S., Europe and Japan among other territories. We therefore believe that the split between intravenous and non-intravenous administration of ofatumumab will, in practice, align with the split

between cancer and non-cancer treatments, and we therefore generally refer to the higher royalty rate as being applicable to cancer treatments and the lower royalty rate as being applicable to non-cancer treatments.

The royalties are on a country-by-country basis subject to reduction in a specified amount based on the market share of competing products or a joint committee determination that a license of intellectual property owned by a third party is necessary for commercialization. Novartis can terminate the agreement in its entirety or on a country-by-country basis at any time on nine months' prior written notice. In August 2020, the FDA approved the use of Kesimpta injection for SC use, for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In March 2021 Kesimpta was approved by the EC in adults with active disease defined by clinical or imaging features. Kesimpta was also approved in Japan in March 2021 and is currently approved in over 60 countries.

Roche / Horizon Teprotumumab Collaboration

In May 2001, Genmab entered a collaboration with Roche to develop human antibodies to disease targets identified by Roche. In 2002, this alliance was expanded, and Roche made an equity investment in Genmab. Under the agreement, Genmab will receive milestones as well as royalty payments on successful products and, in certain circumstances, Genmab could obtain rights to develop products based on disease targets identified by Roche. Teprotumumab was created by Genmab under the collaboration with Roche, and development and commercialization of the product, which was approved in 2020 by the FDA, as TEPEZZA, for the treatment of thyroid eye disease, is now being conducted by Horizon Therapeutics under a license from Roche. Under the terms of Genmab's agreement with Roche, Genmab will receive mid-single digit royalties on sales of TEPEZZA.

Janssen Amivantamab Collaboration Agreement

In July 2012, Genmab entered into a collaboration with Janssen to create and develop bispecific antibodies using Genmab's DuoBody technology platform. The two antibody libraries used to produce amivantamab were both generated by Genmab. In collaboration with Janssen, the antibody pair used to create amivantamab was selected. Janssen has led the development of amivantamab. In May 2021, Janssen received approval from the FDA for amivantamab, as RYBREVANT, for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. RYBREVANT has also been approved in the EU and other markets. These are the first regulatory approvals for a therapy that was created using Genmab's proprietary DuoBody bispecific technology platform. Under our agreement with Janssen, Genmab will receive milestones and royalties between 8% and 10% on net sales of RYBREVANT.

Certain Collaborations for our Proprietary Product Candidates

AbbVie Collaboration Agreement

In June 2020, we entered into a Collaboration and License Agreement with AbbVie to jointly develop and commercialize three of our early-stage investigational bispecific antibody product candidates. In addition, under the agreement, we agreed with AbbVie to enter into a discovery research collaboration for future differentiated antibody therapeutics for cancer. The joint development efforts involve our three bispecific antibody programs epcoritamab (DuoBody-CD3xCD20), DuoHexaBody-CD37 and DuoBody-CD3x5T4.

For epcoritamab, we share commercial responsibilities with AbbVie in the United States and Japan, while AbbVie is responsible for global commercialization outside of the United States and Japan. We will book net sales of epcoritamab in the United States and Japan and receive tiered royalties on remaining global sales outside these territories. For DuoHexaBody-CD37 and any product candidates developed as a result of the discovery research collaboration, we will share responsibilities with AbbVie for global development and commercialization in the United States and Japan. Subject to certain requirements, we have an option to co-commercialize these products, along with AbbVie, outside of the United States and Japan.

We and AbbVie grant to each other co-exclusive licenses to use certain intellectual property that is necessary for or directly related to the development, manufacture or commercialization of the compounds being developed under the agreement and the resulting licensed products, as further described in the agreement. The licenses can be sublicensed to affiliates of the applicable licensee or to third party sub-contractors meeting certain requirements or if otherwise approved.

Under the terms of the agreement, we received a $750 million upfront payment in June 2020 and we may be entitled to receive an aggregate of up to $3.15 billion in additional development, regulatory and sales milestone payments for all programs. Included in these potential milestones are up to $1.15 billion in payments related to clinical development and commercial success across the three bispecific antibody programs originally included in the agreement, one of which was subsequently stopped. In addition, after we enter into the discovery research collaboration, we are eligible to receive up to $2.0 billion in option exercise and success-based milestone payments under this agreement and the discovery research collaboration agreement if all four next-generation antibody product candidates developed as a result of the discovery research collaboration are successful. We are further entitled to tiered royalties between 22% and 26% on net sales for epcoritamab outside the United States and Japan. Except for these royalty-bearing sales, we will share with AbbVie pre-tax profits from the sale of licensed products on a 50:50 basis.

The agreement expires when neither we nor AbbVie are developing or commercializing any licensed products. AbbVie may terminate the agreement at AbbVie's convenience at any time after a certain notice period, either in whole or on a licensed product-by-licensed product basis or on a region-by-region basis. The United States and Japan as a whole, Europe as a whole, and the rest of the world each constitute one region for this purpose. If we or AbbVie terminate the agreement due to a material breach, insolvency event or force majeure event with respect to the other party, the terminating party will have the exclusive right (including the exclusive right to use the intellectual property licensed to it under the agreement) to develop, manufacture and commercialize the terminated licensed product in the terminated region. The terminating party will pay the other party a royalty on net sales of the terminated product in the terminated region up to certain thresholds depending on which party terminated the agreement. A termination by AbbVie for convenience is treated the same way as a termination by Genmab for a material breach by AbbVie for this purpose, which means that Genmab would have the exclusive right to develop, manufacture and commercialize the terminated licensed product in the terminated region.

In September 2021 we, along with AbbVie, decided that the data did not support the further development of DuoBody-CD3x5T4. The maximum tolerated dose was reached at a dose level that is below the one expected to be active.

Seagen Tisotumab Vedotin Collaboration

In October 2011, we entered into a license and collaboration agreement with Seagen granting us an exclusive right to utilize Seagen's ADC technology with our HuMax-TF antibody in return for milestone payments and royalties. We also granted Seagen a right to exercise a co-development and co-commercialization option at the end of Phase I clinical development for tisotumab vedotin. In August 2017, Seagen exercised this option to co-develop and co-commercialize tisotumab vedotin with us. In October 2020, Genmab 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. In September 2021 tisotumab vedotin received accelerated approval from the FDA as Tivdak, for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

BioNTech DuoBody Collaboration

In May 2015, we entered into an agreement with BioNTech to jointly research, develop and commercialize bispecific antibody products using our DuoBody technology platform and antibodies. Under the terms of the agreement,

BioNTech provides proprietary antibodies against key immunomodulatory targets, while we provide access to our DuoBody technology platform. We paid an upfront fee of $10 million to BioNTech and an additional fee as certain BioNTech assets were selected for further development. If the companies jointly select any product candidates for clinical development, development costs and product ownership will be shared equally going forward. If one of the companies does not wish to move a product candidate forward, the other company is entitled to continue developing the product on predetermined licensing terms. The agreement also includes provisions which will allow the parties to opt out of joint development at key points. Two product candidates are currently in clinical development in connection with this agreement, DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB.

Certain other Collaborations, Agreements and Enabling Technologies

Medarex UltiMAb® System License

In 1999, we entered into a license agreement with Medarex, now a wholly-owned subsidiary of BMS, pursuant to which we received access to the UltiMAb technology, the KM Mouse technology and the right to obtain antibody-exclusive licenses for an unlimited number of antigens and own the worldwide development and commercialization rights to antibody products targeting such antigens. In addition, Medarex granted us antigen-exclusive licenses in exchange for Genmab shares that are fully paid-up subject to, in case the products have been generated in the KM Mouse, pass-through of milestones and royalties payable by Medarex under its own license of the KM Mouse technology. Our principal obligation under this agreement is to make milestone and royalty payments in connection with any such antibody-exclusive licenses or in connection with use of the KM Mouse technology under this agreement. We used technology licensed from Medarex to generate daratumumab, ofatumumab, tisotumab, forming part of tisotumab vedotin, the CD20 antibody forming part of epcoritamab (DuoBody-CD3xCD20), and certain of our other product candidates. Based on the type of license and technology used in their development, product candidates that are subject to future payment obligations under this license agreement include ofatumumab, epcoritamab (DuoBody-CD3xCD20), amivantamab (DuoBody-cMetxEGFR) and Lu AF82422, but do not include daratumumab, tisotumab vedotin and HexaBody-CD38. With respect to ofatumumab and Lu AF82422, Novartis and Lundbeck, respectively, have agreed to bear the majority of our payments to Medarex under these agreements. Milestones for the product candidates subject to payment obligations are payable by us or our partners across all such product candidates currently in development. Royalties are in the low single digits of net sales.

Janssen HexaBody-CD38 Collaboration

In June 2019, we entered into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38, a next-generation human CD38 mAb product incorporating our proprietary HexaBody technology. Under the terms of the agreement, we have agreed to collaborate exclusively with Janssen on HexaBody-CD38 and to fund research and development activities until completion of clinical proof of concept studies in MM and DLBCL. Based on the data from these studies, Janssen may exercise its option and receive a worldwide exclusive license to certain of our intellectual property and an exclusive sublicense to certain intellectual property that we license from third parties, in each case, to develop, manufacture and commercialize HexaBody-CD38. If Janssen exercises this option, we will be entitled to a $150 million option exercise fee and up to $125 million in development milestones, as well as a flat royalty rate of 20% on sales of HexaBody-CD38 until a specified time in 2031, followed by 13-20% tiered royalties on net sales thereafter. Upon exercising the option, Janssen will be entitled to terminate the agreement in its entirety or on a country-by-country basis for any reason with 150 days prior written notice to us. Should Janssen not exercise its option, the agreement will terminate, and we may unilaterally continue to develop and commercialize HexaBody-CD38 for daratumumab-resistant patients, and in all other indications except those MM or amyloidosis indications where daratumumab is either approved or is being actively developed. The IND for HexaBody-CD38 was submitted to the FDA in October 2020. The first patient was dosed with HexaBody-CD38 in March 2021.

Janssen DuoBody Collaboration

In July 2012, Genmab entered into a collaboration with Janssen to create and develop bispecific antibodies using our DuoBody platform. Under this original agreement, Janssen had the right to use the DuoBody technology to create panels of bispecific antibodies (up to 10 DuoBody programs) to multiple disease target combinations. Genmab received an

upfront payment of $3.5 million from Janssen and will potentially be entitled to milestone and license payments of up to approximately $175 million, as well as royalties for each commercialized DuoBody product.

Under the terms of a December 2013 amendment, Janssen was entitled to work on up to 10 additional programs. Genmab received an initial payment of $2 million from Janssen. Under the terms of the original agreement, for each of the additional programs that Janssen successfully initiates, develops and commercializes, Genmab will potentially be entitled to receive average milestone and license payments of approximately $191 million. In addition, Genmab will be entitled to mid-single digit royalties on net sales of any commercialized products with the exception of RYBREVANT. Under our agreement with Janssen, Genmab will receive milestones and royalties between 8% and 10% on net sales of RYBREVANT. All research work is funded by Janssen.

Janssen has exercised 14 licenses under this collaboration, not all of which are active, and no further options remain for use by Janssen. One of these, RYBREVANT, is the first product created using the DuoBody technology platform to receive regulatory approval and regulatory submissions for a second, Janssen's teclistamab, have been submitted to the FDA and EMA.

Other Collaborations and Agreements

We have other active collaborations and agreements with a number of companies, including Janssen, ADC Therapeutics, BMS, Lundbeck, Amgen, Immatics, Novo Nordisk, CureVac, Bolt Biotherapeutics, Inc. and Tempus to create, develop and/or commercialize antibody candidates and/or license certain of our product candidates and use of our technology platforms. Under certain collaborations and agreements, which we have entered into in the ordinary course of business, and where we have licensed our product candidates or technology platforms, we typically receive or are entitled to receive upfront cash payments, progress- and sales-dependent milestones for the achievement by our collaborators of certain events, and, where applicable, research funding. We also are entitled to receive royalties on net sales of commercialized products resulting from the collaborations.

We also license technologies from a number of other companies that we use or have used to contribute to the antibody products in our pipeline. Key technologies include Seagen's ADC technologies, the OmniAb transgenic mouse and rat platforms from Open Monoclonal Technology, Inc., certain transgenic mouse technologies from Medarex, the rabbit antibody platform from MAB Discovery GmbH and certain expression systems used by Lonza for production of our product candidates. Pursuant to certain of these licenses, we or our partners are or may be obligated to pay small royalties for certain products generated or produced using these technologies upon commercialization of such products or product candidates. We also license certain targets disclosed and developed from Immatics' XPRESIDENT targets and T-cell receptor technology as part a research collaboration and exclusive license agreement with Immatics to discover and develop next-generation bispecific immunotherapies to target multiple cancer indications. As part of this collaboration, Immatics is or may be eligible to receive certain milestone payments and tiered royalties on net sales. We also entered into a research collaboration and license agreement with CureVac AG focusing on the research and development of differentiated mRNA-based antibody products by combining CureVac's mRNA technology and know-how with Genmab's proprietary antibody technologies and expertise. As part of this agreement CureVac is or may be eligible to receive certain milestone payments and tiered royalties on net sales.

Intellectual Property

Patents

As of December 31, 2021, we held more than 2,200 patents and patent applications, including more than 70 issued U.S. patents and more than 100 U.S. patent applications. All of our current issued patents and patent applications are projected to expire between 2022 and 2042.

Our owned and licensed patents and patent applications are directed to daratumumab, ofatumumab, tisotumab vedotin, our product candidates, antibodies, our proprietary technologies and other antibody based and/or enabling technologies. We commonly seek patent claims directed to compositions of matter, including antibodies, bispecific antibodies, and antibody drug conjugates, as well as methods of using such compositions. When appropriate, we also

seek claims to related technologies, such as antibody format technologies. For daratumumab, ofatumumab, tisotumab vedotin and each of our product candidates, we or our partners have filed or expect to file multiple patent applications. We maintain patents and prosecute applications worldwide for technologies that we have out licensed, such as our DuoBody technology. Similarly, for partnered products and product candidates, such as daratumumab, ofatumumab and tisotumab vedotin, we seek to work closely with our development partners to coordinate patent efforts, including patent application filings, prosecution, patent term extension, defense and enforcement. As our products and product candidates advance through research and development, we and/or our partners seek to diligently identify and protect new inventions, such as formulations, combination therapies, and methods of treatment. We also work closely with our scientific personnel to identify and protect new inventions that could eventually add to our development or technology pipeline.

With respect to daratumumab, we have issued patents and pending patent applications in numerous jurisdictions, including patents issued in the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026. In addition to our key composition of matter patents for daratumumab, we and Janssen have issued patents and pending patent applications in numerous jurisdictions and for specific formulations, indications and combination therapies that may offer additional protection. With respect to ofatumumab, we have issued patents and pending patent applications in numerous jurisdictions, including in the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for ofatumumab do not begin to expire until October 2023, with the U.S. composition of matter patent extended to May 2031. Novartis has issued patents and pending patent applications in numerous jurisdictions that may offer additional protection. With respect to tisotumab vedotin, we have issued patents and pending patent applications in numerous jurisdictions, including the United States, Europe and Japan. Our issued U.S., European and Japanese patents covering the composition of matter for tisotumab vedotin do not begin to expire until December 2029. In addition to our key composition of matter patents for tisotumab vedotin, we have issued patents and pending patent applications in numerous jurisdictions relating to specific formulations, indications and combination therapies that may offer additional protection.

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. This list above does not identify all patents that may be related to daratumumab, ofatumumab, tisotumab vedotin and our product candidates. For example, in addition to the listed patents, we have patents on platform technologies (that relate to certain general classes of products or methods), as well as patents that relate to methods of using, formulating or administering a product or product candidate, which may confer additional patent protection. We also have pending patent applications that may give rise to new patents related to one or more of these product candidates, technologies, formulations and uses.

The information in the above list is based on our current assessment of patents that we own or control or have exclusively licensed. The information is subject to revision, for example, in the event of changes in the law or legal rulings affecting our patents or if we become aware of new information. Significant legal issues remain unresolved as to the extent and scope of available patent protection for biotechnology products and processes in the United States and other important markets outside the United States. We expect that litigation will likely be necessary to determine the term, validity, enforceability, and/or scope of certain of our patents and other proprietary rights. An adverse decision or ruling with respect to one or more of our patents could result in the loss of patent protection for a product and, in turn, the introduction of competitor products or follow-on biologics to the market earlier than anticipated.

Patents expire, on a country-by-country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term adjustment, patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our partners may not be able to develop patentable products or processes or obtain patents from pending patent applications. In the event of patent issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our partners. Our or our partners' current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may

limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in USPTO inter partes review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our partners. Our partners' patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our partners.

Our commercial success depends significantly on our ability to operate without infringing patents and proprietary rights of third parties. Organizations such as pharmaceutical and biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover technologies similar to the technologies owned or licensed to us or to our partners. In addition, we are monitoring the progress of several pending patent applications of other organizations that, if granted in their broadest scope, may require us to license or challenge their validity or enforceability in order to continue commercializing our products and product candidates directly or through our partners. Our and our partners' challenges to patents of other organizations may not be successful, which may affect our and our partners' ability to commercialize daratumumab, ofatumumab, tisotumab vedotin, amivantamab or teprotumumab or our ability to commercialize our product candidates. We cannot determine with certainty whether patents or patent applications of other parties may materially affect our or our partners' ability to make, use or sell daratumumab, ofatumumab, tisotumab vedotin, amivantamab, teprotumumab or any other products or product candidates.

Trademarks

As of January 17, 2022, we and/or our subsidiaries own approximately 260 trademark registrations and applications, hereof 14 U.S. trademark registrations, including: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody® and HexElect®. Tivdak® is a trademark of Seagen Inc. EPCORE™ is a trademark of AbbVie Biotechnology Ltd. Arzerra® is a trademark of Novartis Pharma AG. Kesimpta® is a trademark of Novartis Pharma AG or its affiliates. DARZALEX® and DARZALEX *FASPRO*® are trademarks of Johnson & Johnson. TEPEZZA® is a trademark of Horizon Therapeutics Ireland DAC. Other than the registered trademarks listed above, we currently rely on our unregistered trademarks, trade names and service marks, as well as our domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We are seeking to register and will continue to seek to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate. If we do not secure trademark registration successfully for our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our rights in our trademarks, trade names and service marks against third parties.

Trade Secrets

We require our scientific personnel to maintain laboratory notebooks and other research records in accordance with our policies, which are also designed to strengthen and support our intellectual property protection. In addition to our patented intellectual property, we also rely on trade secrets and other proprietary information, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a proprietary information and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we will own all inventions conceived or reduced to practice by the individual in the course of rendering services to us. Our agreements with partners require them to have a similar policy and agreements with their employees, consultants and

advisors to ensure the agreed upon allotment of intellectual property rights can be enforced. Our policy and agreements and those of our partners may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

Government Regulation

The FDA, the EMA and other regulatory authorities at U.S. federal, state, and local levels, as well as in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with our partners and third-party contractors, are required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and financial resources. The following sections outline the approval process and other rules and regulations applicable to biologics in the United States and the European Union. While the regulatory process in many countries is similar to the United States or the European Union, each jurisdiction has its own regulations, and approval in one jurisdiction does not guarantee approval in any other jurisdiction.

Review and Approval of Biologic Products in the United States

Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and other federal, state, local and foreign statutes and regulations. Our product candidates must be approved by the FDA before they may be legally marketed in the United States.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices (cGLPs) regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("**IRB**"), or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with current cGCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated when significant changes are made.

Prior to beginning the first clinical trial with a product candidate in the United States, we or our partner must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

A clinical trial involves the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with cGCPs, which includes the requirement that all research patients provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or data monitoring committee, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for patients or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I*—The investigational product is initially introduced into human patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- *Phase II*—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials and we often conduct Phase I/II studies. Some of the Phase II studies can potentially provide an adequate basis for regulatory approval.

- *Phase III*—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase IV studies may be made a condition to approval of the BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("**PREA**"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan within sixty days after an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Once a BLA has been submitted, the FDA's goal is to review the application within 10 months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. If the submission is incomplete or there are issues with its content or format, a Refusal to File notice is issued sixty days after submission, rather than acceptance for filing by FDA. The review process may be extended by the FDA's requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us or our partners from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA may issue an approval, which authorizes commercial marketing of the product with specific prescribing information for specific indications or a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for

approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation, or FTD, if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address an unmet medical need for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. An FTD product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. 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. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical objective that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, a sponsor may seek FDA breakthrough therapy designation, or BTD, of its product candidate if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant objectives, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross disciplinary review; assigning a cross disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. BTD also allows the sponsor to submit sections of the BLA for review on a rolling basis.

FTD, priority review, BTD, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Review and Approval of Combination Products

Although most of our product candidates are regulated as biologics, certain of our product candidates are subject to regulation in the United States as combination products. If marketed individually, each component would be subject to different regulatory pathways and would require FDA approval of independent marketing applications by the FDA. A combination product, however, is assigned to a Center within the FDA that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. Our ADC candidates are both drug and biologic molecules. Such ADCs are regulated as therapeutic biologics and the FDA's Center for Drug Evaluation and Research ("**CDER**"), will have primary jurisdiction over pre-market development. We expect to seek approval of these combination products through single BLA reviewed by CDER, and we do not expect that the FDA will require a separate marketing authorization for each of the drug and biologic constituents of such products.

Post-Approval Requirements

Any products manufactured or distributed by us or our partners pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we or our partners may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other regulations. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us or our partners to recall a product from distribution, or withdraw approval of the BLA.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products and product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of any off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict marketing authorization holders' communications on the subject of off-label use of their products.

Biosimilars and Exclusivity

The BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or diminishing efficacy relative to exclusive use of the reference biologic.

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 licensed 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 licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Regulation of Diagnostic Tests

Certain of our product candidates may require use of a diagnostic to identify appropriate patient populations that may benefit from our products. These companion diagnostics are medical devices, often *in vitro* devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and approval of a premarket approval application ("**PMA**") approval. We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

FDA's "In Vitro Companion Diagnostic Devices" guidance states that, for novel drugs such as ours, a companion diagnostic device and its corresponding drug should be approved or cleared contemporaneously by the FDA for the use

indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption ("**IDE**"), regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations.

In the EEA, *in vitro* diagnostics medical devices are required to conform with the essential requirements of the EU Directive on *in vitro* diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of *in vitro* diagnostics medical device and its classification. The conformity assessment of *in vitro* diagnostics medical devices can require the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA.

On April 5, 2017, the European Parliament passed the In Vitro Device Regulation ("**IVDR**"), which repeals and replaces Directive No 98/79/EC. Unlike directives, which must be implemented into the national laws of the EU member states, a regulation is directly applicable, i.e., without the need for adoption of EU member state laws implementing them, in all EEA member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for *in vitro* diagnostic medical devices and ensure a high level of safety and health while supporting innovation. The IVDR will not become fully applicable until five years following its entry into force.

Other Healthcare Laws and Compliance Requirements

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payers and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or a specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or

causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payers, including private insurers.

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

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, included changes to the coverage and payment for drug products under government health care programs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of two percent (2%) per fiscal year, which will remain in effect through 2031 unless additional Congressional action is taken.

Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the ACA. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. We continue to evaluate the effect that the ACA and any repeal and replacement efforts may have on our business but expect that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payers include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payers will provide coverage and reimbursement for our products and product candidates, if approved, these third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time-consuming and expensive for us to seek coverage and reimbursement from third-party payers. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The process for determining whether a payer will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payer will pay for the product. A payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payers for coverage or reimbursement. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. One third-party payer's decision to cover a particular medical product or service does not ensure that other payers will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payers may not consider our products or product candidates to be medically necessary or cost-effective compared to other available therapies.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payers do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payer not to cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures or reduced demand for our products or product candidates once approved.

Review and Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of an MAA and granting of an MAA by these authorities before the product can be marketed and sold in the European Union.

The Clinical Trials Regulation (EU) No 536/2014 will enter into application on January 31, 2022. The Regulation is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase their transparency. Specifically, the new Regulation, which will be directly applicable in all EU Member States, introduces a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials will be introduced and is divided into two parts. Part I is assessed by the competent authorities of a reference member state selected by the trial sponsor largely of the type of clinical trial, risk-benefit analysis, and compliance with technical requirements. This assessment, which is valid for the entire EU, is then submitted to the competent authorities of all the concerned member states in which the trial is to be conducted under Part II. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial. If a clinical trial continues for more than three years from January 31, 2022 the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

In the EEA, which consists of the 27 Member States of the European Union, as well as Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after a related MA has been granted. A company may submit a MAA either on the basis of the centralized or decentralized procedure. Under the centralized procedure, MAAs are submitted to the EMA for scientific review by the EMA's CHMP. The CHMP issues an opinion concerning whether the quality, safety and efficacy of the product has been demonstrated. The opinion is considered by the EC which is responsible for granting a centralized marketing authorization in the form of a binding EC decision. If the application is approved, the EC grants a single marketing authorization that is valid throughout the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a

significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National marketing authorizations, which are issued by the competent authorities of EEA countries and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EEA country, this national marketing authorization can be recognized in another EEA country through the mutual recognition procedure. The mutual recognition procedure provides for the EEA countries selected by the applicant to mutually recognize a national marketing authorization that has already been granted by the competent authority of another EEA country, referred to as the Reference Member State ("**RMS**"). The decentralized procedure is used when the product in question has yet to be granted a marketing authorization in any EEA country. Under this procedure the applicant can select the EEA country that will act as the RMS. In both the mutual recognition and decentralized procedures, the RMS reviews the application and submits its assessment of the application to the EEA countries for which marketing authorizations are being sought, referred to as Concerned Member States. Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether to recognize the RMS assessment or reject it on the basis of potential serious risk to public health. If the disputed points cannot be resolved, the matter is first referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures for agreement. If the Group cannot reach an agreement, a referral is made to the EMA. The CHMP will provide an opinion that will form the basis of a decision to be issued by the EC that is binding on all EEA countries. If the application is successful during the decentralized or mutual recognition procedure, national marketing authorizations will be granted by the competent authorities in each of the EEA countries chosen by the applicant.

In the EU, conditional marketing authorizations may be granted in the centralized procedure for a limited number of medicinal products for human use in cases where the related clinical dataset is not yet complete. A conditional marketing authorization may be granted for a medicinal product, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive data after the authorization, (3) the medicinal product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. The authorization is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

In the EU, innovative medicinal products that are subject to marketing authorization on the basis of a full dossier and do not fall within the scope of the concept of global marketing authorization qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The concept of global marketing authorization prevents the same marketing authorization holder or members of the same group, or companies that have concluded tacit or explicit agreements concerning the marketing of the same medicinal product, from obtaining separate data and market exclusivity periods for medicinal products that contain the same active substance. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. However, the generic product or biosimilar products cannot be marketed in the EU for a further two years thereafter. The overall ten-year period may be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a drug can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all EU Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of the 10 years of market exclusivity.

In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union’s stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.

- The manufacturing of authorized medicinal products, for which a separate manufacturer’s license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.

- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and EU Member State laws.

Regulation in the United Kingdom following Brexit

The United Kingdom's ("**U.K**".) withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the U.K. and the EU. The Medicines and Healthcare products Regulatory Agency ("**MHRA**") is now the U.K.'s standalone regulator.

On December 24, 2020, the EU and U.K. reached an agreement in principle on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement ("**Agreement**"). The Agreement primarily focuses on ensuring free trade between the EU and the U.K. in relation to goods, including medicinal products. Although the body of the Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the Agreement.

Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the U.K. will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release.

The U.K. has unilaterally agreed to accept EU batch testing and batch release for a period of at least two years until January 1, 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations s granted by the European Commission.

The U.K. regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into U.K. law, through secondary legislation). It is currently unclear to what extent the U.K. will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation on January 31, 2022.

Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the U.K. Since this date, companies established in the U.K. cannot use the centralized procedure and instead must follow one of the U.K. national authorization procedures to obtain a marketing authorization to market products in the U.K. For a two year period from January 1, 2021, MHRA may rely on a decision taken by the EC on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EEA countries to be granted in Great Britain. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the U.K. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the U.K. national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the U.K., Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

C. ORGANIZATIONAL STRUCTURE

Genmab A/S holds investments either directly or indirectly in the following subsidiaries: Genmab B.V. (Utrecht, the Netherlands), Genmab Holding B.V. (Utrecht, the Netherlands), Genmab US, Inc. (New Jersey, USA) and Genmab K.K. (Tokyo, Japan). The subsidiaries perform certain research and development, selling, general and administrative, and management activities on behalf of Genmab A/S.

D. PROPERTY AND EQUIPMENT

The following table specifies Genmab's leased facilities and their related activities.

Location	Use of facility	Area (in square feet)	Lease expiry date
Copenhagen, Denmark	Corporate headquarters	49,528	December, 2022
Copenhagen, Denmark	Office space	14,924	December, 2022
Copenhagen, Denmark	Office space	20,626	March, 2023[1]
Utrecht, Netherlands	Office, laboratory, and pre-clinical development space	90,061	May, 2032
Zeist, Netherlands	Office, laboratory, and pre-clinical development space	37,908	December, 2022
Princeton, NJ, USA	Office space	24,771	December, 2022[2]
Plainsboro, NJ, USA	Office and laboratory space	135,136	August, 2031
Tokyo, Japan	Office space	17,656	February, 2026

(1) Genmab's leased office space in Copenhagen, Denmark is a swing space that can be cancelled at any time, given that Genmab or the Landlord is given 6 months' prior written notice on the first day of a calendar quarter. As such, the lease is expected to be cancelled in March 2023 to align with the estimated commencement date of Genmab's corporate headquarters in Copenhagen, Denmark. See the following table for additional information.

(2) Genmab's leased office space in Princeton, NJ is currently subleased to two separate third parties, which are set to expire in December 2022 in conjunction with the head lease.

Future expansion plans include the leased facilities specified in the following table, which are intended to augment Genmab's laboratory capacity and upgrade its corporate headquarters. Genmab plans to finance the leases by cash flows from operating activities.

Location	Use of facility	Estimated area (in square feet)	Estimated commencement date	Enforceable lease period
Copenhagen, Denmark	Corporate headquarters	174,558	March, 2023	15 years
Utrecht, Netherlands	Office, laboratory, and preclinical development space	118,768	April, 2022	10 years

See Note 3.3 "Leases" in Genmab's Audited Financial Statements for additional details regarding the leases and associated capital expenditures.

ITEM 4A UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. Operating Results

Overview

We are an international biotechnology company with a core purpose to improve the lives of patients by creating and developing innovative antibody therapeutics. Our vision to transform cancer treatment has driven our passionate, innovative and collaborative teams to invent four next-generation antibody technology platforms that play a key role in building our product pipeline, fueling multiple differentiated cancer treatments that make an impact on people's lives.

Our proprietary pipeline, where we are responsible for at least 50% of development, includes bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. We currently have approximately 20 proprietary and partnered programs in preclinical development and seven product candidates in clinical development, including one approved product, Tivdak, developed in collaboration with Seagen. Tivdak was granted accelerated approval by the FDA for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tivdak is the first and only FDA approved ADC in this indication.

To develop and deliver novel therapies to patients, we have formed around 20 strategic partnerships with biotechnology and pharmaceutical companies. We selectively enter into collaborations with other biotechnology and pharmaceutical companies that build our network in the biotechnology space and give us access to complementary technologies or products that move us closer to achieving our vision and fulfilling our core purpose. In addition to our own pipeline of product candidates, our innovation and proprietary technology are applied in the pipelines of third-party companies. These companies are running clinical development programs with antibodies created by us or created using our DuoBody bispecific antibody technology. The programs run from Phase 1 development to approved medicines. Under the agreements for these products we are entitled to certain potential milestones and royalties. There are currently four approved products being developed by third-party companies; daratumumab, marketed by Janssen as DARZALEX (IV formulation) and DARZALEX FASPRO or DARZALEX SC (SC formulation), approved in the U.S., Europe, Japan and certain other territories for the treatment of certain indications of MM and AL amyloidosis, amivantamab, marketed in the U.S., Europe and certain other territories as RYBREVANT for the treatment of certain adult patients with locally-advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, SC ofatumumab, marketed in the U.S., Europe, Japan and certain other territories as Kesimpta by Novartis for the treatment of RMS, and teprotumumab, marketed in the U.S. as TEPEZZA by Horizon for the treatment of TED.

We are headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.

Our results of operations have been, and we expect them to continue to be, affected by our collaboration with Janssen for the development and commercialization of daratumumab. Since inception, we have funded our operating requirements primarily through proceeds from equity financings and milestone payments and royalties from our partners. We expect to continue to fund a significant portion of our development costs for our proprietary product candidates as well as our planned commercialization activities with funds received from royalties and milestone payments from our partners. 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 for the Halozyme enzyme technology used in the SC 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*".

For a description of certain of our product and technology collaborations including relevant royalty tiers, milestones and expense sharing provisions, please refer to *"Item 4.B—Business Overview—Product and Technology Collaborations"*.

Key Components of Our Results and Related Trends

Revenues

Our revenues are currently comprised of royalties, milestone payments, reimbursement revenue, and collaboration revenue. Royalty revenue from licenses is based on third-party sales of licensed products. Milestone payments are typically related to reaching particular stages in product development, regulatory approval or net sales. Reimbursement revenue is mainly comprised of the reimbursement of certain research and development costs related to the development work under our collaboration agreements. Collaboration revenue includes net profit sharing arrangements for the sale of commercial products. License fees are non-refundable, upfront fees for our intellectual property received from our partners.

In 2021, DKK 6,847 million, or 81% of our total revenues, related to our various collaborations with Janssen, as compared to DKK 4,693 million, or 46% of our total revenues, in 2020. This percentage increase in total revenue 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 2020. Excluding the one-time payment from AbbVie, royalties and milestone payments from our various collaborations with Janssen accounted for 82% of our revenue in 2020. In 2021, DKK 6,507 million, or 95% of our revenues received under our various collaborations with Janssen were related to royalties and milestone revenue with respect to DARZALEX, as compared to DKK 4,513 million, or 96% in 2020.

Of the revenue for 2021, 82% was attributable to royalties, 11% to milestone revenue, 6%, to reimbursement revenue and 1% to collaboration revenue. This is compared to 47% attributable to royalties, 45% to license revenue, 4% to reimbursement revenue and 4% to milestone revenue in 2020. There was no collaboration revenue in 2020, and there was no license revenue in 2021.

At this time, all of our revenue is recognized from our partners under our collaboration agreements. We do not earn any revenue from direct sales of our own products, and we will not earn such revenue unless and until we obtain regulatory approvals for any candidates in our proprietary pipeline and successfully commercialize such candidates. Our reported revenue is affected by the translation of royalties and other income denominated in foreign currencies—primarily U.S. dollars—into Danish kroner as our reporting currency.

Our ability to generate revenue will significantly depend on the success of Janssen's continued ability to effectively maintain and grow sales of DARZALEX for its approved indications, expand its indications, and successfully compete with existing and additional investigational agents and technologies that are currently being marketed or studied for the same indications as DARZALEX.

Our historical revenue also reflects milestone and other payments relating to our other collaborations.

We anticipate that our partners under our collaboration agreements will report results or preliminary data for a number of clinical studies in 2022. However, there can be no assurance that any of the studies conducted by Janssen or Novartis or by us or our other partners will be completed on the expected timeline or at all, or that the final results will be positive. Our ability to generate revenue from our partnered product candidates depends on our and our partners' ability to successfully complete clinical trials for our product candidates and receive regulatory approvals, which could impact the commercial potential of such products and our potential to receive milestone payments and royalties for these products in the future.

Operating Expenses

Our operating expenses currently consist of research and development expenses and selling, general and administrative expenses. Research and development expenses represent the majority of our operating expenses.

Our research and development expenses include internal costs relating to our research and development departments, as well as external costs relating to studies performed by external suppliers and partners. Internal research and development costs consist primarily of salaries and benefits for our research and development staff and related expenses, including expenses related to cash bonuses, warrant and restricted stock unit ("**RSU**") programs as applicable to such personnel, costs of related facilities, equipment and other overhead expenses that have been determined to be directly attributable to research and development, costs associated with obtaining and maintaining patents for intellectual property, amortization of licenses and rights, amortization and impairment of intangible assets and property, and depreciation of capital assets used to develop our product candidates.

Major components of the external costs are fees and other costs paid to CROs in conjunction with preclinical studies and the performance of clinical trials, milestone payments for in-licensed technology, as well as fees paid to CMOs in conjunction with the production of clinical compounds, drug substances and drugs. This includes (i) antibody clinical material for use in clinical trials and (ii) preparation for production of process validation batches for potential future regulatory submissions and related activities. These costs are expensed as incurred, because they do not qualify to be capitalized as inventory under IFRS since the technical feasibility of the materials is not proven and no alternative use

for them exists in the absence of marketing approval. Research and development expenses include amortization of intangible assets only in connection with licenses and rights we have acquired and capitalized. We do not capitalize intellectual property generated through our internal development activities. 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 we increase the number of product candidates under active clinical development. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including timing due to regulatory approvals and enrollment of patients in clinical trials. See ‘‘Item 5.B—Liquidity and Capital Resources’’ below.

Our selling, general and administrative expenses consist primarily of wages and salaries for personnel other than research and development staff, including expenses related to cash bonuses and warrant and RSU programs as applicable to such personnel. Also included are expenses related to pre-launch commercialization activities, depreciation, amortization and impairment of intangible assets and property and equipment, to the extent such expenses are related to the administrative functions and co-promotion expenses related to commercial sales of Tivdak in the U.S. in accordance with our Joint Commercialization Agreement with Seagen.

Overhead expenses are allocated to research and development expenses or selling, general and administrative expenses based on the number of employees and their relevant functions. The Dutch Research and Development Act (“**WBSO**”), provides compensation for a part of research and development wages and other costs at our Utrecht facility through a reduction in payroll taxes in the Netherlands. WBSO grant amounts are offset against wages and salaries included in research and development costs.

Our ongoing research and development and, increasingly, commercialization 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 proprietary pipeline and building our commercial capabilities. Our proprietary product candidates will require significant further development, financial resources and personnel to pursue and obtain regulatory approval and develop them into commercially viable products, if they are approved and commercialized at all. Our commitment of resources to the research and continued development of our product candidates and expansion of our proprietary 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.

Potential Impact of COVID-19

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. See *“Item 3.D—Risk Factors—Risks Related to Our Business—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.”*

Results of Operations

Financial Results for the Year Ended December 31, 2021 Compared to the Year Ended December 31, 2020

The information on pages 61-65 in our Annual Report 2021 under the heading “Financial Review” is incorporated herein by reference.

Financial Results for the Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

The information on pages 63-68 in our Annual Report 2020 under the heading “Financial Review” is incorporated herein by reference.

Significant Accounting Policies

The information in Note 1.1 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference.

Implementation of New and Revised Standards and Interpretations

The information in Note 1.2 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference.

Standards and Interpretations Not Yet in Effect

The information in Note 1.2 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference.

B. Liquidity and Capital Resources

The information on pages 64-65 in our Annual Report 2021 under the heading “Liquidity and Capital Resources” is incorporated herein by reference.

The description of our lease obligations in Note 3.3 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference.

The description of our short term contractual obligations related to a number of agreements primarily related to research and development activities in Note 5.4 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference.

The description of our contingent commitments under our license and collaboration agreements that may become due for future payments in Note 5.4 to our Audited Financial Statements included in our Annual Report 2021 is incorporated herein by reference. The contingent commitments entail uncertainties in relation to the period in which payments are due because these obligations are dependent on milestone achievements, most of which are not expected to be incurred within the next five years.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule and adjust our requirements based on our business needs prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

C. Research and Development, Patents and Licenses, etc.

See “Item 4.B—Business Overview” and “Item 5.A—Operating Results”.

D. Trend Information

See “Item 5.A—Operating Results—Key Components of Our Results and Related Trends”.

E. Critical Accounting Estimates

Not applicable.

ITEM 6 DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our board of directors ("**Board**") members as of the date of this Annual Report on Form 20-F, except Mr. Peacock, who has stepped down from the Board effective November 15, 2021. Our Board consists of five members elected by our shareholders at the general meeting ("**Shareholder Elected Members**" and each, a "**Shareholder Elected Member**"), and three members elected by our employees ("**Employee Elected Members**" and each, an "**Employee Elected Member**"). Shareholder Elected Members are elected by our shareholders every year and Employee Elected Members are elected by our employees every third year. The terms of office of the Shareholder Elected Members and the Employee Elected Members expire in 2022. All members of the Board, however elected, are eligible for re-election.

The business address of our directors is our registered office address at c/o Genmab A/S, Kalvebod Brygge 43, 1560 Copenhagen V, Denmark.

Name of Board Member	Age	Position(s)
Deirdre P. Connelly	61	Chair (independent, Shareholder Elected)
Pernille Erenbjerg	54	Deputy Chair (independent, Shareholder Elected)
Anders Gersel Pedersen	70	Board member (non-independent, Shareholder Elected)
Paolo Paoletti	71	Board member (independent, Shareholder Elected)
Rolf Hoffmann	62	Board member (independent, Shareholder Elected)
Peter Storm Kristensen	47	Board member (non-independent, Employee Elected)
Mijke Zachariasse	48	Board member (non-independent, Employee Elected)
Rima Bawarshi Nassar	68	Board member (non-independent, Employee Elected)
Jonathan Peacock[1]	63	Board member (independent, Shareholder Elected)

(1) Mr. Peacock stepped down from the Board effective November 15, 2021.

The following is a brief summary of the business experience of our Board members:

Deirdre P. Connelly was elected to the Board in 2017 and currently acts as Chair of the Board and as the Chair of the Nominating and Corporate Governance Committee. She is a member of the Audit and Finance Committee and Compensation Committee. Ms. Connelly was formerly the President of North America Pharmaceuticals for GlaxoSmithKline plc from 2009 to 2015 and currently serves on the board of directors of the Lincoln Financial Corporation where she is Chair of the Corporate Governance Committee and a member of the Audit Committee. She also serves on the board of directors at Macy's, Inc. where she is Chair of the Nominating and Governance Committee and a member of the Compensation and Management Development Committee. Prior to her time at GlaxoSmithKline plc, she spent 26 years with Eli Lilly and Company from 1984 to 2009, which included tenures as President of U.S. Eli Lilly and Company and Vice President of Human Resources and President of Global Women's Health. She holds a bachelor's degree in Economics and Marketing from Lycoming University and is a graduate of Harvard University's Advanced Management Program.

Pernille Erenbjerg was elected to the Board in 2015 and currently acts as Deputy Chair of the Board and as the Chair of the Audit and Finance Committee and as a member of the Nominating and Corporate Governance Committee. Ms. Erenbjerg qualifies as an audit committee financial expert. Ms. Erenbjerg previously served as the Group CEO and President of TDC A/S, and prior to that she served as the Group CFO of the same Company. She serves as Chair of the Board at the Nordic Entertainment Group (NENT). Ms. Erenbjerg also serves as Deputy Chair of Millicom where she is also Chair of the Compensation Committee. In addition she is a member of the board of the RTL Group and where she is also a member of the Audit Committee and a member of the board of GlobalConnect. She is formerly a partner at Deloitte Touche Tohmatsu Limited and spent 14 years as a CPA at Arthur Anderson LLP from 1987 to 2002. Ms. Erenbjerg holds a B.S. and a M.Sc. in Economics from Copenhagen Business School.

Anders Gersel Pedersen was elected to the Board in 2003 and currently serves as the Chair of the Compensation Committee and is a member of the Nominating and Corporate Governance Committee and the Scientific Committee. Dr. Pedersen currently serves as the Chair of the board of Aelis Farma S.A.S., Deputy Chair of the board of Bavarian Nordic A/S where he is also a member of the Nomination and Compensation Committee and a member of the Science, Technology & Investment Committee. He is a member of the board of Hansa Biopharma AB where he is also Chair of the Scientific Committee and a member of the Remuneration Committee and he is a member of the board of Bond 2 development 2GP limited, and was formerly the Executive Vice President of Research & Development at H. Lundbeck A/S. Dr. Pedersen holds a medical degree and a doctoral degree in neuro-oncology from University of Copenhagen and a B.S. in Business Administration from Copenhagen Business School. He is a member of the European Society of Medical Oncology, the American Society of Clinical Oncology, the Danish Society of Medical Oncology, the Danish Society of Internal Medicine and the International Association for the Study of Lung Cancer.

Paolo Paoletti was elected to the Board in 2015 and currently serves as the Chair of the Scientific Committee and is a member of the Compensation Committee. Dr. Paoletti served as President of Oncology at GlaxoSmithKline plc and in various roles at Eli Lilly and Company, including Vice President of Oncology Research. Dr. Paoletti is the CEO of GammaDelta Therapeutics Limited and is a member of the board of GammaDelta Therapeutics Limited and PsiOxus Therapeutics Limited. He was formerly the CEO of Kesios Therapeutics Ltd. from 2015 to 2017 and previously served as a member of the board of NuCana BioMed Ltd. Dr. Paoletti holds a medical degree from the University of Pisa.

Rolf Hoffmann was elected to the Board in 2017 and is a member of the Audit and Finance Committee and the Scientific Committee. Mr. Hoffmann has over 20 years of experience in the international pharmaceutical and biotechnology industries at Eli Lilly and Company from 1987 to 2004 and Amgen Inc. from 2004 to 2016. Mr. Hoffmann is currently an adjunct professor of Strategy and Entrepreneurship at the University of North Carolina Business School and serves as Chair of the board of directors at Biotest AG. He is a board member at EUSA Pharma, Inc. where he is also Chair of the Remuneration Committee. He is a member of the board of Paratek Pharmaceuticals, Inc. where he is also a member of the Nominating and Corporate Governance Committee and he is a member of the board of IDT Biologika and of Semdor Pharma. He holds an M.A. in English from the University of Cologne, an MA in Kinesiology from Deutsche Sporthochschule Köln in Cologne, Germany and an M.B.A. from the University of North Carolina at Chapel Hill.

Peter Storm Kristensen was elected to the Board in 2016. Mr. Kristensen currently serves as our Director, Legal Lead Corporate. Prior to joining Genmab, he was a lawyer at Copenhagen University Hospital and Patienterstatningen from 2005 to 2007. He holds a law degree from the University of Copenhagen.

Mijke Zachariasse was elected to the Board in 2019. Dr. Zachariasse joined us in 2017 and currently serves as our Senior Director, Head of Antibody Research Materials. Prior to joining us, from 2010 to 2017, she was a Research Policy Advisor/Head of the Research Support Office at Utrecht University. From 2008 to 2010, Dr. Zachariasse was Managing Director of the Leiden Institute of Physics. Dr. Zachariasse served as a Programme Officer at the Foundation for Fundamental Research on Matter from 2002 to 2008. She received her Doctorate in Physics from the Technical University of Eindhoven in 2002.

Rima Bawarshi Nassar was elected to the Board in 2020. Dr. Nassar joined Genmab in 2018 and currently serves as our Vice President, Head of Global Regulatory Affairs. Prior to joining us, from 2012 to 2017, she was the Associate Vice President, Global Regulatory Affairs at Sanofi. Dr. Nassar received her Ph.D. in Pharmaceutical Sciences from the University of Kentucky.

Jonathan Peacock was elected to the Board in 2020. Mr. Peacock has extensive experience in corporate finance, strategy and international expansion in the pharmaceutical industry. He was involved in several large and small acquisitions and partnerships of commercial, pipeline and research assets covering diverse global markets as CFO at Novartis Pharma and CFO at Amgen. He serves as Chairman of the board of directors at Bellerophon Therapeutics Inc. and as a board member at Avantor Inc., W20 Group and a Trustee of the Natural History Museum of Los Angeles. Mr. Peacock holds a degree in Economics, is a chartered accountant and has a background as a partner at McKinsey and Price Waterhouse. Mr. Peacock stepped down from the Board effective November 15, 2021, due to increased responsibilities in connection with his other board commitments.

Senior Management

The following table sets forth information with respect to each of the members of our senior management, including their respective ages and their positions as of the date of this Annual Report on Form 20-F. The business address of these members of our senior management is our registered office address at c/o Genmab A/S, Kalvebod Brygge 43, 1560 Copenhagen V, Denmark. We note that only Jan G. J. van de Winkel, Anthony Pagano, Judith Klimovsky, Anthony Mancini and Tahamtan Ahmadi are registered with the Danish Business Authority as members of executive management, or registered managers, within the meaning of the Danish Companies Act ("**DCA**").

Name of Member of Senior Management	Age	Position(s)
Jan G. J. van de Winkel	60	President and Chief Executive Officer
Anthony Pagano	44	Executive Vice President and Chief Financial Officer
Judith Klimovsky	65	Executive Vice President and Chief Development Officer
Anthony Mancini	51	Executive Vice President and Chief Operating Officer
Tahamtan Ahmadi	49	Executive Vice President and Chief Medical Officer, Head of Experimental Medicines
Birgitte Stephensen	61	Senior Vice President, Head of Global IPR & Legal
Christopher Cozic	44	Senior Vice President, Global Human Resources
Martine J. van Vugt	51	Senior Vice President, Corporate Strategy and Planning

The following is a brief summary of the business experience of our senior management.

Jan G. J. van de Winkel is our co-founder and served as President, Research & Development and Chief Scientific Officer of the Company until his appointment as President & Chief Executive Officer in 2010. Dr. van de Winkel served as Vice President and Scientific Director of Medarex Europe prior to founding Genmab. Dr. van de Winkel holds a professorship of immunotherapy at Utrecht University. He is Chairman of the board of directors of Hookipa Pharma Inc. and a member of the board of directors of LEO Pharma A/S and Omega Alpha SPAC. He holds an M.Sc. and a Ph.D. from the University of Nijmegen in the Netherlands.

Anthony Pagano joined Genmab in 2007. His positions increased in seniority during his tenure with us and he currently serves as our Executive Vice President and Chief Financial Officer. Prior to joining us, Mr. Pagano was Corporate Controller and Senior Director of Business Planning at NovaDel Pharma, Inc. from 2005 to 2007, a publicly-traded specialty pharmaceutical company. He previously worked as a Manager at KPMG LLP from 1999 to 2005. He is a Certified Public Accountant and received a B.S. in Accounting from The College of New Jersey, as well as an M.B.A. from the Stern School of Business at New York University.

Judith Klimovsky joined us in 2017 and currently serves as the Executive Vice President and Chief Development Officer. She worked previously as a drug developer and has more than 20 years of experience in research and development leadership roles at Bristol-Myers Squibb Company and Novartis Pharma AG. Dr. Klimovsky is also a medical doctor who has worked as a clinician in hospital environments. Prior to joining us, she held various positions at Novartis Pharma AG from 2009 to 2017, including Senior Vice President, Head of Clinical Development. Dr. Klimovsky is a member of the board of directors of Bellicum Pharmaceuticals. She holds a medical degree from the Universidad de Buenos Aires in Argentina.

Anthony Mancini joined Genmab in March 2020 as Executive Vice President and Chief Operating Officer. Prior to joining Genmab, Mr. Mancini served in a variety of strategic and operational leadership roles over a 24-year career at Bristol Myers Squibb (BMS) including the leadership of BMS' US Innovative Medicines Unit, a cross-functional team of over 1100 people, across multiple therapeutic areas including Immunology & Cardiovascular diseases. He holds a Bachelor of Science in Biochemistry from the University of Ottawa, Canada, an MBA from Clemson University, South Carolina, USA, and participated in the General Management Program, CEDEP at INSEAD, Fontainebleau, France.

Tahamtan Ahmadi joined us in 2017 and became the Executive Vice President and Chief Medical Officer, Head of Experimental Medicines effective March 1, 2021. Prior to that, Dr. Ahmadi was Head of Experimental Medicine and

Early Development Oncology at Janssen and a member of the Senior Leadership Team for Oncology from 2012 to 2017. During his time at Janssen, he led the global development of daratumumab including clinical R&D and medical affairs strategy across indications. Dr. Ahmadi was previously a faculty member of the Department of Hematology and Oncology at the University of Pennsylvania. He holds an M.D. from the University of Cologne and a Ph.D. from the University of Freiburg, both in Germany, and has experience in translational research, strategic product development, global regulatory submissions and clinical development.

Birgitte Stephensen joined us in 2002 and was appointed Senior Vice President in 2010. Ms. Stephensen has experience in both private practice and industry working with legal and intellectual property matters within the pharmaceutical and biotechnology fields. Prior to joining us, Ms. Stephensen worked in a patent law firm from 1988 to 1997, and was with the patent department of Novo Nordisk A/S from 1997 to 2002. Ms. Stephensen qualified as a European patent attorney in 1994. She earned an M.Sc. from the School of Pharmaceutical Sciences at the University of Copenhagen.

Christopher Cozic joined Genmab in 2017. Prior to joining Genmab, Mr. Cozic was Vice President of Human Resources at Ipsen from 2014 to 2017. Previously, he spent over eight years at Eisai, where he served as Director, Global Human Resources, after joining the company in 2006. He received his bachelor's degree in English and Communications from Quinnipiac University and also attained Professional in Human Resources, Senior Professional in Human Resources, and Global Professional in Human Resources certifications.

Martine J. van Vugt started her professional career with us in 2001 and was appointed Senior Vice President in July 2014 and is currently responsible for Corporate Strategy and Planning. Previously, she was responsible for our Portfolio, Project and Alliance Management as well as Strategic Initiatives and continues to oversee these areas. She has been active in business development operations since 2011. From 1998 until joining us in 2001, she studied dendritic cell vaccination therapy as a post-doctoral fellow. Dr. van Vugt holds an M.Sc. from the University of Wageningen and a Ph.D. from Utrecht University.

B. Compensation

In 2021, the aggregate remuneration paid to the Board was DKK 12.4 million.

No member of the Board is entitled to any kind of remuneration upon retirement from his or her position as a member of the Board. We have not allocated funds for any pension benefits, severance schemes or similar measures, or undertaken any other obligations to do so on behalf of the Board, and we have no obligation to do so.

In 2021, the aggregate remuneration to our executive management was DKK 97.8 million, all of which was fully accrued at December 31, 2021. This amount includes base salary, defined contribution plans, other benefits, share-based compensation expenses and annual cash bonuses. See "Compensation of Members of Our Board of Directors and Executive Management" and Note 5.1 to our Audited Financial Statements included in our Annual Report 2021 for details on compensation of our executive management. In addition, the aggregate remuneration to our senior management was DKK 115.3 million, all of which was fully accrued at December 31, 2021, and includes the remuneration of our executive management and our extended senior leadership team.

Genmab A/S' shareholders have adopted a remuneration policy for the Board of Directors and Executive Management of Genmab A/S (the "**Remuneration Policy**").

Compensation of Members of Our Board of Directors and Executive Management

See Note 5.1 to our Audited Financial Statements included in our Annual Report 2021 for details on compensation of our directors in connection with their membership to the Board and our executive management in connection with their employment with us.

Certain Senior Management Agreements

Remuneration given to our President and CEO, Jan G. J. van de Winkel, our Executive Vice President and CFO, Anthony Pagano, our Executive Vice President and CDO, Judith Klimovsky, our Executive Vice President and COO, Anthony Mancini and our Executive Vice President and Chief Medical Officer, Head of Experimental Medicines, Tahamtan Ahmadi, in accordance with their service agreements consists of a base salary, a cash bonus, RSUs and warrants. The maximum bonus opportunity for Dr. van de Winkel is in accordance with the Remuneration Policy and as recommended by the Compensation Committee and approved by the Board in a range of 0 to 150 percent of his annual base salary. The maximum bonus opportunity for Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi are conditional upon the recommendation of the CEO, in an amount between 0 and 90 percent of the individual's annual base salary, in accordance with the Remuneration Policy and as recommended by the Compensation Committee and approved by the Board; however, any bonus in excess of 100 percent of base salary for Dr. van de Winkel and 60 percent of base salary for Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi will be deferred into RSUs subject to three years vesting in accordance with Genmab's Renumeration Policy. RSUs have been granted to Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky and Mr. Mancini under our RSU program for the 2020 performance year on February 26, 2021. Effective March 1, 2021, Dr. Ahmadi, previously Senior Vice President, Head of Oncology, was appointed Executive Vice President and Chief Medical Officer, Head of Experimental Medicines and was granted RSUs and warrants on April 13, 2021. The above-named individuals qualify for all of our benefit programs, including pension plans.

Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi can terminate their employment with us by giving a six-month notice. We can terminate their employment with us by giving them a 12-month notice. In the event that we terminate the service agreements without cause, we will be obliged to pay the then existing salary (including all benefits set forth in their respective service agreements) to Dr. van de Winkel for two years, and to Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi for one year, after the end of the 12-month notice period.

In the event of a termination by us without cause in connection with a change in control (as defined in the individuals' service agreements), the notice period will be extended up to 24 months in the first year after the change of control. In addition, we will pay an additional two years of then current salary (including all benefits set forth in his service agreement) to Dr. van de Winkel, and an additional year of then current salary (including all benefits set forth in their respective service agreements) to Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi. Dr. van de Winkel will also receive an amount equal to two times the highest total bonus awarded to him, and Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi will each receive an amount equal to the highest total bonus awarded to them, in any year during the term of their respective employment, in each case payable in a lump sum payment on the individual's last working day.

Other than as set out above, Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi are not entitled to any kind of remuneration upon termination of employment. We have not granted any loans, issued any guarantees or undertaken any other obligations to do so on behalf of any member of our senior management.

For further details on the terms and conditions of the warrants, see "—Warrant Program" below. For further details on the terms and conditions of the RSUs, see "—Restricted Stock Unit Program" below.

Other than as set out above, no exceptional or extraordinary agreements, including agreements regarding bonus schemes, other than ordinary incentive schemes and remuneration of the senior management implying financial obligations for us, have been concluded with members of our senior management.

Warrant Program

We have established a warrant program ("**Warrant Program**"), as an incentive for our employees and members of senior management. Warrants are granted by the Board in accordance with authorizations given to it by our shareholders. Warrant grants are subject to the relevant terms of our articles of association and, if applicable, the Remuneration Policy or any incentive guidelines or remuneration principles adopted by the shareholders at the general meeting preceding the Remuneration Policy. Under the terms of the Warrant Program, (i) warrants are granted at an exercise price equal to the share price on the grant date, (ii) the exercise price cannot be fixed at a lower price than the market price at the grant date

and (iii) in connection with exercise, the warrants are to be settled with the delivery of our shares. The Warrant Program contains anti-dilution provisions if changes occur in our share capital prior to the warrants being exercised.

In case of a change of control event as defined in the Warrant Program amended in August 2004, April 2012 and March 2017, the warrant holder will immediately be granted the right to exercise all of his or her warrants regardless of the fact that such warrants would otherwise only become fully vested at a later point in time. Warrant holders who are no longer employed by or affiliated with us will, however, only be entitled to exercise such percentages of warrants as would otherwise have vested under the terms of the Warrant Program.

Warrants granted under the terms of the Warrant Program amended in August 2004, April 2012 and March 2017 are generally subject to provisions reflecting the principles of the former section 4 and 5 of the Danish Stock Option Act (*Aktieoptionsloven*), which allows for the forfeiture of unexercised warrants if the grantee separates from the company or one of our subsidiaries under circumstances in which the warrant holder is considered a "bad-leaver," understood as, for example, being dismissed for cause or resigning without us having materially breached the employment contract. Warrant holders may maintain all granted warrants if they separate from the company or one of our subsidiaries under circumstances where they are considered as "good-leavers," such as dismissal without cause, leaving us pursuant to an agreed severance agreement or retirement, warrant holder's resignation due to our material breach of contract or the warrant holder's death.

Warrants granted on terms as amended in August 2004 can be exercised starting from one year after the grant date and lapse on the tenth anniversary of the grant date. As a general rule, the warrant holder may only exercise 25% of the warrants granted per full year of employment or affiliation with us after the grant date. However, the warrant holder will be entitled to continue to be able to exercise all warrants on a regular schedule in instances where the employment relationship is terminated by us without cause.

Warrants granted on terms as amended in April 2012 will lapse at the seventh anniversary of the grant date. All other terms of these warrants are identical to those issued pursuant to the August 2004 amendment.

Warrants granted on terms as amended in March 2017 are subject to a cliff vesting period and become fully vested three years from the date of grant. All other terms of such warrants are identical to those issued pursuant to the April 2012 amendment.

In February 2021, the Warrant Program was amended (the "**2021 Warrant Program**"). Under the terms of the 2021 Warrant Program, the Board may decide, in its sole discretion, to accelerate the vesting of the warrants held by a warrant holder in case of (1) a change of control event as defined in the 2021 Warrant Program, if a warrant holder's employment terms are materially changed to his or her detriment during the 12-month period following a change in control event, or (2) certain other extraordinary transactions as described in the 2021 Warrant Program.

Under the 2021 Warrant Program, if a warrant holder separates from the Company under circumstances in which the warrant holder is considered a "bad-leaver," such as being dismissed for cause or during the employment probationary period, unvested warrants will be forfeited. Warrant holders may maintain a pro rata portion of unvested warrants if they separate from the Company under circumstances where they are considered "good-leavers," such as dismissal without cause or termination of employment due to the Company's material breach of the warrant holder's employment terms. All unvested warrants will be forfeited in the event of termination of employment due to the warrant holder's death.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2021 for our outstanding warrants and a summary of the holders of such warrants as of December 31, 2021.

Warrant Compensation

During 2021, our Board granted the following warrants to our executive management:

Name of Board Member or Executive Management, Position	Award Date	Granted	Strike Price (DKK)
Jan van de Winkel, Chief Executive Officer	2021	-	-
Anthony Pagano, Chief Financial Officer	2021	-	-
Anthony Mancini, Chief Operating Officer	2021	-	-
Judith Klimovsky, Chief Development Officer	2021	-	-
Tahamtan Ahmadi, Chief Medical Officer*	April 13, 2021	1,287	2,148

* Effective March 1, 2021, Tahamtan Ahmadi, previously Senior Vice President, Head of Oncology, was appointed Executive Vice President and Chief Medical Officer, Head of Experimental Medicines.

Restricted Stock Unit Program

We have established an RSU program as an incentive for all our employees, members of senior management and members of the Board.

RSUs are granted and performance vesting criteria, if any, decided by the Board in its sole discretion. RSUs granted to members of senior management and members of the Board are subject to the Remuneration Policy or any incentive guidelines or remuneration principles adopted by the shareholders at the general meeting preceding the Remuneration Policy. Under the terms of the RSU program, RSUs are subject to a cliff vesting period and become fully vested on the first banking day of the month following a period of three years from the date of grant.

Under the terms of the RSU program amended in 2016, if an employee, member of senior management, or member of the Board ceases his or her employment or Board membership prior to the vesting date, all RSUs that are granted but not yet vested will lapse automatically. However, if an employee, a member of senior management or a member of the Board ceases employment or Board membership due to retirement or age limitation in our articles of association, death, serious sickness or serious injury then all RSUs that are granted, but not yet vested will remain outstanding and will be settled in accordance with their terms. In addition, for an employee or a member of senior management, RSUs that are granted but not yet vested will remain outstanding and will be settled in accordance with their terms in instances where the employment relationship is terminated by us without cause. Within 30 days of the vesting date, the holder of an RSU receives one share in the Company for each RSU. In jurisdictions in which Genmab as an employer is required to withhold tax and settle with the tax authority on behalf of the employee, Genmab withholds the number of RSUs that are equal to the monetary value of the employee's tax obligation from the total number of RSUs that otherwise would have been issued to the employee upon vesting ("net settlement"). We may, at our sole discretion in extraordinary circumstances, choose to make a cash settlement instead of delivering shares.

The RSU program contains anti-dilution provisions if changes occur in our share capital prior to the vesting date and provisions to accelerate vesting of RSUs in the event of a change of control as defined in the RSU program.

We intend to purchase our own shares in order to cover our obligations in relation to the RSUs. Authorization to purchase our own shares up to a nominal value of DKK 500,000 (500,000 shares) was given by the shareholders at the annual general meeting in March 2016. The March 2016 authorization expired in March 2021. Additionally, in March 2019, our shareholders authorized us to repurchase up to an additional nominal value of DKK 500,000 (500,000 shares). The March 2019 authorization expires in March 2024. A portion of the shares that may be repurchased under

this authorization may be used to cover our obligations in relation to the RSUs. Moreover, in April 2021, our shareholders authorized us to repurchase up to an additional nominal value of DKK 500,000 (500,000 shares). The weighted average fair value of RSUs granted in 2021 was DKK 2,236.44. Between February 24, 2021 and March 9, 2021, we repurchased 30,000 shares pursuant to the March 2016 authorization and between March 9, 2021 and June 30, 2021, we repurchased 170,000 shares pursuant to the March 2019 authorization. No shares have been repurchased pursuant to the 2021 authorization.

In February 2021, the RSU program was amended (the "**2021 RSU Program**"). Under the terms of the 2021 RSU Program, the Board may decide, in its sole discretion, to accelerate the vesting of the RSUs held by a participant, or accelerate the vesting of the RSUs and make a cash settlement in case of (1) a change of control event as defined in the 2021 RSU Program, if a participant's employment terms are materially changed to his or her detriment during the 12-month period following the change in control event, or if the participant, who is a member of the Board, is replaced by a new board member or such participant's seat on the Board is eliminated due to a reduction in the number of board members, or (2) certain other extraordinary transactions as described in the 2021 RSU Program.

Under the terms of the 2021 RSU Program, in the event an RSU holder separates from the Company under circumstances in which the RSU holder is considered a "bad-leaver," such as being dismissed for cause or during the employment probationary period, unvested RSU will be forfeited. RSU holders may maintain a pro rata portion of unvested RSUs if they separate from the Company under circumstances where they are considered "good-leavers," such as dismissal without cause or termination of employment due to the Company's material breach of the RSU holder's employment terms, or if the participant is a member of the Board, if the membership of the Board ceases for any other reason than as a result of the participants death. All unvested RSUs will be forfeited in the event of termination of employment due to the RSU holder's death.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2021 for our outstanding RSUs and a summary of the holders of such RSUs as of December 31, 2021.

Restricted Stock Unit Compensation

During 2021, our Board granted the following RSUs to members of our Board and our executive management:

Name of Board Member or Executive Management, Position	Award Date	Granted	Share Price at Date of Grant (DKK)
Deirdre P. Connelly, Chair	November 22, 2021	454	2,641
Pernille Erenbjerg, Deputy Chair	November 22, 2021	340	2,641
Anders Gersel Pedersen, Board Member	November 22, 2021	227	2,641
Paolo Paoletti, Board Member	November 22, 2021	227	2,641
Rolf Hoffmann, Board Member	November 22, 2021	227	2,641
Peter Storm Kristensen, Employee Elected Member	November 22, 2021	227	2,641
Rima Bawarshi Nassar, Employee Elected Member	November 22, 2021	227	2,641
Mijke Zachariasse, Employee Elected Member	November 22, 2021	227	2,641
Jan van de Winkel, Chief Executive Officer	February 26, 2021	12,077	2,070
Anthony Pagano, Chief Financial Officer	February 26, 2021	5,405	2,070
Anthony Mancini, Chief Operating Officer	February 26, 2021	5,467	2,070
Judith Klimovsky, Chief Development Officer	February 26, 2021	7,268	2,070
Tahamtan Ahmadi, Chief Medical Officer*	April 13, 2021	1,200	2,148

* Effective March 1, 2021, Tahamtan Ahmadi, previously Senior Vice President, Head of Oncology, was appointed Executive Vice President and Chief Medical Officer, Head of Experimental Medicines.

Insurance and Discharge of Liability

According to the DCA, shareholders, at the general meeting, are permitted to discharge our Board members and registered managers from liability for any particular financial year based on a resolution relating to the period covered by the financial statements for the previous financial year. This discharge means that the shareholders will relieve such Board members and registered managers from liability to us. However, shareholders cannot discharge any claims by individual shareholders or other third parties. In addition, the discharge can be set aside in case the general meeting prior to its decision to discharge was not presented with all reasonable information necessary for the general meeting to assess the matter at hand.

In addition, we provide our Board members and registered managers with directors' and officers' liability insurance.

We have not granted any loans, guarantees, or other commitments to or on behalf of any members of our board of directors or senior management.

Employment Agreement and Warrant Grants

We have entered into employment agreements with, and issued RSUs and warrants to, our senior management. See "—Compensation—Certain Senior Management Agreements" and "—Compensation—Warrant Program" and "—Compensation—Restricted Stock Unit Program" for more information.

C. Board Practices

Board of Directors

The Board plays an active role in setting our strategies and goals and monitoring our operations and results. Board duties include establishing policies for strategy, accounting, organization and finance and the appointment of the Company's registered managers. The Board also assesses our capital and share structure and is responsible for approving share issues and the grant of warrants and RSUs. In addition, the Board ensures that our affairs are managed in accordance with our articles of association and applicable law.

The Board performs its duties in accordance with the rules of procedure of the Board. The rules of procedure are reviewed and updated by all members of the Board on a regular basis. The Board meets for at least eight scheduled face-to-face, telephonic, videoconference or Teams meetings during the year. During 2021, the Board held 10 meetings in addition to the informal ongoing communication between Board members and our CEO. Our Board may consist of between three and nine Shareholder Elected Members, elected for terms of one year, with possibility of re-election. In addition, our employees may, pursuant to Danish statutory rules regarding the representation of employees on the board of directors and election regulations adopted by the Board, elect employee representatives to the Board, for terms of three years, with possibility of re-election. The employees of the Company have adopted a voluntary program which allows for election of employee representatives from the Company's directly and indirectly owned subsidiaries. Currently, the Board has three Employee Elected Members, Peter Storm Kristensen, Mijke Zachariasse and Rima Bawarshi Nassar. In total, our Board currently consists of eight Board members (including five Shareholder Elected Members and three Employee Elected Members). The Board elects a chair and deputy chair from among its members. The majority of our Board members are considered to be independent under the corporate governance standards of the Nasdaq Stock Market and Nasdaq Copenhagen.

Senior Management

Registered managers are appointed by the Board, which sets out the terms and conditions of their employment and the framework for their duties. Registered managers are responsible for our day to day management, including all assignments that rest upon them according to the Board and under Danish law, in compliance with the guidelines and directions issued by the Board. Management of our day to day operations does not include transactions of an unusual nature or of significant importance, or transactions being outside our business plan, which must be authorized by the Board. Registered managers appoint other members of senior management.

Committees of the Board of Directors

The Board has established and appointed a Compensation Committee, an Audit and Finance Committee, a Nominating and Corporate Governance Committee and a Scientific Committee. These committees are charged with reviewing issues pertaining to their respective fields that are due to be considered at Board meetings. Under Danish corporate law, it is not possible to delegate the decision-making authority of the entire Board to board committees. Written charters specifying the tasks and responsibilities for each of the committees have been adopted by the Board.

Audit and Finance Committee

According to the Audit and Finance Committee charter, the Audit and Finance Committee must consist of at least three non-executive Board members, all of whom must be independent. Furthermore, the Chair of the Board shall not be Chair of the Audit and Finance Committee. As of the date of this Annual Report on Form 20-F, the Audit and Finance Committee consists of members Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg. The Audit

and Finance Committee assists the Board with the oversight of the financial reporting process, the effectiveness of internal controls over financial reporting and risk management, the independent audit process and compliance with legal and regulatory requirements, in accordance with the Audit and Finance Committee charter. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an "Audit Committee financial expert," as defined in Nasdaq Rule 5605(c)(2)(A) and as determined by our Board.

Our Audit and Finance Committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. Our Audit and Finance Committee has the following principal responsibilities:

- overseeing the accounting and financial reporting principles and process to ensure compliance with legal and regulatory requirements and the quality, transparency and integrity of the published financial information;
- overseeing the appropriateness and effectiveness of our internal controls over financial reporting and risk management system and evaluating the need for an internal audit;
- overseeing our audits and the independent auditor process, including recommending the appointment of the independent auditors and overseeing the annual assessment of their performance and qualifications, overseeing non-audit services and, to the extent permitted by applicable law, being directly responsible for the appointment, retention and compensation of the independent auditors in connection with audit, review or attestation services;
- overseeing the operation of the Company's internal audit function, including approving the internal audit charter, the staffing and organizational structure of the internal audit function, and monitoring management's responsiveness to the internal auditor's findings and recommendations;
- considering the independence of the independent auditors and any potential conflicts of interest, including by (a) ensuring receipt from the independent auditors of a formal written statement delineating all relationships with the Company, (b) actively engaging in dialogue with the independent auditors with respect to factors that may impact the independent auditors' objectivity and independence, and (c) taking, or recommending that the Board takes, appropriate action to oversee auditor independence;
- ensuring that significant adjustments, unadjusted differences, disagreements between management and the independent auditors and management responses thereto are discussed with the independent auditors and resolving disagreements between management and the independent auditors;
- assessing transactions between the Company and the Company's related parties and, in respect of material related party transactions, submitting a recommendation for approval or non-approval of such transactions to the Board prior to their completion;
- overseeing compliance with legal and regulatory requirements in relation to financial reporting and auditing regulation;
- authority to obtain advice and assistance from independent counsel and other advisors;
- obtaining appropriate funding, as determined by the Audit and Finance Committee, for compensation to the independent auditor and to any advisors that the Audit and Finance Committee chooses to engage;
- monitoring the whistleblower function, including establishment of procedures for the receipt, retention and treatment of any complaints, including confidential anonymous submissions from our employees regarding accounting, auditing and internal control issues received through a formalized complaint process, as well as review of such complaints; and

- evaluating its own performance and the achievement of its duties on a regular basis, and annually reviewing and updating the Audit and Finance Committee charter and discussing any required changes thereto with the Board.

The Audit and Finance Committee also performs such other functions and exercises such other powers as may be delegated to it by the Board from time to time.

Compensation Committee

According to its charter, our Compensation Committee must consist of at least two non-executive directors, appointed by the Board. A majority of the members must be independent. As of the date of this Annual Report on Form 20-F, the Compensation Committee consists of members Paolo Paoletti and Deirdre P. Connelly and is chaired by Anders Gersel Pedersen. Paolo Paoletti and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Stock Market. In accordance with the Danish corporate governance recommendations, we consider Anders Gersel Pedersen non-independent solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. The Compensation Committee assists the Board in the areas of compensation of managers and the adoption of policies that concern our compensation programs, including equity-based programs and benefit plans. The Compensation Committee also makes recommendations to the Board regarding specific remuneration packages for each of the members of the Board as well as our registered managers, including pension rights and any compensation payments. The proposed remuneration policy, if adopted by the Board, are subject to the approval of our shareholders at the annual general meeting. The Compensation Committee's primary responsibilities are as follows:

- reviewing trends in compensation and the competitiveness of our executive compensation programs to ensure (a) the attraction and retention of registered managers, (b) the motivation of registered managers to achieve our business objectives, and (c) the alignment of the interests of key leadership with the long-term interests of our shareholders;

- making proposals for the approval of the Board prior to approval by shareholders at the general meeting, on the remuneration policy for members of the Board and the registered managers, including the overall principles of incentive pay schemes, compensation structure and long-term incentive compensation plans and a remuneration policy applicable to the Company in general;

- reviewing goals and objectives of our CEO and evaluating his performance to make recommendations concerning CEO compensation; the CEO may not be present during deliberations or voting concerning the CEO's compensation;

- overseeing the evaluation of the performance of the Company's registered managers, and discussing their annual compensation, including salary, bonus, incentive and equity compensation, and the selection of performance measures, the setting of performance targets and the assessment of performance against those targets;

- reviewing the Company's policies relating to claw-back of incentive awards and confirm that such policies continue to be appropriate;

- reviewing plans for registered managers' development and corporate succession plans for registered management;

- reviewing termination and compensation packages for new registered managers as requested by management;

- in its sole discretion, retaining, terminating and receiving advice from outside counsel, compensation consultants or other advisers, upon consideration of (i) whether such counsel, consultant or adviser

provides other services to the Company and the amount of fees they receive from the Company as a percentage of their total revenue, (ii) the policies of such counsel, consultant or adviser designed to prevent conflicts of interest, (iii) any business or personal relationship of the consultant, counsel or adviser with a member of the Compensation Committee or a member of senior management of the Company, and (iv) any ownership of shares in the Company by the consultant, legal counsel or adviser;

- approving the fees of outside counsel, compensation consultants or other advisers, to be appropriately funded by the Company and directly overseeing the work of such counsel, consultants or advisers; and

- overseeing that the information in the annual report on the compensation of the Board and registered managers is correct, true and sufficient.

The Compensation Committee also performs such other functions and exercises such other powers as may be delegated to it by the Board from time to time.

Nominating and Corporate Governance Committee

According to its charter, our Nominating and Corporate Governance Committee must include at least two non-executive directors, appointed by the Board. A majority of members must be independent. As of the date of this Annual Report on Form 20-F, the Nominating and Corporate Governance Committee consists of members Pernille Erenbjerg and Anders Gersel Pedersen and is chaired by Deirdre P. Connelly. Pernille Erenbjerg and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Global Select Market. In accordance with the Danish corporate governance recommendations, we consider Anders Gersel Pedersen non-independent solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. The Nominating and Corporate Governance Committee identifies, reviews, evaluates and recommends to the full Board candidates to serve as directors of the Company and makes recommendations to the Board regarding Board and committee members and corporate governance issues. The Nominating and Corporate Governance Committee's primary responsibilities include the following:

- proposing to the full Board policies on the size and composition of the Board, including proposals for specific changes to Board size, composition or internal rules of the Board;

- describing the qualifications required for the Board and the registered managers and for a given position and identifying and recommending qualified candidates to the Board;

- evaluating at least annually the skills, knowledge and experience of the individual members of the Board and the registered managers and evaluating, reviewing and considering whether to recommend existing directors for re-election;

- maintaining an orientation and continuing education program for directors;

- establishing a process for the periodic review and assessment of the performance of the Board and its committees and conducting such review of the structure and performance of each board committee and committee member, recommending any changes considered appropriate, as well as recommending the establishment of new or special committees as desirable or necessary from time to time;

- periodically assessing the independence of directors and our corporate governance principles and their application, and recommending any changes deemed appropriate to the Board, including in connection with any proposals submitted by shareholders that relate to corporate governance, corporate social responsibility and environment, social and governance matters;

- overseeing and reviewing the processes and procedures in place to ensure that the Board and its committees timely receive accurate, relevant and appropriately detailed information;

- reviewing the adequacy of internal rules of the Board, management and any other codes of ethics with the Board and management;
- overseeing the preparation and periodic review of a diversity policy for the Board's approval;
- overseeing our policies and practices regarding philanthropic and political activities; and
- periodically reviewing, discussing and assessing the performance of the committee as well as the adequacy of its charter, and recommending any proposed changes to the Board for approval.

Scientific Committee

According to its charter, the Scientific Committee must include at least three non-executive directors, the majority of whom must be independent, with a broad scientific and medical understanding and experience, appointed by the Board. As of the date of this Annual Report on Form 20-F, the Scientific Committee consists of members Anders Gersel Pedersen and Rolf Hoffmann and is chaired by Paolo Paoletti. The Scientific Committee provides input and advises the Board in matters relating to our research and development strategy, including reviewing our preclinical and clinical product pipeline in view of our overall strategy and vision. The Scientific Committee's primary responsibilities include the following:

- reviewing and discussing our preclinical and clinical product portfolio, including the commercial attractiveness and the ranking thereof;
- reviewing and discussing our research and development strategy and reviewing scientific and technological trends that we believe are of significant importance and providing strategic advice and making recommendations with respect to our ongoing research and development programs;
- reviewing the quality of our research and development capacity and its organization, including the product development process; and
- reviewing and discussing the Company's intellectual property strategies.

D. Employees

As of December 31, 2021, we had 1,212 employees; 312 in Denmark, 437 in the Netherlands, 420 in the U.S. and 43 in Japan. Of these employees, 927 were engaged in or support research and development and 285 were in selling, administrative and business related positions. Each of our employees has signed confidentiality and inventions assignment agreements, or have signed employment agreements containing confidentiality and inventions assignment provisions, and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

E. Share Ownership

For information regarding the share ownership of our directors and members of senior management, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of February 16, 2022 by:

- each person, or group of affiliated persons, known by us to beneficially own equal to or more than 5% of our outstanding shares;
- each of our directors; and
- each member of our senior management

	Share Beneficial Ownership			
Name of Beneficial Owner	Number of Shares Beneficially Owned	Number of Warrants Exercisable and RSUs to be Settled Within 60 days	Fully Diluted Number of Shares Beneficially Owned	Fully Diluted Percentage of Beneficial Ownership
5% Shareholders				
BlackRock, Inc.(1)			4,726,840	7.20 %
Board Members and Senior Management				
Deirdre P. Connelly	4,444	—	4,444	0.01 %
Pernille Lyngvold Erenbjerg	4,349	—	4,349	0.01 %
Anders Gersel Pedersen	11,278	—	11,278	0.02 %
Paolo Augusto Paoletti	608	—	608	0.00 %
Rolf Hoffmann	2,949	—	2,949	0.00 %
Mijke Zachariasse	92	557	649	0.00 %
Peter Storm Kristensen	973	1,452	2,425	0.00 %
Rima Nassar	1,038	4,585	5,623	0.01 %
Jan van de Winkel	614,657	65,668	680,325	1.04 %
Anthony Pagano	3,087	17,042	20,129	0.03 %
Anthony Mancini	—	—	—	0.00 %
Judith Klimovsky	5,247	36,932	42,179	0.06 %
Tahamtan Ahmadi	2,414	16,081	18,495	0.03 %
Birgitte Stephensen	*	*	*	*
Christopher Cozic	*	*	*	*
Martine van Vugt	*	*	*	*
All board members and senior management as a group (16 persons)	658,740	159,785	818,525	1.25 %

* Indicates beneficial ownership of less than 1% of the total outstanding shares.

(1) This information is based solely on the Schedule 13G filed by BlackRock, Inc. on February 3, 2022 with the SEC. BlackRock, Inc. does not have different voting rights from other shareholders.

The number of shares beneficially owned by each entity, person or member of our board of directors or senior management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares for which the individual has the right to subscribe within 60 days of February 16, 2022 through the exercise of any options, warrants or other rights. There are 159,785 shares for which our board members and senior management as a group have the right to subscribe within 60 days of February 16, 2022 pursuant to the exercise of warrants or settlement of restricted stock units.

Subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares owned by that person. The percentage of shares beneficially owned is computed on the basis of 65,718,456 shares outstanding as of February 16, 2022. Shares for which a person has the right to subscribe within 60 days of February 16, 2022 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. We conducted our last beneficial ownership analysis in the second quarter of 2021 and we estimated that approximately 35%, or 23 million (including shares in the form of ADSs) of our outstanding shares as of such date, were beneficially held by U.S. residents.

B. Related-Party Transactions

In the year ended December 31, 2021, there were no material related party transactions. The Company has employment agreements with, and has made equity compensation grants to, members of senior management in the ordinary course of business. The Company also has renumeration packages for members of the board of directors. See “Item 6.B—Compensation—Compensation of Members of Our Board of Directors and Executive Management” and Note 5.2 to our Audited Financial Statements included in our Annual Report 2021 for details on related party transactions.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8 FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Financial Statements

See “Item 18—Financial Statements” which contains our financial statements prepared in accordance with IFRS.

Legal Proceedings

From time to time in the ordinary course of business we may become involved in various lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to the defense and enforcement of our patent or other intellectual property rights. These proceedings are costly and time consuming. Successful challenges to our patent or other intellectual property rights through these proceedings could result in a loss of rights in the relevant jurisdiction and may allow third parties to use our proprietary products and technologies without a license from us or our partners.

In September 2020, Genmab commenced binding arbitration of two matters arising under its license agreement with Janssen relating to daratumumab. Under the license agreement, Genmab is, among other things, entitled to royalties from Janssen on sales of daratumumab (marketed as DARZALEX for IV administration and as DARZALEX FASPRO in the United States and DARZALEX SC in Europe for SC administration). The arbitration first is to settle whether Genmab is required to share in Janssen’s royalty payments to Halozyme for the Halozyme enzyme technology used in the SC formulation of daratumumab. The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SC daratumumab sales. Janssen has started reducing its royalty payments to Genmab by what it claims to be Genmab’s share of Janssen’s royalty payments to Halozyme beginning in the second quarter of 2020 and has continued to do so through December 31, 2021. Given the ongoing arbitration, Genmab has reflected this reduction in its royalty revenues each quarter. To date, the cumulative impact to royalties is estimated to be DKK 501 million (2021: DKK 421 million, 2020: DKK 80 million). The arbitration is also to settle whether Janssen’s obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement.

Dividends

We do not currently pay out cash dividends on our shares and have not paid out any dividends within the last three financial years. Any future determination related to our dividend policy and the declaration of any dividends will be made at the discretion of our Board of Directors and will depend on a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

B. Significant Changes

None.

ITEM 9 THE OFFER AND LISTING

A. Offer and Listing Details

Our shares are listed on NASDAQ Copenhagen in Denmark under the symbol “GMAB.” Our ADSs are listed on the NASDAQ in the United States under the symbol “GMAB.”

B. Plan of Distribution

Not applicable.

C. Markets

Our shares have been publicly traded since October 2000 and have been listed on NASDAQ Copenhagen in Denmark since that time.

ADSs representing the shares, as evidenced by ADSs issued by Deutsche Bank Trust Company Americas, as the Depository, have been listed on the NASDAQ since July 2019.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10 ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The sections entitled “Description of Share Capital and Certain Corporate Matters—Shareholders’ Register,” “Description of Share Capital and Certain Corporate Matters—Articles of Association and Danish Corporate Law” and

"Description of Share Capital and Certain Corporate Matters—Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law" in the Company's prospectus, filed with the SEC on July 19, 2019 are incorporated herein by reference.

C. Material Contracts

Except as otherwise disclosed in this Annual Report on Form 20-F (including the Exhibits), we are not currently party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

There are no governmental laws, decrees, or regulations in Denmark (including, but not limited to, foreign exchange controls) that restrict the export or import of capital, or that affect the remittance of dividends, interest or other payments to non-resident holders of the shares or the ADSs (please see below under "Item 10.E—Taxation" in respect of Danish withholding tax on dividends). There are no limitations on the right of non-resident or foreign owners to hold or vote the shares or the ADSs imposed by the laws of Denmark or the Articles of Association of the Company solely due to the fact that such holders are non-residents or foreign owners.

E. Taxation

Payment of Taxes

Holders will be responsible for any taxes or other governmental charges payable, or which become payable, on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register or transfer their ADSs or allow holders to withdraw the deposited securities represented by their ADSs until such taxes or other charges are paid. It may apply payments owed to holders or sell deposited securities represented by their ADSs to pay any taxes owed and holders will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to holders any net proceeds, or send to holders any property, remaining after it has paid the taxes. Holders agree to indemnify us, the depositary, the custodian and each of our and their respective agents, directors, employees and affiliates for, and hold each of them harmless from, any claims with respect to taxes (including applicable interest and penalties thereon) arising from any refund of taxes, reduced rate of withholding at source or other tax benefit obtained for holders. Holders' obligations under this paragraph shall survive any transfer of ADRs, any surrender of ADRs and withdrawal of deposited securities or the termination of the deposit agreement.

Material U.S. Federal Income Tax Considerations

General

The following discussion is a summary of the material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of the ADSs. This summary does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a particular person's decision to acquire the ADSs. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, and U.S. Treasury regulations promulgated thereunder ("**Treasury Regulations**"), as well as judicial and administrative interpretations thereof as in effect as of the date of this Annual Report on Form 20-F. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below, and there can be no assurance that the U.S. Internal Revenue Service ("**IRS**"), or U.S. courts will agree with the tax consequences described in this summary. The Company undertakes no obligation to publicly update or otherwise revise this summary whether as a result of new Treasury Regulations, Code sections, judicial and administrative interpretations or otherwise.

This summary applies only to U.S. Holders (as defined below) that hold the ADSs as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not address any U.S. federal estate and gift tax, alternative minimum tax or Medicare tax on net investment income consequences, or any U.S. state or local or non-U.S. tax consequences. This summary also does not address the tax considerations that may be relevant to certain types of investors subject to special treatment under U.S. federal income tax laws, such as:

- banks and other financial institutions;
- insurance companies;
- regulated investment companies or real estate investment trusts;
- dealers or traders in securities or currencies that use a mark-to-market method of accounting;
- broker-dealers;
- tax exempt organizations, retirement plans, individual retirement accounts and other tax deferred accounts;
- persons holding the ADSs as part of a straddle, hedging, conversion or integrated transaction for U.S. federal income tax purposes;
- U.S. expatriates;
- U.S. Holders whose functional currency is not the U.S. dollar;
- any entity or arrangement classified as a partnership for U.S. federal income tax purposes or investors therein;
- persons who own or are deemed to own, directly or constructively, 10% or more of the total combined voting power of all classes of the Company's voting stock or 10% or more of the total value of shares of all classes of the Company's stock;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the ADSs being taken into account in an applicable financial statement;
- persons who acquire ADSs pursuant to the exercise of an employee stock option or otherwise as compensation; or
- persons holding the ADSs in connection with a trade or business conducted outside the United States

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT BELOW IS FOR GENERAL INFORMATION ONLY. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ADSS.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of the ADSs that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions of the trust or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

The U.S. federal income tax treatment of a partner in an entity or arrangement treated as a partnership for U.S. federal income tax purposes that holds ADSs generally will depend on the status of the partner and the activities of the partnership. Partnerships considering an investment in the ADSs and partners in such partnerships should consult their tax advisors regarding the specific U.S. federal income tax consequences to them of the acquisition, ownership and disposition of the ADSs.

The discussion below assumes that the representations contained in the deposit agreement and any related agreement are true and that the obligations in such agreements will be complied with in accordance with their terms.

ADSs

For U.S. federal income tax purposes, U.S. Holders of ADSs generally will be treated as the beneficial owners of the underlying shares represented by the ADSs and an exchange of ADSs for the underlying shares generally will not be subject to U.S. federal income tax.

The U.S. Treasury Department and the IRS have expressed concerns that U.S. Holders of ADSs may be claiming foreign tax credits in situations where an intermediary in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS has taken actions that are inconsistent with the U.S. Holder of the ADS being treated as the beneficial owner of the underlying security. Such actions (for example, a pre-release of an ADS by a depositary) also may be inconsistent with the claiming of the reduced rate of tax applicable to certain dividends received by non-corporate U.S. Holders of ADSs, including individual U.S. Holders. Accordingly, the availability of foreign tax credits or the reduced U.S. federal income tax rate for "qualified dividend income," each discussed below, could be affected by actions taken by intermediaries in the chain of ownership between the holder of an ADS and the Company, if as a result of such actions the U.S. Holder of an ADS is not properly treated as the beneficial owner of the underlying share.

Dividends and Other Distributions

Subject to the PFIC rules discussed below, the gross amount of any distribution made by the Company to a U.S. Holder with respect to the ADSs (including the amount of any taxes withheld therefrom) generally will be included in such holder's gross income as non-U.S. source dividend income in the year actually or constructively received by the depository, but only to the extent that the distribution is paid out of the Company's current or accumulated earnings and profits (as determined under U.S. federal income tax principles). As a non-U.S. company, the Company does not maintain calculations of its earnings and profits under U.S. federal income tax principles. Therefore, it is expected that any distributions generally will be reported to U.S. Holders as dividends. Any dividends that the Company pays will not be eligible for the dividends-received deduction allowed to qualifying corporations under Section 243 of the Code.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends paid on the ADSs may be eligible to be taxed at favorable rates applicable to "qualified dividend income," provided that (1) the ADSs are readily tradable on an established securities market in the United States, (2) the Company is not a PFIC (as discussed

below) with respect to the relevant U.S. Holder for either its taxable year in which the dividend is paid or the preceding taxable year and (3) certain minimum holding period and other requirements are met.

Under a published IRS Notice, common or ordinary shares, or ADSs representing such shares, are considered to be readily tradable on an established securities market in the United States if they are listed on the Nasdaq Global Select Market. Our ADSs are readily tradable on the Nasdaq Global Select Market. However, based on existing guidance, it is unclear whether the shares will be considered to be readily tradable on an established securities market in the United States, because only the ADSs, and not the underlying shares, are listed on a securities market in the United States. U.S. Holders should consult their tax advisors regarding the availability of the favorable rate applicable to qualified dividend income for any dividends the Company pays with respect to the ADSs.

The amount of any distribution paid in Danish kroner will be included in a U.S. Holder's income in an amount equal to the U.S. dollar value of such Danish kroner calculated by reference to the exchange rate in effect on the date the distribution is actually or constructively received by the depository, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the distribution is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the distribution. A U.S. Holder may have foreign currency gain or loss if the distribution is converted into, or exchanged for, U.S. dollars after the date of receipt.

Any dividends the Company pays to U.S. Holders generally will constitute non-U.S. source "passive category" income for U.S. foreign tax credit limitation purposes. If any Danish taxes are withheld with respect to dividends paid to a U.S. Holder with respect to the ADSs, subject to certain conditions and limitations provided in the Code and the applicable Treasury Regulations (including a minimum holding period requirement), such taxes may be treated as non-U.S. taxes eligible for credit against such U.S. Holder's U.S. federal income tax liability (to the extent not exceeding the withholding rate applicable to the U.S. Holder). In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct non-U.S. taxes, including any Danish taxes withheld from dividends on the ADSs, in computing their taxable income, subject to generally applicable limitations under U.S. federal income tax law. An election to deduct non-U.S. taxes instead of claiming foreign tax credits applies to all non-U.S. taxes paid or accrued in the taxable year. If a refund of the tax withheld is available under the laws of Denmark or under an applicable income tax treaty, the amount of tax withheld that is refundable will not be eligible for such credit against a U.S. Holder's U.S. federal income tax liability (and will not be eligible for the deduction against U.S. federal taxable income). If the dividends constitute qualified dividend income as discussed above, the amount of the dividend taken into account for purposes of calculating the U.S. foreign tax credit limitation generally will be limited to the gross amount of the dividend, multiplied by the reduced rate applicable to the qualified dividend income, divided by the highest rate of tax normally applicable to dividends.

The rules relating to the determination of the U.S. foreign tax credit and the deduction of non-U.S. taxes are complex, and U.S. Holders should consult their tax advisors to determine whether and to what extent a credit or deduction may be available in their particular circumstances.

Taxable Dispositions of the ADSs

Subject to the PFIC rules discussed below, a U.S. Holder generally will recognize taxable gain or loss on any sale, exchange or other taxable disposition of an ADS in an amount equal to the difference between the sum of the fair market value of any property and the amount of cash received in such disposition and the holder's tax basis in the ADS. The U.S. Holder's tax basis in the ADSs generally will equal the cost of the ADSs to the U.S. Holder. The gain or loss generally will be capital gain or loss, and generally will be a long term capital gain or loss if the U.S. Holder has held the ADS for more than one year at the time of disposition. For certain non-corporate taxpayers (including individuals), long term capital gains are subject to tax at favorable rates. The deductibility of capital losses is subject to limitations.

Any gain or loss that a U.S. Holder recognizes on a sale or other taxable disposition of an ADS generally will be treated as U.S. source income or loss for U.S. foreign tax credit limitation purposes. U.S. Holders should consult their

tax advisors regarding the proper treatment of any gain or loss in their particular circumstances, including the effects of any applicable income tax treaties.

Passive Foreign Investment Company Considerations

Based on the current and anticipated value of our assets and the nature and composition of the Company's income and assets, the Company does not expect to be a PFIC for our current taxable year ending December 31, 2021, or in the foreseeable future. However, the determination of PFIC status is based on an annual determination that cannot be made until the close of a taxable year, involves extensive factual investigation, including ascertaining the fair market value of all of our assets on a quarterly basis and the active or passive character of each item of income that we earn, and is subject to uncertainty in several respects. Changes in the nature or composition of our income or assets, the structure of our operation or the value of our assets may cause us to become a PFIC. The determination of the value of our assets may depend in part upon the value of our goodwill not reflected on our balance sheet (which may depend upon the market value of the ADSs from time to time, which may be volatile). Accordingly, we cannot assure you that we will not be a PFIC for our current taxable year ending December 31, 2021, or for any future taxable year. If we are a PFIC for any year during which a U.S. Holder holds the ADSs, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds the ADSs, even if we ceased to meet the threshold requirements for PFIC status in any particular year, unless the U.S. Holder has made a “deemed sale” election under the PFIC Rules when we cease to be a PFIC.

A non-U.S. corporation such as the Company will be treated as a PFIC for U.S. federal income tax purposes for any taxable year if, applying applicable look-through rules, either:

- at least 75% of its gross income for such year is “passive income” for purposes of the PFIC rules; or
- at least 50% of the value of its assets (generally, determined based on a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income.

For this purpose, passive income generally includes dividends, interest, royalties and rents other than certain royalties and rents derived in the active conduct of a trade or business and not derived from a related person. The Company will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, more than 25% by value of the stock.

For purposes of the income test, we believe that we are engaged in an active trade or business of discovering and developing antibody therapeutics and that the royalties and milestone payments we receive from unrelated parties should be treated as derived in the active conduct of a trade or business and not characterized as passive income. However, we have no assurance that these anticipated milestone payments and royalties will be paid when expected. If any such payments are delayed or not received then, depending on the amount of passive income we receive from other sources, the relative percentage of our income that is passive could increase and potentially cause us to be classified as a PFIC. There can be no assurances that we will not be classified as a PFIC for the current taxable year or for any future taxable year.

If we were a PFIC for any taxable year during which a U.S. Holder holds ADSs, then, unless such U.S. Holder makes a “mark-to-market” election (as discussed below), such U.S. Holder generally would be subject to special adverse tax rules with respect to any “excess distribution” that it receives from the Company and any gain that it recognizes from a sale or other disposition, including, in certain circumstances, a pledge, of ADSs. For this purpose, distributions that a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions that it received during the shorter of the three preceding taxable years or its holding period for the ADSs will be treated as an excess distribution. Under these rules:

- the excess distribution or recognized gain would be allocated ratably over the U.S. Holder’s holding period for the ADSs;

- the amount of the excess distribution or recognized gain allocated to the taxable year of distribution or gain, and to any taxable years in the U.S. Holder's holding period prior to the first taxable year in which the Company was treated as a PFIC, would be treated as ordinary income; and
- the amount of the excess distribution or recognized gain allocated to each other taxable year would be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the resulting tax will be subject to the interest charge generally applicable to underpayments of tax.

If the Company were a PFIC for any taxable year during which a U.S. Holder holds ADSs and any of our non-U.S. subsidiaries or other corporate entities in which we own equity interests is also a PFIC, the U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of each such non-U.S. entity classified as a PFIC, each such entity referred to as a lower-tier PFIC, for purposes of the application of these rules. U.S. Holders should consult their own tax advisor regarding the application of the PFIC rules to any of the Company's lower-tier PFICs.

If the Company were a PFIC for any taxable year during which a U.S. Holder holds ADSs, then in lieu of being subject to the tax and interest-charge rules discussed above, the U.S. Holder may make an election to include gain on the ADSs as ordinary income under a mark-to-market method, provided that our ADSs constitute "marketable stock." Marketable stock is stock that is regularly traded on a qualified exchange or other market, as defined in applicable Treasury Regulations. The Company expects that the ADSs, but not our shares, will be listed on the Nasdaq Global Select Market, which is a qualified exchange or other market for these purposes.

Consequently, if the ADSs are listed on the Nasdaq Global Select Market and are regularly traded, we expect that the mark-to-market election would be available to U.S. Holders of ADSs if the Company were to become a PFIC, but no assurances are given in this regard.

Because a mark-to-market election cannot be made for any lower-tier PFICs that the Company may own (unless the shares in such lower-tier PFIC are themselves treated as marketable stock), if the Company were a PFIC for any taxable year, a U.S. Holder that makes the mark-to-market election may continue to be subject to the tax and interest charges under the general PFIC rules with respect to such U.S. Holder's indirect interest in any investments held by the Company that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

In certain circumstances, a shareholder in a PFIC may avoid the adverse tax and interest-charge regime described above by making a "qualified electing fund" election to include in income its share of the corporation's income on a current basis. However, a U.S. Holder may make a qualified electing fund election with respect to the ADSs only if the Company agrees to furnish such U.S. Holder annually with a PFIC annual information statement as specified in the applicable Treasury Regulations. There is no assurance that we will provide such information that would enable a U.S. Holder to make a qualified electing fund election.

If a U.S. Holder owns ADSs during any year in which the Company is a PFIC, such U.S. Holder (including, potentially, indirect holders) generally will be required to file an IRS Form 8621 with such holder's U.S. federal income tax return for that year. U.S. Holders should consult their own tax advisors regarding the application of the PFIC rules to their ownership of the ADSs.

Information Reporting and Backup Withholding

Dividend payments with respect to the ADSs and proceeds from a sale, exchange, redemption or other taxable disposition of the ADSs made within the United States or through certain U.S. related financial intermediaries may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and makes any other required certification on IRS Form W-9 or that is otherwise exempt from backup withholding. U.S. Holders of the ADSs should consult their tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against such U.S. Holder's U.S. federal income tax liability, and such holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Certain U.S. Holders may be required to comply with certain reporting requirements relating to the ADSs, including filing IRS Form 8938, with respect to the holding of certain foreign financial assets, including stock of foreign issuers (such as the Company), either directly or through certain foreign financial institutions, if the aggregate value of all such assets exceeds U.S. $50,000 on the last day of the tax year or U.S. $75,000 at any time during the tax year. U.S. Holders who fail to report the required information could be subject to substantial penalties. U.S. Holders should consult their own tax advisors regarding the application of these rules to their ownership of the ADSs.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE IMPORTANT TO YOU. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ADSS.

Material Danish Income Tax Considerations

The following is a summary of material Danish tax considerations relating to the ownership and disposition of ADSs. The summary is for general information purposes only and does not constitute exhaustive tax or legal advice.

It is noted specifically that the summary does not address all possible tax consequences relating to the ownership and disposition of ADSs. The summary does accordingly not apply to investors to whom special tax rules apply, and, therefore, may not be relevant, for example, to investors subject to the Danish Tax on Pension Yields Act (i.e., pension savings), professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and investors with tax liability on return on pension investments. The summary does further not apply to non-Danish tax resident investors that carry on business activities in Denmark through a permanent establishment, or to non-Danish tax resident investors, who are resident in jurisdictions, which are considered non-cooperative tax jurisdictions by the EU.

In the context of the following section, "companies" mean entities that are treated as separate taxable entities under domestic tax laws of their jurisdiction of incorporation.

The summary is based solely on the tax laws of Denmark in effect on the date of this Annual Report on Form 20-F. Danish tax laws may be subject to change, potentially with retroactive effect.

Potential investors in the ADSs are advised to consult their tax advisors regarding the applicable tax consequences of ownership and disposition of the ADSs based on their particular circumstances.

Tax Treatment of ADSs Under Danish Tax Law

It is currently not clear under Danish tax legislation or case law how ADSs are to be treated for Danish tax purposes. Recent public guidance from the Danish tax authorities indicate that the ADSs may not be treated as shares for Danish tax purposes, and that the ADS holder may not be treated as the direct owner of the shares underlying the ADSs and accordingly not as the shareholder for Danish tax purposes. Thus, according to recent communications from the Danish tax authorities, the Danish tax authorities are of the opinion that, in general, the depositary bank - and not the ADS holder - is the owner of the shares underlying the ADSs, and that the qualification of whether the ADS holder or the depositary bank is the holder of the underlying shares for Danish tax purposes depend on an assessment of the specific ADS program, with the main emphasis on the allocation of the administrative rights attached to the shares, in particular the voting rights. Furthermore, the Danish tax authorities are of the opinion that the ADS holder cannot be

regarded as holders of the underlying shares for Danish tax purposes to the extent the number of ADS certificates held by the ADS holder represents a fraction of a share.

While it therefore is highly uncertain whether the ADS holder in respect of the ADSs is treated as the direct owner of the shares underlying the ADSs and accordingly as the shareholder for Danish domestic tax law purposes, the below summary assumes that the ADS holder for Danish tax purposes is treated as the direct owner of the shares underlying the ADSs, but if this is not the case, then this will impact the Danish tax treatment of the holders of the ADSs including the respect of the taxation of dividends.

Danish Tax Resident Individuals

Sale of Shares

Capital gains from the sale of shares realized by Danish tax resident individuals are taxed as share income at a rate of 27% on the first DKK 57,200 (for cohabiting spouses, a total of DKK 114,400) and at a rate of 42% on share income exceeding DKK 57,200 (for cohabiting spouses over DKK 114,400) (all 2022 amounts and thresholds). The threshold is subject to annual adjustments and include all share income included in the calculation (*i.e.*, all capital gains on shares and dividends derived by the individual or cohabiting spouses, respectively).

Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is based on the average purchase price paid for the shares in the company (*i.e.*, not the purchase price paid for each share).

Losses on the sale of listed shares can only be offset against other share income deriving from listed shares (*i.e.*, dividends and capital gains on the sale of listed shares) and subject to the Danish tax authorities having received certain information concerning the ownership of the shares in due time. Unused losses will automatically be offset against a cohabiting spouse's share income deriving from listed shares and any additional losses can be carried forward and offset against future share income deriving from listed shares.

Dividends

It is highly uncertain if the actual distribution of dividends to the ADS holder are considered dividends for Danish tax purposes. However, if dividends paid to Danish tax resident individuals who are holders of ADSs are treated as dividends for Danish tax purposes, then such dividends are included in the individual’s share income and taxed as such, as outlined above. Dividends paid to Danish tax resident individuals are generally subject to withholding tax at the rate of 27%.

Non-Danish Tax Resident Individuals

Sale of Shares

Non-Danish tax resident individuals, including individuals tax resident in the United States, are generally not taxed in Denmark on gains realized on the sale of shares, subject to certain anti-avoidance rules (see below).

Dividends

Dividends paid on the shares underlying the ADSs to non-Danish tax resident individuals, including individuals tax resident in the United States, are generally subject to withholding tax at the rate of 27%. No additional tax will be imposed.

It is highly uncertain if the ADS holder is considered the holder of the shares underlying the ADSs. If the ADS holder is considered to be the owner of the shares underlying the ADSs for Danish tax purposes and is the beneficial owner of the dividends paid on the shares, then the ADS holder may in certain circumstances seek a refund of tax withheld on dividends paid on the shares.

In the event this is the case, and the ADS holder is tax resident in a state with which Denmark has entered into a tax treaty and is entitled to benefits under such tax treaty, the ADS holder may seek a refund from the Danish Tax Agency of the tax withheld in excess of the applicable treaty rate (Danish tax treaties typically provide for a 15% tax rate). Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all EU member states. The treaty between Denmark and the United States generally provides for a 15% tax rate.

Similarly, in the event the ADS holder for Danish tax purposes is considered the owner of the underlying shares and the beneficial owner of the dividends paid on the shares, Danish domestic tax law provides for a 15% tax rate, if the ADS holder holds less than 10% of the nominal share capital in the company and is tax resident in a state that is obligated to exchange information with Denmark under a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters. If the ADS holder is tax resident outside the EU, it is an additional requirement for application of the 15% tax rate that the ADS holder together with related shareholders holds less than 10% of the share capital of the company.

If the depositary bank is considered the owner of the shares underlying the ADSs for Danish tax purposes, then the depositary bank may potentially in certain circumstances seek a refund of tax withheld on dividends paid on the shares.

Any reduced tax rate according to an applicable tax treaty and/or Danish domestic tax law will not affect the withholding rate (27%). In order to receive a refund (from 27% to *e.g.*, 15%), the shareholder must make a claim for such refund through certain certification procedures.

As a general rule, the refund shall be paid within six months following the Danish Tax Agency's receipt of the refund claim. If the refund is paid later than six months after the receipt of the claim, interest will in general be calculated on the amount of refund. The rate per month will be 0.4% plus a premium fixed annually. The six-month deadline is suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer's affairs. If the deadline is suspended accordingly, computation of interest is also suspended.

The Danish Tax Agency has published guidance on the documentation necessary for processing refund claims. The guidance is available in English from the Danish tax authorities' website, https://skat.dk. The information on, or information that can be accessed through, such website is not part of and should not be incorporated by reference into this Annual Report on Form 20-F. We have included such website address as an inactive textual reference only.

Danish Tax Resident Companies

Sale of Shares

For the purpose of taxation of sales of shares made by corporate shareholders (and dividends received by corporate shareholders, see below), a distinction is made between:

"**Subsidiary Shares**," which are generally defined as shares owned by a shareholder holding at least 10% of the share capital of the issuing company;

"**Group Shares**," which are generally defined as shares in a company in which the shareholder of the company and the issuing company are subject to Danish joint taxation or satisfy the requirements for international joint taxation under Danish law;

"**Tax-Exempt Portfolio Shares**," which are generally defined as unlisted shares owned by a shareholder holding less than 10% of the share capital of the issuing company; and

"**Taxable Portfolio Shares**," which are defined as shares that do not qualify as Subsidiary Shares, Group Shares or Tax-Exempt Portfolio Shares.

Gains and losses on disposal of Subsidiary Shares, Group Shares and Tax-Exempt Portfolio Shares realized by Danish tax resident companies are generally not included in the taxable income of the shareholder, subject to certain anti-avoidance rules (see below).

Capital gains on listed Taxable Portfolio Shares are taxable at the general corporate tax rate of 22% and losses on such shares are generally deductible. Gains and losses on listed Taxable Portfolio Shares are taxed under the mark-to-market principle irrespective of realization.

Dividends

It is highly uncertain if the actual distribution of dividends to the ADS holder are considered dividends for Danish tax purposes. However, if dividends paid to Danish tax resident companies who are holders of ADSs are treated as dividends for Danish tax purposes, then the following should apply:

Dividends received on Subsidiary Shares and Group Shares are generally tax-exempt, subject to certain anti-avoidance rules (see below).

Dividends received on Taxable Portfolio Shares are taxable at the general corporate tax rate of 22% and tax is generally withheld similarly at 22%.

Non-Danish Tax Resident Companies

Sale of Shares

Non-Danish tax resident companies, including companies tax resident in the United States, are generally not taxed in Denmark on gains realized on the sale of shares, subject to certain anti-avoidance rules (see below).

Dividends

Dividends paid on the shares underlying the ADSs to non-Danish tax resident companies, including companies tax resident in the United States, are generally subject to withholding tax at the rate of 27%.

It is highly uncertain if the ADS holder is considered the holder of the shares underlying the ADSs. If the ADS holder is considered to be the owner of the shares underlying the ADSs for Danish tax purposes and is the beneficial owner of the dividends paid on the shares, then the ADS holder may in certain circumstances benefit from certain exemptions from withholding tax on dividends or seek a refund of tax withheld on dividends paid on the shares.

If the ADS holder for Danish tax purposes is considered the holder of the shares underlying the ADSs and is considered the beneficial owner of dividends paid on the shares, then the following exemptions apply if the shares held by the ADS holder qualify as Subsidiary Shares or Group Shares: dividends received on Subsidiary Shares are exempt from Danish withholding tax provided that taxation shall be waived or reduced under the Parent-Subsidiary Directive (2011/96/EU) or under an applicable tax treaty. Similarly, dividends received on Group Shares, which are not Subsidiary Shares, are exempt from Danish withholding tax if the shareholder is resident in the EU or the EEA and provided that taxation shall be waived or reduced under the Parent-Subsidiary Directive (2011/96/EU) or under an applicable tax treaty had the shares been Subsidiary Shares.

In other cases, dividends will generally be subject to tax at a rate of 22% effective for dividends distributed. However, the withholding rate is 27%, meaning that foreign corporate shareholders receiving taxable dividends distributed from Danish companies generally will be able to ask for a refund of at least 5% of the total dividend.

Further, if the ADS holder for Danish tax purposes is considered the holder of the shares underlying the ADSs, is considered the beneficial owner of dividends paid on the shares and is tax resident in a state with which Denmark has entered into a tax treaty and is entitled to the benefits under such tax treaty, the ADS holder may seek a refund from the Danish Tax Agency of the tax withheld in excess of the applicable treaty rate (Danish tax treaties typically provide for a 15% tax rate). Denmark has entered into tax treaties with approximately 80 countries, including the United States and almost all EU member states. The treaty between Denmark and the United States generally provides for a 15% tax rate.

Similarly, in the event the ADS holder for Danish tax purposes is considered the owner of the underlying shares and the beneficial owner of the dividends paid on the shares, Danish domestic tax law provides for an applicable 15% tax rate, if the ADS holder holds less than 10% of the share capital in the company and is tax resident in a state that is obligated to exchange information with Denmark under a tax treaty or an international agreement, convention or other administrative agreement on assistance in tax matters. If the ADS holder is tax resident outside the EU, it is an additional requirement for eligibility for the 15% tax rate that the ADS holder together with related shareholders holds less than 10% of the nominal share capital of the company.

If the depositary bank is considered the owner of the shares underlying the ADSs for Danish tax purposes, then the depositary bank may potentially in certain circumstances seek a refund of tax withheld on dividends paid on the shares.

Any reduced tax rate according to an applicable tax treaty (and/or the 15% tax rate provided for under Danish domestic tax law) will not affect the withholding rate (27%). In order to receive a refund (from 27% to *e.g.*, 15%), the shareholder must make a claim for such refund through certain certification procedures.

As a general rule, the refund shall be paid within six months following the Danish Tax Agency's receipt of the refund claim. If the refund is paid later than six months after the receipt of the claim, interest will be calculated on the amount of refund. The rate per month will be 0.4% plus a premium fixed annually. The six-month deadline can be suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer's affairs. If the deadline is suspended accordingly, computation of interest is also suspended.

The Danish Tax Agency has published guidance on the documentation necessary for processing refund claims. The guidance is available in English from the Danish tax authorities' website, https://skat.dk. The information on, or information that can be accessed through, such website is not part of and should not be incorporated by reference into this Annual Report on Form 20-F. We have included such website address as an inactive textual reference only.

Danish Anti-Avoidance Rules

The below summary of Danish anti-avoidance rules is not exhaustive.

Payments may be subject to Danish withholding tax irrespective of the above, if the shareholder is not the beneficial owner of the shares and dividend (e.g., if the shareholder reassigns the payments to a person or entity not itself entitled to the above exemptions).

Further, Danish law has certain general anti-avoidance rules ("**GAAR**"), which focus on substance over form. Under these rules the Danish tax authorities can set aside a setup, which, having been put into place for the main purpose or one of the main purposes of obtaining a tax advantage that defeats the object or purpose of the applicable tax law, is not genuine having regard to all relevant facts and circumstances. Subject to the conditions of the GAAR an investor might be denied the benefits of the Parent-Subsidiary Directive (2011/96/EU) or a tax treaty, and Danish withholding tax of 27% will in such cases be levied.

Finally, it should be noted that it is the shareholder who owns the share at the time of the general meeting where the decision to distribute dividend is passed to the shareholder, who is subject to Danish taxation on the dividend, and thereby is entitled to make a tax reclaim if any.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

Copies of this Annual Report on Form 20-F, as well as our Annual Report 2021, which includes our Audited Financial Statements, can be downloaded from the “Investors” page at www.genmab.com. The contents of our website are not incorporated by reference into this Annual Report on Form 20-F. This Annual Report on Form 20-F is also filed and can be viewed via EDGAR on www.sec.gov.

I. Subsidiary Information

Not applicable.

ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

For qualitative and quantitative disclosures about market risks including foreign currency risk interest rate risk, and credit risk, see Note 4.2 to our Audited Financial Statements included in our Annual Report 2021.

ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Genmab’s ADS program is administered by Deutsche Bank Trust Company Americas, as depositary. The principal executive office of the depositary is located at 60 Wall Street, New York, NY 10005, USA. Below is a summary of fees and expenses payable by ADS holders and of fees and payments by the depositary to us. Please refer to Exhibit 2.3 hereto for a summary of certain other material provisions of the amended and restated deposit agreement related to our ADS program. For more complete information, holders should read the entire amended and restated deposit agreement and the form of American Depositary Receipt incorporated by reference as Exhibit 2.1 and 2.2 hereto, respectively.

Fees and Expenses

ADS holders will be required to pay the following service fees to the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of their ADSs):

Service	Fees
● To any person to which ADSs are issued or to any person to which a distribution is made in respect of ADS distributions pursuant to stock dividends or other free distributions of stock, bonus distributions, stock splits or other distributions (except where converted to cash)	Up to $0.05 per ADS issued
● Cancellation of ADSs, including the case of termination of the deposit agreement	Up to $0.05 per ADS cancelled
● Distribution of cash dividends	Up to $0.05 per ADS held
● Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements	Up to $0.05 per ADS held
● Distribution of ADSs pursuant to exercise of rights.	Up to $0.05 per ADS held
● Distribution of securities other than ADSs or rights to purchase additional ADSs	Up to $0.05 per ADS held
● Depositary services	Up to $0.05 per ADS held on the applicable record date(s) established by the depositary bank

ADS holders will also be responsible to pay certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of their ADSs) such as:

- fees for the transfer and registration of shares charged by the registrar and issuing agent for the shares in the Kingdom of Denmark (i.e., upon deposit and withdrawal of shares);
- expenses incurred for converting foreign currency into U.S. dollars;
- expenses for cable, telex and fax transmissions and for delivery of securities;
- taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when shares are deposited or withdrawn from deposit);
- fees and expenses incurred in connection with the delivery or servicing of shares on deposit;
- fees and expenses incurred in connection with complying with exchange control regulations and other regulatory requirements applicable to shares, deposited securities, ADSs and ADRs; and
- any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (*i.e.*, share dividends, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via the Depositary Trust Company ("**DTC**")), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

Fees and Payments by the Depositary to Us

The depositary may make payments to us or reimburse us for certain costs and expenses, by making available a portion of the ADS fees collected in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

PART II

ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14 MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15 CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 20-F. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2021.

Report of Genmab Management on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS as issued by the IASB.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2021, using the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the

Treadway Commission ("COSO"). Based on this assessment our management concluded that, as of December 31, 2021, Genmab's internal control over financial reporting was effective based on criteria stated in Internal Control – Integrated Framework (2013) issued by the COSO.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2021 has been audited by PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, Denmark, an independent registered public accounting firm, as stated in their report which appears on page 135 of this Annual Report on Form 20-F.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the period covered by this Annual Report on Form 20-F that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

ITEM 16A AUDIT COMMITTEE FINANCIAL EXPERTS

Our Audit and Finance Committee consists of members Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an "audit committee financial expert," as defined in Nasdaq Rule 5605(c)(2)(A) and as determined by our Board of Directors.

ITEM 16B CODE OF ETHICS

We have adopted a written Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our directors and employees. This document is available under the "Corporate Governance" tab on the "Investors" page of our website (www.genmab.com). The contents of this website are not incorporated by reference into this Annual Report on Form 20-F.

During 2021, the Company amended its Code of Conduct to include articulation of 19 key Company standards with links to global practices and guidance. During 2021 the Company did not grant any waiver, including any implicit waiver, from any provision of the Code of Conduct to any of its directors or employees. We expect that any amendments to the current Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

ITEM 16C PRINCIPAL ACCOUNTANT FEES AND SERVICES

For principal accountant fees and services, see Note 5.6 to our Audited Financial Statements included in our Annual Report 2021.

Audit Fees

Audit fees consist of fees billed for professional services rendered by the principal accountant for the audit of the registrant's annual financial statements or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those fiscal years.

Audit-Related Fees

Audit-Related fees consist of assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of the registrant's financial statements and are not reported under "Audit Fees". Fees for audit-related services include consultations concerning financial accounting reporting standards.

Tax Fees

Tax fees consist of fees billed for professional services rendered by the principal accountant for tax compliance, tax advice, and tax planning, including tax fees billed for tax consultations.

All Other Fees

All other fees consist of products and services provided by the principal accountant, other than the services reported in "Audit Fees," "Audit-Related Fees" and "Tax Fees".

Fees for other services comprise fees billed for other permitted services, primarily related to Genmab's initial public offering and listing of ADSs on the Nasdaq in the United States.

Pre-Approval Policies

The Audit Committee assesses and pre-approves all audit and non-audit services provided by the statutory auditors.

ITEM 16D EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

In 2021, Genmab made the following purchases of its ordinary shares in connection with covering its obligations under its RSU program, as described in "Item 6—Directors, Senior Management and Employees—B. Compensation—Restricted Stock Unit Program."

Period	Total Number of Shares Purchased	Average Price Paid per Share in DKK	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
Share Repurchase Programs				
February 22, 2021 - February 26, 2021	10,000	2,141.49	10,000	-
March 1, 2021 - March 31, 2021	90,000	2,046.31	90,000	-
April 6, 2021 - April 29, 2021	28,900	2,189.67	28,900	-
May 3, 2021 - May 31, 2021	27,800	2,336.00	27,800	-
June 1, 2021 - June 30, 2021	43,300	2,596.43	43,300	-
Total	**200,000**	**-**	**200,000**	**-**

Share repurchases were conducted pursuant to a share buy-back program providing for repurchase of up to 200,000 ordinary shares (the "Share Buy-Back Program"), which was announced on February 23, 2021 and expired on June 30, 2021. The Share Buy-Back Program was conducted pursuant to the 2016 Authorization, which expired on March 10, 2021, and the 2019 Authorization, which is expiring in March 2024. No shares remain to be repurchased under the Share Buy-Back Program, but up to 330,000 and 500,000 shares are authorized for repurchase by the shareholders pursuant to the 2019 Authorization and the 2021 Authorization, respectively, should additional share buy-back programs be implemented in the future. See "Item 6—Directors, Senior Management and Employees—B. Compensation—Restricted Stock Unit Program" for more details.

ITEM 16F CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

ITEM 16G CORPORATE GOVERNANCE

The listing rules of the Nasdaq (the "**Nasdaq Listing Rules**") provide that foreign private issuers may follow home country practice in lieu of Nasdaq Global Select Market corporate governance standards, subject to certain exceptions

and except to the extent that such exemptions would be contrary to U.S. federal securities laws. The home country practices we follow in lieu of the Nasdaq Listing Rules are described below.

- We do not follow the quorum requirements of the Nasdaq Stock Market applicable to meetings of shareholders. In accordance with Danish corporate law and generally accepted business practice, our articles of association do not provide quorum requirements for general meetings of shareholders.

- We do not follow the requirements of the Nasdaq Stock Market regarding the provision of proxy statements for general meetings of shareholders. Danish corporate law does not have a regulatory regime for the solicitation of proxies. The solicitation of proxies is not a generally accepted business practice in Denmark, although it has recently become more common for listed companies to do so. However, a shareholder may be represented at a general meeting by proxy. Unless containing a provision to the contrary, instruments of proxy will be deemed to be in force until revoked in writing by notification to the company. Rather than providing proxy statements, we provide notice convening a general meeting, including an agenda and other relevant documents, to the Danish Business Authority and written notice to all registered shareholders who have so requested.

- We do not follow the requirements of the Nasdaq Stock Market regarding shareholder approval for certain issuances of securities under Nasdaq Listing Rule 5635. Pursuant to Danish corporate law and our articles of association, our shareholders have authorized our Board to issue securities, including shares and warrants.

- We do not follow the requirement of the Nasdaq Stock Market that each member of the Compensation Committee be independent as defined under Nasdaq Listing Rule 5605(a)(2). No such requirement exists pursuant to Danish law. We do not have an independent Compensation Committee within the meaning of the Nasdaq Listing Rules because we consider Anders Gersel Pedersen, a member of the Compensation Committee, to be a non-independent director solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. We do not consider Dr. Pedersen's tenure as material to his ability to be independent from senior management in connection with his duties as a Compensation Committee member. The charter of the Compensation Committee requires a majority of its members to be independent.

- We do not follow the requirement of the Nasdaq Stock Market that we have independent director oversight of director nominations as prescribed by Nasdaq Listing Rule 5605(e)(1). No such requirement exists pursuant to Danish law. We do not have independent oversight of director nominations because we consider Anders Gersel Pedersen to be a non-independent director solely by virtue of the length of his tenure on our Board, following his election to the Board in 2003. We do not consider Dr. Pedersen's tenure as material to his ability to be independent from senior management in connection with his duties as a member of the Nominating and Corporate Governance Committee. The charter of the Nominating and Corporate Governance Committee requires a majority of its members to be independent.

- We do not follow the requirement of the Nasdaq Stock Market that our independent directors must have regularly scheduled meetings at which only independent directors are present. No such requirement exists pursuant to Danish law. Our directors regularly meet in executive sessions without the participation of management. However, our Employee Elected Directors, who are not independent within the meaning of the Nasdaq Listing Rules, attend these executive sessions.

ITEM 16H MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17 FINANCIAL STATEMENTS

See “Item 18—Financial Statements.”

ITEM 18 FINANCIAL STATEMENTS

The financial statements required by this item are incorporated herein by reference to pages 87-132 of our Annual Report 2021.

ITEM 19 EXHIBITS

a. Annual Report

The following pages from our Annual Report 2021, furnished to the SEC as Exhibit 99.1(a) to Form 6-K, dated February 16, 2022, and from our Annual Report 2020, furnished to the SEC as Exhibit 99.1(a) to Form 6-K, dated February 23, 2021, are incorporated by reference into this Form 20-F. The content of websites, scientific articles and other sources referenced on these pages are not incorporated by reference into this Annual Report on Form 20-F.

Page(s) incorporated by reference from our Annual Report 2021

Financial Review - pages 61-65

Consolidated Financial Statements for the Genmab Group – pages 87-132

Consolidated Statements of Comprehensive Income for the years ended December 31, 2021, 2020 and 2019 – page 88

Consolidated Balance Sheets as of December 31, 2021 and 2020 – page 89

Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019 – page 90

Consolidated Statements of Changes in Equity for the years ended December 31, 2021, 2020 and 2019 – page 91

Notes to the Consolidated Financial Statements – pages 92-132

Page(s) incorporated by reference from our Annual Report 2020

Financial Review - pages 63-68

b. **Exhibits**

Exhibit Index

Exhibit No.	Description	Method of filing
1.1	English translation of Articles of Association of Genmab A/S, as currently in effect	Incorporated by reference to the Registrant’s Report furnished to the SEC on Form 6-K on February 3, 2022
2.1	Amended and Restated Deposit Agreement	Incorporated by reference to Exhibit (a)(3) to the Registrant’s Form F-6 filed with the SEC on July 15, 2019

Exhibit No.	Description	Method of filing
2.2	Form of American Depositary Receipt	Included in Exhibit 2.1, which is incorporated by reference to Exhibit (a)(3) to the Registrant's Form F-6 filed with the SEC on July 15, 2019
2.3	Description of Securities Registered under Section 12 of the Exchange Act	Incorporated by reference to Exhibit 2.3 to the Registrant's Annual Report on Form 20-F filed with the SEC on March 29, 2021
4.1†	License Agreement, dated as of August 30, 2012, by and between Janssen Biotech, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.2†	Amendment Number 1 to the License Agreement, dated as of January 31, 2013, by and between Janssen Biotech, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.3†	Amendment Number 2 to the License Agreement, dated as of October 10, 2013, by and between Janssen Biotech, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.4†	License and Collaboration Agreement, dated as of October 7, 2011, by and between Seagen, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.5†	Joint Commercialization Agreement dated October 19, 2020 between Genmab A/S and Seagen Inc.	Incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 20-F filed with the SEC on March 29, 2021
4.6†	Co-development and Collaboration Agreement, dated as of December 19, 2006, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.7†	Amendment Number 1 to the Co-development and Collaboration Agreement, dated as of June 30, 2008, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.8†	Amendment Number 2 to the Co-development and Collaboration Agreement, dated as of December 18, 2008, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.7 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.9†	Amendment Number 3 to the Co-development and Collaboration Agreement, dated as of July 1, 2010, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.8 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.10†	Amendment Number 4 to the Co-development and Collaboration Agreement, dated as of December 20, 2010, by and between Glaxo Group Limited and Genmab A/S	Incorporated by reference to Exhibit 10.9 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.11†	Novation Agreement, dated as of November 3, 2014, by and among Glaxo Group Limited, Novartis Pharma AG and Genmab A/S	Incorporated by reference to Exhibit 10.10 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.12†	Amendment Number 5 to the Co-development and Collaboration Agreement, dated as of January 22, 2018, by and between Novartis Pharma AG and Genmab A/S	Incorporated by reference to Exhibit 10.11 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.13†	Amended and Restated Evaluation and Commercialization Agreement, dated as of July 12, 2012, by and among BristolMyer Squibb Corporation, Medarex, Inc., GenPharm International, Inc. and Genmab A/S	Incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form F-1/A filed with the SEC on July 16, 2019
4.14†	Collaboration and License Agreement, dated as of June 10, 2020 by and between AbbVie Biotechnology Ltd. and Genmab A/S	Incorporated by reference to Exhibit 4.14 to the Registrant's Annual Report on Form 20-F filed with the SEC on March 29, 2021

Exhibit No.	Description	Method of filing
8.1	List of Subsidiaries	Incorporated by reference to Exhibit 8.1 to the Registrant's Annual Report on Form 20-F filed with the SEC on March 29, 2021
12.1	Certification of the Principal Executive Officer	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2021
12.2	Certification of the Principal Financial Officer	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2021
13.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. section 1350	Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2021
13.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. section 1350	Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2021
15.1	Consent of Independent Registered Public Accounting Firm	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2021
EX-101.INS	XBRL Instance Document	Incorporated by reference to Exhibit 101.INS to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022
EX-101.SCH	XBRL Taxonomy Extension Schema Document	Incorporated by reference to Exhibit 101.SCH to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Incorporated by reference to Exhibit 101.CAL to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Incorporated by reference to Exhibit 101.DEF to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022
EX-101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	Incorporated by reference to Exhibit 101.LAB to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Incorporated by reference to Exhibit 101.PRE to the Registrant's report furnished to the SEC on Form 6-K on February 16, 2022

† Portions of this exhibit, marked by brackets, have been omitted pursuant to Instruction 4(a) to Exhibits to Form 20-F because they are both (i) not material and (ii) include information of the type that we treat as private or confidential.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

Genmab A/S

/s/ Jan G. van de Winkel

Name: Jan G. van de Winkel
Title: President and Chief Executive Officer

Dated: February 16, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Genmab A/S

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Genmab A/S and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2021, including the related notes, as listed in the index appearing under Item 19a (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and International Financial Reporting Standards as adopted by the European Union. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the COSO.

Basis for Opinions

The Company's Management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the Report of Genmab Management on Internal Control over Financial Reporting appearing under Item 15. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by Management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely

detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition of DARZALEX
As described in note 5.5 to the consolidated financial statements, the Company in September 2020 commenced binding arbitration of matters arising under its license agreement with Janssen Biotech, Inc. (Janssen) relating to DARZALEX. The arbitration is to settle whether the Company is required to share in Janssen's royalty payments to Halozyme Therapeutics, Inc. (Halozyme) for the Halozyme enzyme technology used in the SC formulation of daratumumab. Janssen has started reducing its royalty payments to the Company by what it claims to be the Company's share of Janssen's royalty payments to Halozyme beginning in the second quarter of 2020 and through December 31, 2021. Based on discussions with external and in-house legal counsel, the Company has considered revenue subject to this arbitration as a variable consideration where it is not highly probable that the Company will not reverse this revenue in the future. Therefore, the Company has not recognized revenue in relation to the royalty payments subject to the arbitration. The estimated life to date impact on royalty revenue is DKK 501 million.

The principal considerations for our determination that performing procedures relating to revenue recognition of DARZALEX is a critical audit matter are the significant judgment by Management when determining the estimate of the variable consideration. This in turn led to significant audit effort in performing procedures and evaluating evidence to assess the reasonableness of the estimates of the variable consideration.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the process to record revenue, including controls related to the estimate of the variable consideration. These procedures also included, among others, evaluating and testing Management's process for determining the variable consideration and assessing the reasonableness of the estimate. This included (i) gaining an understanding of the Company's process around the accounting and reporting for the arbitration; (ii) discussing the status of the arbitration with the Company's in-house legal counsel as well as obtaining legal letter from the external legal counsel; (iii) evaluating the reasonableness of Management's estimate regarding recognition of the variable consideration; and (iv) evaluating the presentation and disclosure within the consolidated financial statements.

/s/ PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
Hellerup, Denmark
February 16, 2022

We have served as the Company's auditor since 2001.

EXHIBIT 12.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

I, Jan G. van de Winkel, certify that:

1. I have reviewed this annual report on Form 20-F of Genmab A/S;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Genmab A/S as of, and for, the periods presented in this report;

4. The other certifying officer of Genmab A/S and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for Genmab A/S and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Genmab A/S, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of disclosure controls and procedures of Genmab A/S and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in internal control over financial reporting of Genmab A/S that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect internal control over financial reporting of Genmab A/S.

5. The other certifying officer of Genmab A/S and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the auditors of Genmab A/S and the audit committee of the board of directors of Genmab A/S (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the ability of Genmab A/S to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the internal control over financial reporting of Genmab A/S.

Date: February 16, 2022

/s/ Jan G. van de Winkel

AMERICAS/2017215015.2

EXHIBIT 12.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER

I, Anthony Pagano, certify that:

1. I have reviewed this annual report on Form 20-F of Genmab A/S;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Genmab A/S as of, and for, the periods presented in this report;

4. The other certifying officer of Genmab A/S and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for Genmab A/S and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Genmab A/S, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of disclosure controls and procedures of Genmab A/S and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in internal control over financial reporting of Genmab A/S that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect internal control over financial reporting of Genmab A/S.

5. The other certifying officer of Genmab A/S and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the auditors of Genmab A/S and the audit committee of the board of directors of Genmab A/S (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the ability of Genmab A/S to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the internal control over financial reporting of Genmab A/S.

Date: February 16, 2022

/s/ Anthony Pagano

AMERICAS/2017215013.2

EXHIBIT 13.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Jan G. van de Winkel, President and Chief Executive Officer of Genmab A/S, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Annual Report on Form 20-F of Genmab A/S for the period ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Genmab A/S.

Date: February 16, 2022

/s/ Jan G. van de Winkel

AMERICAS/2017215013.2

EXHIBIT 13.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION
PURSUANT T`O 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Anthony Pagano, Executive Vice President and Chief Financial Officer of Genmab A/S, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Annual Report on Form 20-F of Genmab A/S for the period ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Genmab A/S.

Date: February 16, 2022

/s/ Anthony Pagano

AMERICAS/2017215013.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-253519 and 333-232693) of Genmab A/S of our report dated February 16, 2022 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
Hellerup, Denmark
February 16, 2022