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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, 2022**

**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)

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(Name, telephone, e-mail and/or facsimile number and address of Company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
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.

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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.

**65,961,573 Ordinary Shares (including shares underlying American Depositary Shares)**

**46,612,010 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<sup>†</sup> provided pursuant to Section 13(a) of the Exchange Act.

<sup>†</sup> 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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b).

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 2022 (the “**Annual Report 2022**”), included as Exhibit 99.1(a) to Form 6-K furnished to the U.S. Securities and Exchange Commission (the “**SEC**”) on February 22, 2023 and 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 SEC on February 16, 2022. Therefore, the information in this Annual Report on Form 20-F should be read in conjunction with the incorporated portions of the Annual Report 2022 and the Annual Report 2021. Items not contained or not specifically referenced to within the Annual Report 2022 or the Annual Report 2021 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, marketed as DARZALEX, amivantamab, marketed as RYBREVA, teclistamab, marketed as TECVAYLI, ofatumumab, marketed as Kesimpta and teprotumumab, marketed as TEPEZZA, 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, marketed as Tivdak, 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 pre-clinical product candidates;
- our receipt of future milestone payments and royalties from our collaboration 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;

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- 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 collaboration partners to pursue the development, approval and commercialization of our products and product candidates;
- our and our collaboration 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 collaboration partners' ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of our pre-clinical trials 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 and our collaboration partners' 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 collaboration 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 collaboration 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 collaboration 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 2022 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, trials 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 our 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 depository shares (“**ADSs**”). The principal risks and uncertainties affecting our business include the following:

- Our financial results and near-term prospects are substantially dependent on the commercial success of DARZALEX.
- Our future prospects for amivantamab, marketed as RYBREVAANT; ofatumumab, marketed as KESIMPTA; teclistamab, marketed as TECVAYLI; teprotumumab, marketed as Tepezza; and tisotumab vedotin, marketed as Tivdak, are dependent on our collaboration partners’ abilities to successfully expand the indications for these products, and to effectively commercialize them for their current indications and any new indications, and in current or new markets, as well as on other external factors that could impact the future success of such products.
- Biopharmaceutical product development involves a substantial degree of uncertainty.
- We have a very limited history of commercializing our marketed products.
- Collaborations continue to be an important part of our strategy and we may not be able to continue or optimize our current collaborations or establish additional collaborations.
- Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.
- We may not meet publicly announced product development objectives.
- We rely on third parties to conduct our clinical trials.
- The U.S. Food and Drug Administration (“**FDA**”) may not accept data from trials we or our collaboration partners conduct outside the United States or may require additional U.S.-based trials as a condition of regulatory approval.
- Any approval granted for our products or product candidates in the United States does not assure approval of such products in the European Union or other foreign jurisdictions.
- We may be affected by reports of adverse events or safety concerns relating to our products or product candidates.
- We rely on a limited number of contract manufacturers.
- Sales of our products and product candidates will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

- We may face product liability claims related to the use or misuse of our products or technologies.
- Our internal computer systems, or those of our collaboration partners, contractors or consultants, may fail or suffer cyber or other security breaches.
- The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.
- Our ability to compete may decline if we or our collaboration partners are unable to or do not adequately protect intellectual property rights or if our intellectual property rights are inadequate.
- Government restrictions on pricing and reimbursement, as well as other healthcare payer cost-containment initiatives, may negatively impact our ability to generate revenue.
- We are subject to healthcare laws and regulations.

### ***Risks Related to Our Business***

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

In 2022, royalties and milestone payments from Janssen related to daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the United States and as DARZALEX SC in Europe for subcutaneous (“SC”) administration) for certain indications of multiple myeloma (“MM”) and light-chain (“AL”) amyloidosis, accounted for 69% of our revenue, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. Janssen is currently fully responsible for developing and commercializing daratumumab and all costs associated therewith, and consequently, our revenue and resulting operating profit and near-term prospects are substantially dependent on Janssen’s efforts and the success of this collaboration.

The royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen’s obligation to pay royalties under this agreement will expire on a country-by-country basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration of the last-to-expire relevant Genmab-owned patent (as defined in the agreement) covering daratumumab in such country. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026.

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

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

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

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

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

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

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

- Amivantamab – The two antibody libraries used to produce amivantamab were both generated by Genmab, but the antibody pair used to create amivantamab was selected in collaboration between Genmab and Janssen with subsequent development work and commercialization led by Janssen;
- Ofatumumab – Novartis is fully responsible for the development and commercialization of ofatumumab and all costs associated therewith;

- Teclistamab - The antibody for this product was created by Janssen by leveraging Genmab's DuoBody technology, and under our agreement with Janssen, the development and commercialization of the product is now being conducted by Janssen;
- Teprotumumab – The antibody for this product was created by Genmab, under a collaboration with Roche, and development and commercialization of the product is now being conducted by Horizon under a license from Roche; and
- Tisotumab Vedotin – This product is being developed in collaboration with Seagen Inc. (“**Seagen**”), and under our agreement, Seagen and Genmab are each responsible for leading commercialization activities in certain territories.

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

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

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

- our collaboration partners have significant discretion regarding whether and on what timeline to pursue planned activities;
- we cannot control the quantity and nature of the resources our collaboration partners may devote to the development, commercialization, marketing and distribution of products or product candidates;
- our collaboration partners may not develop products generated using our antibody technology as expected;
- disputes between us and our collaboration partners may delay or terminate the research, development or commercialization of the applicable products and product candidates or result in costly litigation or arbitration that diverts management's attention and resources;
- with respect to collaborations under which we have an active role, we and our collaboration partners may have differing opinions or priorities, or we may encounter challenges in joint decision making, which may delay or terminate the research, development or commercialization of the applicable products and product candidates;
- we may not receive milestone payments from our collaboration partners, at the expected time or at all, if our collaboration partners do not achieve future milestones or if we and our collaboration partners disagree about whether a milestone has been reached;
- our collaboration partners may require, terminate or repeat clinical trials or require a new formulation of a product candidate for clinical testing, or may abandon a product candidate;
- our relationships with our collaboration partners may divert significant time and effort of our scientific staff and management team;

- our collaboration partners may be subject to regulatory sanctions that could adversely affect the development, approval or commercialization of the applicable products or product candidates;
- our collaboration partners may not properly maintain or defend relevant intellectual property rights, or may infringe the intellectual property rights of third parties, or may use our or third parties' proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- our collaboration partners may develop competing products, therapeutic approaches or technologies;
- business combinations, financial difficulties or significant changes in a collaboration partner's business strategy, including as a result of the COVID-19 pandemic, may adversely affect that collaboration partner's willingness or ability to continue to pursue our products or product candidates; and
- our collaborations may be terminated, breached or allowed to expire, or our collaboration partners may reduce the scope of our agreements with them.

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

***Biopharmaceutical product development involves a substantial degree of uncertainty.***

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

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, we or our collaboration partners may not successfully develop any of our product candidates, or we or our collaboration partners may choose to discontinue the development or co-development of product candidates for a variety of reasons, including due to safety, risk versus benefit profile, exclusivity, competitive landscape, commercialization potential, production limitations or prioritization of our or our collaboration partners' resources. In addition, our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates suitable for clinical development or commercialization. Likewise, we and our collaboration partners have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance. For example, in September 2021, we decided that the data did not support the further development of HexaBody-DR5/DR5, and we and AbbVie Inc. ("**AbbVie**") decided to halt further development of DuoBody-CD3x5T4. In June 2022, AbbVie decided to discontinue co-development of DuoHexaBody-CD37 and upon expiry of the 180-day notice period on December 24, 2022, we became solely responsible for the further development of DuoHexaBody-CD37. We may not have the resources to invest in all of our current product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates. Decision-making about which product candidates to prioritize involves inherent uncertainty, and our and our collaboration partners' development program decision-making and resource prioritization decisions may not improve our results of operations or future growth prospects.

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

Additionally, with the exception of tisotumab vedotin and epcoritamab we have not advanced any product candidates through late-stage clinical development ourselves. Tisotumab vedotin received accelerated FDA approval in September 2021. We submitted a Biologics License Application (“BLA”) for SC epcoritamab to the FDA in September 2022, which was accepted with Priority Review in November 2022 with a target action date of May 21, 2023, and a Japan New Drug Application (“JNDA”) to the Ministry of Health, Labor and Welfare (“MHLW”) in December 2022. Our collaboration partner, AbbVie, submitted a marketing authorization application (“MAA”) to the European Medical Agency (“EMA”) in October 2022, which was also validated in October 2022. If we are unable to develop late-stage development capabilities, we will be required to continue to contract with third parties via licensing and development agreements to complete the development of our proprietary product candidates, which we may not be able to do on a timely basis, on terms favorable to us, or at all, and the development of our proprietary product candidates could be delayed or terminated. Our failure to effectively advance our development programs could have a material adverse effect on our business, financial condition, results of operations and future growth prospects, and cause the market price of our ADSs to decline.

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

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

We are currently building and expanding our commercialization capabilities to allow us to market our own products for the indications and in the geographies we determine would be most effective to create value for patients and our shareholders. Our goal is to become a commercial-stage company with an initial focus on successfully commercializing tisotumab vedotin, marketed as Tivdak in the U.S. for the treatment of cervical cancer following the receipt of accelerated FDA approval in September 2021. We are developing tisotumab vedotin in collaboration with Seagen.

We continue to develop our market-based commercialization operations in the U.S. and Japan. Building comprehensive commercialization capabilities will require substantial investment of time and money and will require significant management focus and resources. We will be competing with pharmaceutical and biotechnology companies with established commercialization and marketing capabilities. In addition, we may be unable to develop productive relationships with local medical experts, patients and other key stakeholders or may face barriers due to cultural or regulatory differences. We will also compete for staffing with transnational and local pharmaceutical and biotechnology firms and local medical, healthcare and research organizations. Accordingly, there can be no assurance that our efforts to build and expand comprehensive commercialization capabilities will be successful.

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

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

Part of the clinical development strategy for certain of our product candidates, including daratumumab, is to seek to identify patients or patient subsets within a disease category whose treatment may benefit from our products in combination with other therapeutic products. Approval of a product for the treatment of a disease indication in

combination with other therapeutic products exposes us and our collaboration partners to certain risks related to those other therapeutic products, including the risks that such products will become less competitive or obsolete or will be found to have safety concerns, which could potentially result in removal of such products from the market. Furthermore, seeking to heighten immune or other therapeutic responses through combination treatments carries an inherent risk that the combination may cause unexpected side effects or safety issues not observed in treatment with the individual products alone.

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

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

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

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

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

collaboration partners may be unable to obtain marketing approval for product candidates on a timely basis or at all, which could impact our reputation, business, financial condition, results of operations and future growth prospects.

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

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

- we or our collaboration partners may be unable to manufacture or obtain sufficient quantities of qualified materials for clinical trials or may be required to modify manufacturing processes;
- patient recruitment may be slower than expected and we may have difficulty accessing potential clinical trial sites;
- a product candidate may be ineffective, inferior to existing approved products for the same indications, unacceptably toxic or have unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- a clinical trial may be delayed, suspended or terminated by the institutional review board or ethics committee responsible for overseeing the clinical trial, by regulatory authorities or by us or our collaboration partners due to failure to meet clinical protocols, safety issues or adverse effects, failure to demonstrate product efficacy, changes in clinical protocols, may require additional dose finding and/or dose optimization, or applicable regulatory requirements, lack of funding or other factors;
- investigators or other third parties could conduct clinical trials on our products or product candidates that could lead to adverse events or results that could negatively impact the development, regulatory approval or marketability of such products;
- extension trials on long-term tolerance could invalidate the use of our product;
- clinical trials may not demonstrate statistically sufficient levels of safety and efficacy to obtain the requisite regulatory approvals;
- even if data is sufficient for regulatory approval, it may not be sufficient to secure pricing reimbursement or to secure validation of our products by key industry players, which could delay or prevent the commercial launch of a product; and
- our collaboration partners or CROs may be unable or unwilling to perform under their contracts.

***We may not meet publicly announced product development objectives.***

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

***We rely on third parties to conduct our clinical trials.***

We do not currently have the ability to independently conduct clinical trials. With respect to our proprietary product candidates or any other product candidates for which we control the clinical development, we rely on third parties, such as CROs, to conduct clinical trials on our product candidates. For our out-licensed products and product candidates, or for any product candidates where our collaboration partner is responsible for clinical development, we rely on such collaboration partners to conduct clinical trials. These collaboration partners may also hire CROs or other third parties to conduct clinical trials on our products and product candidates. The third parties with whom we and our collaboration partners contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and in compliance with applicable regulations and standards, commonly referred to as cGCPs.

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

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

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

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

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

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the trial population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

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

Even if we and our collaboration partners are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our and our collaboration partners' ability to advance the development of our product candidates.

***Any approval granted for our products or product candidates in the United States does not assure approval of such products in the European Union or other foreign jurisdictions.***

In order to market and sell our drugs in the European Union and other jurisdictions, we and our collaboration partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, many countries outside the United States require that the drug be approved for reimbursement before the drug can be approved for sale in that country. We and our collaboration partners may not obtain approvals from regulatory authorities outside the United

States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

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

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

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

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

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

Fast Track Designation (“FTD”), Breakthrough Therapy Designation (“BTD”), and pilot programs of the FDA and other regulatory authorities are intended to expedite the review and approval of drug candidates in certain circumstances. These designations and programs do not, however, ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion regarding whether or not to grant these designations or include product candidates within pilot programs, and, even if we or our collaboration partners believe a particular product candidate is eligible for these designations or programs, we cannot assure that such authority would agree. Even if we or our collaboration partners receive such designations or are eligible for inclusion in expedited review pilot programs in the future, we may not experience a faster development, review or approval process compared to conventional procedures. In addition, such designations or processing under such pilot programs may be withdrawn if the FDA or the relevant regulatory body no longer believes such product candidate meets the criteria for the designation

or program. Furthermore, these designations and pilot programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted expedited review or BTB or FTD designation may be ultimately denied based on trial data, trial design or other factors, and even if our product candidates are accepted into such a program, this does not assure ultimate approval by the FDA or the applicable regulatory body. See also “—*The FDA may not accept data from trials we or our collaboration partners conduct outside the United States or may require additional U.S.-based trials as a condition of regulatory approval.*” See “*Item 4 – Information on the Company – Government Regulation*” for more information about BTB and FTD and other programs for expedited review.

***We rely on a limited number of contract manufacturers.***

To ultimately be successful, our antibody products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Janssen is responsible for the manufacture of daratumumab, amivantamab, and teclistamab. Novartis is responsible for the manufacture of ofatumumab, Horizon is responsible for the manufacture of teprotumumab, and Seagen is responsible for the manufacturing of tisotumab vedotin. For the product candidates and products we are entirely responsible to manufacture, we currently rely primarily upon one single source third-party CMO, Lonza Group AG (“**Lonza**”), to manufacture and supply large quantities of our product candidates. We expect to negotiate contracts for commercial production on a product-by-product basis for products that we choose to commercialize ourselves and currently have no plans to build our own clinical or commercial scale manufacturing capabilities.

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

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

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

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

In addition, we lack direct control over our manufacturers' compliance with these regulations and standards and manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other regulatory requirements. The discovery of manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with cGMP or other requirements after approval of a product may result in restrictions on the marketing of a product, revocation of the license, withdrawal of the product from the market, seizures, injunctions, fines or criminal sanctions. If the safety of any product supplied is compromised due to the manufacturers' failure to adhere to applicable laws or for other reasons, we or our collaboration partners may not be able to continue clinical trials for our product candidates, obtain regulatory approval for or successfully commercialize our products, and we or our collaboration partners may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products and product candidates or entail higher costs or impair our reputation. No assurance is given that third-party manufacturers will be able to comply adequately with the applicable regulations.

***We face intense competition and rapid technological change.***

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

In the United States, the Biologics Price Competition and Innovation Act of 2009 ("**BPCIA**"), created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" or "biosimilar" to or "interchangeable" with an FDA-approved biological product, which may be used by our competitors to receive approval for, and commercialize, product candidates that compete with our products with less effort and expense than would otherwise be required. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. However, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior approvals of a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the ultimate impact of the BPCIA is subject to uncertainty.

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

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

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

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

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

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

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

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

Periodically, we and our collaboration partners make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various sources and internally generated analysis and use such estimates in making decisions regarding product development strategy, including determining indications on which to focus in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data, or patient incidence and prevalence for selected indications may evolve over time as treatments and patient outcomes change. The number of

patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to.

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

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

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

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

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

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

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

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

***We are exposed to foreign exchange risk.***

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

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

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

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

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

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

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

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

Should attractive opportunities arise, we may acquire companies or technologies that facilitate our access to new medicines, research projects or geographical areas, or that enable us to achieve synergies with our existing operations. However, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions on favorable terms and could be led to finance these acquisitions using cash and marketable securities that could otherwise be allocated to other purposes in the context of our existing operations, or issuances of equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders and adversely affect the market price of our ADSs. If we acquire or enter into collaborations with businesses with promising markets or technologies, we may not be able to realize the benefits of such acquisitions or collaborations, including if we are unable to successfully integrate them with our existing operations and company culture, or if we encounter difficulties in developing, manufacturing and marketing any new products resulting from such acquisitions or collaborations. We cannot assure that we will achieve the expected synergies to justify any such transaction, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors' ability to realize on their investments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have experienced rapid growth over the last several years, and we anticipate further growth as our pipeline advances, and we move toward further commercialization of products. Since 2019 Genmab has grown from 548 employees to 1,660 at the end of 2022. In 2019 there were 12 ongoing clinical trials for Genmab proprietary products, which are those owned at least 50% by Genmab. By the end of 2022 this number had more than doubled to 25, including multiple Phase III trials. Such growth has put significant demands on our management and infrastructure, including new operational and financial systems, as well as extending manufacturing and commercial outsource arrangements. Our success will depend in part upon our ability to manage this growth effectively, including by maintaining our collaborative culture. As we continue to grow, we must continuously improve our operational, financial and management controls and our reporting systems and procedures. We must ensure that our policies and procedures evolve to reflect our dynamic operating model and implementation of financial systems. We must also continue to effectively retain existing employees and to attract, hire, train and retain new employees. Any failure to expand these areas and implement appropriate procedures and controls in an efficient manner and at a pace consistent with our business objectives could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

Our commercial success and viability depend in part on our and our collaboration partners' ability to obtain and maintain adequate intellectual property protection in the United States, Europe and other countries with respect to our existing products, product candidates and processes and related technologies owned by us and to successfully defend these rights against third party challenges, successfully enforce these rights to prevent third-party infringement, as well as our ability to maintain adequate intellectual property protection for any future technologies and products. If we or our collaboration partners do not adequately protect our intellectual property, competitors may be able to use our

technologies or products and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and significantly reduce our revenues and potential profits.

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

The patent position and other intellectual property rights of biopharmaceutical companies involve complex legal, administrative and factual questions, and the issuance, scope, validity and enforceability of patents cannot be predicted with certainty. Also, intellectual property rights have limitations and do not necessarily address all potential threats to our competitive advantage. Our and our collaboration partners' ability to obtain patent protection for our or their technologies, products and product candidates is uncertain and the degree of future protection afforded by such intellectual property rights is uncertain due to a number of factors, including, but not limited to:

- we or our collaboration partners may not have been the first to make or file patent applications for the inventions covered by pending patent applications or issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions and uses thereof;
- any or all of our or our collaboration partners' pending or any future patent applications may not result in issued patents;
- any patents issued to us or our collaboration partners may not provide a basis for commercially viable products, or may not provide any competitive advantages in countries of significant business opportunity;
- third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the U.S. Patent and Trademark Office (“USPTO”), or oppositions in the European Patent Office (“EPO”), or observations or protests, or any similar actions in other patent administrative or court proceedings worldwide that challenge the validity, enforceability or scope of such patents, which may result in our patent claims being narrowed or invalidated which could limit our ability to prevent competitors from developing and marketing similar products;
- our or our collaboration partners' technologies, compositions and methods may not be patentable;
- others may design around our or our collaboration partners' patent claims to produce competitive products or uses which fall outside of the scope of our patents;
- third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology;
- patent terms may be inadequate to protect our competitive position on our technologies, products and product candidates for an adequate amount of time;
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, or change the patent lifetime of, our or our collaboration partners' patents; and

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction

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

Even if patents do successfully issue and even if such patents cover our technologies, products, product candidates, compositions and methods of use, third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the USPTO, third-party oppositions in the EPO or observations or protests, or similar actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in our or our collaboration partners' patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products. Further, if we or our collaboration partners initiate legal proceedings against a third party to enforce a patent covering our product, product candidate or technology, the defendant could counterclaim that the patent covering our product, product candidate or technology is invalid or unenforceable. In patent litigation in the United States, certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products.

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

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

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

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

license rights to us. Even if we are able to obtain a license under third-party intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access the same technologies licensed to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

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

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

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

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

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

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

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

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

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

In addition to seeking patent protection for our products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaboration partners, consultants, advisors, vendors, university and/or institutional researchers and other third parties. We also have entered or seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and once disclosed we may lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties

by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable and may be inadequate. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

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

Obtaining and maintaining a patent portfolio entails significant expense and resources. Filing, prosecuting and defending patents on our technologies, products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and, therefore, we typically elect to seek protections in certain jurisdictions only. We may choose not to pursue or maintain protection for particular inventions, products or product candidates. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products in a manner that exploits our technologies and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States or in Europe, and thus such protection may not be sufficient to prevent or stop infringing activities.

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

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

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

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

#### **Risks Related to Government Regulation**

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

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

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

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

Moreover, increasing efforts by governmental and third-party payers in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products.

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

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

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

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

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

Within the European Union, once a marketing authorization is obtained, numerous post-approval requirements also apply. The requirements are promulgated by both EU regulations (such as reporting of adverse events, etc.) as well as national applicable regulations (related to, for example, prices and promotional material). In addition, as part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for

Human Use (“CHMP”), to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that target the treatment, prevention, or medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products. The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete non-clinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied.

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

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

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

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which, due to subsequent legislative amendments, will stay in effect through fiscal year 2031, with the exception of a temporary suspension from May 1, 2020 through March 30, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. The American Taxpayer Relief Act, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the U.S. government to recover overpayments to

providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on patients for our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

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

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

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

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

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

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

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

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

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

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

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

We are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials, and the cost of compliance is substantial. Our business activities involve the controlled storage, use and disposal of hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are

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

***We are subject to healthcare laws and regulations.***

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

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely continue to be time-consuming and costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, in which case we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could substantially disrupt our business. For more information about these and other applicable regulations, see "*Item 4 – Information on the Company – Government Regulation*" below.

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

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

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. If we, our collaboration partners or our

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

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

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

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

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

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

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

downgrades our securities, demand for ADSs could decrease, which could cause the price of the ADSs and their trading volume to decline.

***ADS holders do not directly hold our shares.***

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

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

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

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

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

Holders' ADSs, which will be evidenced by American depositary receipts ("ADRs"), are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of holders' ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to holders' right to cancel their ADSs and withdraw the underlying shares. Temporary delays in the cancellation of holders' ADSs and withdrawal of the underlying shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our shares. In addition, holders may not be able to cancel their ADSs and withdraw the underlying shares when the holders owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities. For more information, see the description of our securities registered under Section 12 of the Exchange Act included as an exhibit to this Annual Report on Form 20-F.

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

The deposit agreement governing the ADSs provides that the depository 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 depository'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 depository 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 depository 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 depository 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 depository. If a lawsuit is brought against us and/or the depository 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 depository of compliance with any substantive provision of, or a disclaimer of liability under, the U.S. federal securities laws and the rules and regulations promulgated thereunder.

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

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

The United States and Denmark currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a U.S. court, whether or not predicated solely upon U.S. securities laws, would not be enforceable in Denmark. In order to obtain a judgment that is enforceable in Denmark, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim again with a court of competent jurisdiction in Denmark. The Danish court will not be bound by the judgment by the U.S. court, but the

judgment may be submitted as evidence. It is up to the Danish court to assess the judgment by the U.S. court and decide if and to what extent the judgment should be followed. Danish courts are likely to deny claims for punitive damages and may grant a reduced amount of damages compared to U.S. courts.

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

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

We are a “foreign private issuer,” as defined in the SEC’s rules and regulations, and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our directors and senior management are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently publish annual and quarterly reports on our website pursuant to the rules of Nasdaq Copenhagen and expect to file such financial reports on an annual and quarterly basis with the SEC, we will not be required to file such reports with the SEC as frequently or as promptly as U.S. public companies and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K that a U.S. domestic company would be required to file under the Exchange Act. Accordingly, there may be less publicly available information concerning our company than there would be if we were not a foreign private issuer. In addition, as a foreign private issuer and as permitted by the listing requirements of the Nasdaq Stock Market LLC (“NASDAQ”), we will comply with certain home country corporate governance practices rather than the corporate governance requirements of the Nasdaq Stock Market.

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

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter and, accordingly, we could lose our foreign private issuer status in the future. Our foreign private issuer status will next be determined as of June 30, 2023.

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

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

A non-U.S. corporation will be a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes for any taxable year if either (i) at least 75% of its gross income for such taxable year is “passive income” (as defined in the relevant provisions of the U.S. Internal Revenue Code of 1986, as amended (“Code”)) or (ii) at least 50%

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, 2023 or in the foreseeable future. However, the determination of whether we are a PFIC or not according to the PFIC rules is made on an annual basis and will depend on the nature and composition of our income and assets and the value of our assets from time to time. Therefore, changes in the nature and composition of our income or assets or the value of our assets may cause us to become a PFIC. The determination of the value of our assets (including goodwill not reflected on our balance sheet) may be based, in part, on the total market value of our shares and ADSs, which is subject to change and may be volatile.

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

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

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

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

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

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. Danish, U.S., or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our subsidiaries pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate.

## **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.

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Our shares are listed on Nasdaq Copenhagen under the symbol “GMAB”. Our ADSs are listed on the 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](http://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 that our team will improve the lives of patients through innovative and differentiated 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 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. Our pipeline includes bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. We currently have nine proprietary product candidates, where we are responsible for at least 50% of development, in clinical development. Our most advanced products are tisotumab vedotin and epcoritamab. Tisotumab vedotin, marketed as Tivdak, is being 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. Epcoritamab is being developed in collaboration with AbbVie. In September 2022, we submitted a BLA for SC epcoritamab to the FDA, which was subsequently accepted with Priority Review in November 2022 with a target action date of May 21, 2023. In December 2022 we submitted a JNDA to the MHLW. AbbVie submitted an MAA to the EMA in October 2022, which was validated that same month. In addition to our marketed products and clinical product candidates, we have multiple in-house and partnered pre-clinical programs.

In addition to Genmab’s own pipeline of product candidates, our innovation and proprietary technology platforms are applied in the pipelines of global pharmaceutical and biotechnology companies. These companies are running clinical development programs with antibodies created by Genmab or created using Genmab’s proprietary DuoBody bispecific antibody technology platform. The programs run from Phase 1 development to approved medicines. The five approved medicines created by Genmab or that incorporate Genmab’s innovation are daratumumab, marketed by Janssen as DARZALEX (intravenous (“**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 non-small cell lung cancer (“**NSCLC**”) with epidermal growth factor receptor (“**EGFR**”) exon 20 insertion mutations; teclistamab, marketed in the U.S. and Europe as TECVAYLI for certain indications of MM; SC ofatumumab, marketed in the U.S., Europe, Japan and certain other territories as Kesimpta by Novartis for the treatment of relapsing multiple sclerosis (“**RMS**”); teprotumumab, marketed in the U.S. as TEPEZZA by Horizon for the treatment of thyroid eye disease (“**TED**”). In addition, in December 2022

and January 2023, Janssen submitted a BLA to the FDA and an MAA to the EMA, respectively, for an additional DuoBody-based product, talquetamab, for the treatment of relapsed or refractory (“R/R”) MM. Under the agreements for these products Genmab is entitled to certain potential milestones and royalties.

Our portfolio 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 collaborations 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 medicines or product candidates in development by Genmab or by collaborators who are leveraging Genmab’s innovation and technology.

### Genmab’s Proprietary<sup>1</sup> Products

All Genmab owned  $\geq 50\%$  medicines or product candidates in ongoing clinical development are included in the chart below.

#### Approved Medicine

Approved Product	Target	Developed By	Disease Indication
<b>Tivdak</b> (tisotumab vedotin-tftv)	Tissue factor (“TF”)	Co-development Genmab / Seagen	Adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy <sup>2</sup>

<sup>1</sup>Approved and investigational medicines where Genmab has  $\geq 50\%$  ownership, in co-development with partners as indicated.

<sup>2</sup> Refer to local country prescribing information for precise indication and safety information.

**Pipeline, Including Further Development for Approved Medicine**

Product	Target	Developed By	Disease Indications	Most Advanced Development Phase				
				Pre-clinical	1	1/2	2	3
Tisotumab vedotin	TF	Co-development Genmab / Seagen	Cervical cancer					
			Solid tumors					
Epcoritamab	CD3, CD20	Co-development Genmab / AbbVie	R/R diffuse large B-cell lymphoma ("DLBCL")					
			R/R follicular lymphoma ("FL") (combo)					
			B-cell non-Hodgkin lymphoma ("NHL")					
			B-cell NHL (combo)					
			R/R CLL Richter's Syndrome					
			Indolent NHL, pediatric patients					
DuoBody-PD-L1x4-1BB (GEN1046/BNT311)	PD-L1, 4-1BB	Co-development Genmab / BioNTech	NSCLC					
			Solid tumors					
DuoBody-CD40x4-1BB (GEN1042/BNT312)	CD40, 4-1BB	Co-development Genmab / BioNTech	Solid tumors					
DuoHexaBody-CD37 (GEN3009)	CD37	Genmab <sup>1</sup>	Hematologic malignancies					
HexaBody-CD38 (GEN3014)	CD38	Genmab <sup>2</sup>	Hematologic malignancies					
DuoBody-CD3xB7H4 (GEN1047)	CD3, B7H4	Genmab	Solid tumors					
HexaBody-CD27 (GEN1053/BNT313)	CD27	Co-development Genmab / BioNTech	Solid tumors					
GEN1056 (BNT322)	Undisclosed	Co-development Genmab / BioNTech	Solid tumors					

<sup>1</sup>In June 2022, AbbVie decided to discontinue co-development of DuoHexaBody-CD37. Upon expiry of the 180-day notice period on December 24, 2022, Genmab became solely responsible for the further development of DuoHexaBody-CD37 with low-single digit royalty payments payable by Genmab to AbbVie, up to an agreed maximum total royalty amount, based on future potential sales of the product (if any).

<sup>2</sup>Genmab is developing HexaBody-CD38 in an exclusive worldwide license and option agreement with Janssen.

**Programs Incorporating Genmab's Innovation and Technology<sup>1</sup>**

**Approved Medicines**

Approved Product	Discovered and/or Developed & Marketed By	Disease Indication(s)
<b>DARZALEX</b> (daratumumab) / <b>DARZALEX FASPRO</b> (daratumumab and hyaluronidase-fihj)	Janssen (Royalties to Genmab on net global sales)	MM <sup>2</sup> AL Amyloidosis <sup>2</sup>
<b>Kesimpta</b> (ofatumumab)	Novartis (Royalties to Genmab on net global sales)	RMS <sup>2</sup>
<b>TEPEZZA</b> (teprotumumab-trbw)	Horizon (under sublicense from Roche, royalties to Genmab on net global sales)	TED <sup>2</sup>
<b>RYBREVANT</b> (amivantamab / amivantamab-vmjw)	Janssen (Royalties to Genmab on net global sales)	NSCLC <sup>2</sup>
<b>TECVAYLI</b> (teclistamab / teclistamab-cqyv)	Janssen (Royalties to Genmab on net global sales)	R/R MM <sup>2</sup>

<sup>1</sup>Approved and investigational medicines created by Genmab or created by collaboration partners leveraging Genmab's DuoBody technology platform, under development and where relevant commercialized by a third-party.

<sup>2</sup>See local prescribing information for precise indication and safety information.

**Pipeline, Including Further Development for Approved Medicines, ≥ Phase II Development**

Product	Technology	Discovered and/or Developed By	Disease Indications	Most Advanced Development Phase				
				Pre-clinical	1	1/2	2	3
Daratumumab	UltiMab®	Janssen	MM	█	█	█	█	█
			AL Amyloidosis	█	█	█	█	█
Ofatumumab	UltiMab	Novartis	RMS	█	█	█	█	█
Teprotumumab	UltiMab	Horizon	TED	█	█	█	█	█
Amivantamab	DuoBody	Janssen	NSCLC	█	█	█	█	█
			Advanced or metastatic gastric or esophageal cancer	█	█	█	█	█
			Hepatocellular carcinoma	█	█	█	█	█
			Advanced or metastatic colorectal cancer	█	█	█	█	█
Teclistamab	DuoBody	Janssen	MM	█	█	█	█	█
Talquetamab (JNJ-64407564)	DuoBody	Janssen	R/R MM	█	█	█	█	█
Inclacumab	UltiMab	Global Blood Therapeutics	Vaso-occlusive crises in sickle cell disease	█	█	█	█	█
Mim8	DuoBody	Novo Nordisk	Hemophilia A	█	█	█	█	█
Camidanlumab tesirine (ADCT-301)	UltiMab	ADC Therapeutics	R/R Hodgkin lymphoma	█	█	█	█	█
PRV-015 (AMG 714)	UltiMab	Provention Bio	Celiac disease	█	█	█	█	█
Lu AF82422	UltiMab	Lundbeck	Multiple system atrophy	█	█	█	█	█

**Our Business Strategy**

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

- **Generate recurring revenue streams from collaborations.**
  - DARZALEX: Janssen is marketing daratumumab for the treatment of MM and AL amyloidosis. Janssen is also 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 marketing amivantamab for the treatment of NSCLC. Amivantamab is the first product created using Genmab’s proprietary DuoBody technology platform to receive regulatory approval.
  - TECVAYLI: Janssen is marketing teclistamab for the treatment of MM. Teclistamab is the second product creating using Genmab’s proprietary DuoBody technology platform to receive regulatory approval.
  - Kesimpta: Novartis is marketing ofatumumab for the treatment of RMS.

- TEPEZZA: Horizon is marketing teprotumumab for the treatment of 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 through selective collaborations.
- **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 collaborations and 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 collaborations and generating revenue. Multiple new product candidates are currently being developed by us and our collaboration partners using our technology platforms, including proprietary product candidates created with our DuoBody and HexaBody technologies. We actively seek collaboration 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 patients and our 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 is co-promoting Tivdak in the U.S. and will lead commercial operational activities in Japan. We have the potential for a second product on the market with epcoritamab, which is being co-developed by Genmab and AbbVie. In September 2022, we submitted a BLA for SC epcoritamab to the FDA, which was subsequently accepted with Priority Review in November 2022 with a target action date of May 21, 2023. In December 2022 we submitted a JNDA to the MHLW.

## Our Products and Product Candidates

### *Daratumumab (DARZALEX)*

Daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the United States and as DARZALEX SC in Europe for SC administration) is a human monoclonal antibody 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 plasma cells. Genmab used technology licensed from Medarex to generate the CD38 antibody. Daratumumab is being developed by Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, under an exclusive worldwide license from Genmab to develop, manufacture and commercialize daratumumab. Under the terms of the agreement, which we entered into in 2012, Genmab is entitled to double digit royalties between 12% and 20% with Janssen reducing such royalty payments for Genmab's share of Janssen's royalty payments made to Halozyne. Daratumumab is approved in a large number of territories for the treatment of adult patients with certain MM indications and is the only approved therapy in the U.S., Europe and Japan for the treatment of adult patients with AL amyloidosis.

#### *Development Status*

Beyond the current labeled indications, Janssen is conducting additional clinical trials for daratumumab, including multiple Phase III trials 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, including Janssen's DuoBody-based teclistamab and talquetamab. The majority of these Phase III trials 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 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 randomized, multicenter, open-label CENTAURUS (SMM2001) trial 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 trial 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 trials, 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) trial, 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 trial recruited patients ( $\geq 18$  y) who have had a confirmed diagnosis of SMM for  $\leq 5$  years, have factors indicating a high risk of progression, and have an Eastern Cooperative Oncology Group performance status of  $\leq 1$ , which refers to impact of the disease on the patient's daily living abilities. The primary endpoint is Progression-free Survival ("PFS") as assessed by an independent review committee. Secondary endpoints include time to biochemical or diagnostic ("SLiM-CRAB") progression, overall response rate ("ORR"), complete response rate ("CR"), 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 overall survival ("OS"). Disease will be evaluated per International Myeloma Working Group response criteria. The trial completed enrollment in May 2019.

##### 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) trial is evaluating the SC formulation of daratumumab in combination with bortezomib, lenalidomide and dexamethasone ("VRd") compared to VRd alone in approximately 690 participants with previously untreated MM. The primary endpoint of the trial is PFS from randomization to the date of disease progression or death. Secondary endpoints include minimal residual disease ("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-autologous stem cell transplantation ("ASCT"). The PERSEUS trial completed enrollment in November 2019.

The Phase III randomized, open-label AURIGA (MMY3021) trial is evaluating SC daratumumab in combination with lenalidomide as maintenance treatment in 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.

##### Daratumumab for Frontline Treatment for Non-Transplant Eligible Patients

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

The Phase III CEPHEUS (MMY3019) trial is evaluating the SC formulation of daratumumab in combination with bortezomib, lenalidomide and dexamethasone, or VRd, compared to VRd alone in patients with frontline MM for whom hematopoietic stem cell transplant is not planned as initial therapy. The primary endpoint of the trial is the percentage of participants with negative MRD status, measured after randomization and prior to progressive disease ("PD") or

subsequent anti-MM therapy. Secondary endpoints include PFS, CR, MRD-negativity rate at one year, ORR, very good partial response (“**VGPR**”), PFS on the next line of therapy, duration of response (“**DoR**”), health-related quality of life, pharmacokinetics, immunogenicity, and OS. The CEPHEUS trial completed enrollment in September 2019.

### ***Amivantamab***

In July 2012, Genmab entered into a collaboration with Janssen to create and develop bispecific antibodies using Genmab’s DuoBody technology platform. One of these, amivantamab, is a fully human bispecific antibody that targets EGFR and cMet, 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.

In 2021, Janssen received approvals in the U.S., Europe and other markets for amivantamab as RYBREVANT for the treatment of certain adult patients with NSCLC with EGFR exon 20 insertion mutations. These were 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 amivantamab.

### *Key Ongoing Trials in NSCLC*

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

The Phase III PAPHILLON trial is a randomized, open-label trial of the combination of amivantamab and carboplatin-pemetrexed therapy compared with carboplatin-pemetrexed alone in patients with EGFR exon 20 insertion mutated locally advanced or metastatic NSCLC.

The Phase III MARIPOSA trial is a randomized trial 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 Phase III MARIPOSA-2 trial is a randomized, open-label trial of amivantamab and lazertinib in combination with platinum-based chemotherapy compared with platinum-based chemotherapy alone in patients with EGFR-mutated locally advanced or metastatic NSCLC after osimertinib failure.

The Phase II PALOMA-2 trial is a non-randomized parallel cohort study of SC amivantamab in multiple regimens in patients with advanced or metastatic solid tumors including EGFR-mutated NSCLC.

The Phase III PALOMA-3 trial is an open-label randomized trial of lazertinib with SC amivantamab administered via manual injection compared with IV amivantamab or amivantamab SC on body delivery system in patients with EGFR-mutated advanced or metastatic NSCLC after progression on osimertinib and chemotherapy.

A Phase I/II open-label platform study to evaluate the safety and efficacy of multiple amivantamab-based therapeutic combinations in patients with advanced, unresectable lung cancer.

### *Additional Trials of Interest*

Phase Ib PALOMA trial to assess the safety and pharmacokinetics of the SC formulation of amivantamab in advanced solid malignancies.

Phase I/II open-label trial of amivantamab monotherapy and in addition to standard-of-care chemotherapy in patients with advanced or metastatic colorectal cancer.

Phase II open-label trial of amivantamab in patients with previously treated advanced or metastatic gastric or esophageal cancer.

Phase II open-label study is evaluating the safety, efficacy and pharmacokinetics of amivantamab monotherapy in patients with previously treated advanced hepatocellular carcinoma.

### ***Teclistamab***

In July 2012, Genmab entered into a collaboration with Janssen to create and develop bispecific antibodies using Genmab's DuoBody technology platform. One of the products subsequently created, discovered and developed by Janssen is teclistamab, a bispecific antibody that targets CD3, which is expressed on T-cells and B-cell maturation antigen (BCMA), which is expressed on mature B lymphocytes.

In August 2022, Janssen received conditional marketing authorization from the European Commission for subcutaneously administered teclistamab as TECVAYLI as monotherapy for the treatment of adult patients with relapsed and refractory MM. Patients must have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and a CD38 antibody and have demonstrated disease progression on the last therapy. In October 2022, Janssen received FDA approval of teclistamab for the treatment of adult patients with R/R MM, who previously received four or more prior lines of therapy, including a proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody. Teclistamab is the second therapy created using Genmab's proprietary DuoBody bispecific technology platform to receive regulatory approval. Under our agreement with Janssen, Genmab will receive milestones and a mid-single digit royalty on net sales of teclistamab.

### ***Key Ongoing Trials***

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

The Phase III MajesTEC-3 trial is a randomized trial comparing teclistamab in combination with SC daratumumab versus SC daratumumab, pomalidomide, and dexamethasone or SC daratumumab, bortezomib, and dexamethasone in patients with R/R MM.

The Phase III MajesTEC-4 trial is a trial of teclistamab in combination with lenalidomide versus lenalidomide alone in participants with newly diagnosed MM as maintenance therapy following autologous stem cell transplantation.

The Phase III MajesTEC-7 trial is comparing teclistamab in combination with SC daratumumab and lenalidomide versus SC daratumumab, lenalidomide, and dexamethasone in patients with newly diagnosed MM who are either ineligible or not intended for autologous stem cell transplant as initial therapy.

The Phase III MajesTEC-9 trial is a randomized trial comparing teclistamab monotherapy versus pomalidomide, bortezomib, dexamethasone or carfilzomib, dexamethasone in patients with R/R MM who have received 1 to 3 prior lines of therapy, including an anti-CD38 monoclonal antibody and lenalidomide.

### ***Additional Trials of Interest***

Phase Ib RedirecTT-1 trial is a dose escalation trial of daratumumab, talquetamab and teclistamab in patients with R/R MM.

Phase Ib TRIMM-3 trial is a dose escalation trial of teclistamab or talquetamab in combination with a PD-1 inhibitor for the treatment of patients with R/R MM.

### ***Ofatumumab***

Ofatumumab is a human monoclonal antibody that targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops. Genmab used technology licensed from Medarex to generate the CD20 antibody.

Ofatumumab, marketed as Kesimpta, is approved in territories including the U.S., Europe and Japan for the treatment of certain adult patients with RMS. Ofatumumab is the first B-cell therapy that can be self-administered by patients at home or anywhere using the Sensoready autoinjector pen, once monthly after starting therapy. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis. Under the terms of the agreement, Genmab is entitled to 10% royalties on net sales of ofatumumab.

#### *Key Ongoing Trials*

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

The Phase III OLIKOS trial is a single arm trial evaluating the continued efficacy, safety and tolerability of ofatumumab in patients with RMS who are transitioning from a CD20 monoclonal antibody therapy.

The Phase III ALITHIOS trial is evaluating the long-term safety, tolerability and effectiveness of ofatumumab in patients with RMS. The purpose of this trial is to collect long-term safety, tolerability, effectiveness and health outcomes data in eligible subjects who have participated in a Novartis ofatumumab clinical MS trial.

The Phase III ARTIOS trial is an open-label trial 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 Phase III STHENOS trial is an open-label, rater-blind randomized multi-center parallel-arm active-comparator trial 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 Phase III NEOS trial is a two-year, randomized, three-arm, double-blind, non-inferiority trial comparing the efficacy and safety of ofatumumab and Siponimod versus fingolimod in pediatric patients with MS followed by an open-label extension.

#### ***Teprotumumab***

Teprotumumab, approved by the U.S. FDA under the trade name TEPEZZA, is a human monoclonal antibody that targets the Insulin-like Growth Factor 1 Receptor (“**IGF-1R**”), a well-validated target. Genmab used technology licensed from Medarex to generate the IGF-1R antibody. 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 sublicense from Roche. Under the terms of Genmab's agreement with Roche, Genmab will receive mid-single digit royalties on net sales of teprotumumab.

### ***Tisotumab Vedotin***

Tisotumab vedotin is an ADC created to 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. We used technology licensed from Medarex to generate the TF antibody forming part of tisotumab vedotin. 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.

#### *Tisotumab vedotin for the Treatment of Cervical Cancer*

SEER estimated that 14,100 women would be diagnosed with cervical cancer in the United States in 2022, and that 4,280 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 17.1% and 19.5%, respectively.

In September 2021 the FDA granted Genmab and Seagen accelerated approval for tisotumab vedotin as 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. Tisotumab vedotin 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 trial 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. Favorable topline results from the innovaTV 204 trial 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 emergent adverse events ("TEAEs") (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 of that year. In January 2023, the National Comprehensive Cancer Network ("NCCN") updated their cervical cancer treatment guidelines, upgrading tisotumab vedotin-tftv from "Other recommended Regimen" to "Preferred Regimen" for second-line or subsequent therapy in recurrent or metastatic cervical cancer.

#### *Ongoing Trials*

In collaboration with Seagen, we are currently evaluating tisotumab vedotin for the treatment of cervical cancer and other solid tumors in three clinical trials: innovaTV 205, innovaTV 207 and innovaTV 301.

innovaTV 205 is a Phase I/II trial of tisotumab vedotin as monotherapy or in combination with other therapies in subjects with recurrent or stage IVB cervical cancer. Interim data of tisotumab vedotin in combination with pembrolizumab in patients with recurrent or metastatic cervical cancer who have not received prior systemic therapy was presented in an oral session at the American Society of Clinical Oncology 2022 Annual Meeting in June 2022. The trial 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. The innovaTV 207 trial is a Phase II trial to assess the activity, safety and tolerability of tisotumab vedotin for the treatment of selected solid tumors. Preliminary data from the squamous cell carcinoma of the head and neck cohort of the trial was presented at the American Society

for Radiation Oncology (“ASTRO”) 2022 Multidisciplinary Head and Neck Cancers Symposium in February 2022. The trial is currently recruiting.

The first Phase III trial of tisotumab vedotin, innovaTV 301, was announced in January 2021. The open-label, randomized, global trial of tisotumab vedotin versus chemotherapy is enrolling 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 are randomized to receive either tisotumab vedotin 2.0 mg/kg every three weeks or investigator’s choice of chemotherapy. The primary endpoint of the trial is OS. This global trial is sponsored by Seagen in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups and the Gynecologic Oncology Group. The trial is designed to confirm the potential of tisotumab vedotin as monotherapy for patients with metastatic and/or recurrent cervical cancer. The trial 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, DLBCL, FL and mantle cell lymphoma (“MCL”). We used technology licensed from Medarex to generate the CD20 antibody forming part of epcoritamab. 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. In March 2022, the FDA granted orphan-drug designation to epcoritamab for the treatment of FL. 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 64.6%, based on 2012-2018 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 R/R DLBCL patients is poor, especially for those with high-risk factors, and for most patients with refractory DLBCL there are no curative treatment options.

In September 2022 and December 2022, respectively, Genmab submitted a BLA to the FDA and an JNDA to the MHLW for SC epcoritamab for the treatment of patients with R/R large B-cell lymphoma (“LBCL”) after two or more lines of systemic therapy. In October 2022 AbbVie submitted an MAA to the EMA for SC epcoritamab for the treatment of patients with R/R DLBCL after two or more lines of systemic therapy. The EMA validated for review the MAA in October 2022 and in November 2022 the FDA accepted for Priority Review the BLA with a target action date of May 21, 2023. The submissions were supported by results from the LBCL cohort of the pivotal Phase II EPCORE NHL-1 open-label, multi-center trial evaluating the safety and preliminary efficacy of epcoritamab in patients with relapsed, progressive or refractory CD20+ mature B-NHL, including DLBCL. Data from this trial was presented as part of a late-breaking oral presentation selected for the Presidential Symposium at the European Hematology Association Annual Congress in June 2022. In the trial, treatment with epcoritamab demonstrated deep and durable responses with an ORR of 63% and a CR of 39% in patients who had previously received at least two prior lines of systemic anti-lymphoma therapy. Additionally, patients naïve to treatment with chimeric antigen receptor (“CAR”) T-cell therapy achieved 69% ORR and 42% CR and patients previously treated with CAR T achieved a 54% ORR and 34% CR. After a median follow up of 10.7 months, the median duration of response (“mDOR”) was estimated to be 12 months, while the mDOR among patients achieving a CR was not reached, with 89% still in CR at nine months. The safety profile of epcoritamab was manageable and consistent with previous findings. The TEAEs occurred during the first 12 weeks of treatment and resolved. The most common TEAEs of any grade (greater than or equal to 15%) included cytokine release syndrome (CRS) (49.7%), pyrexia (23.6%), fatigue (22.9%), neutropenia (21.7%), diarrhea (20.4%), injection site reaction (19.7%), nausea (19.7%), and anemia (17.8%). The most common Grade 3 or 4 TEAEs (greater than or equal to 5%) included neutropenia (14.6%), anemia (10.2%), neutrophil count decrease (6.4%), and thrombocytopenia (5.7%). The observed Grade 3 CRS was low (2.5%). No Grade 4/5 CRS was observed.

### *Ongoing Trials*

Along with our collaboration partner, AbbVie, we are currently evaluating SC epcoritamab for the treatment of B-cell malignancies including DLBCL, FL and CLL in multiple clinical trials. Additional trials, including Phase III trials, are expected. In addition to EPCORE NHL-1 as described above, ongoing and announced trials include:

EPCORE NHL-2 is a Phase Ib/II open-label trial to assess the safety and preliminary efficacy of epcoritamab in combination with other agents in patients with B-cell NHL. The trial is currently recruiting.

EPCORE NHL-3 is a Phase I/II trial to evaluate the safety and preliminary efficacy of epcoritamab in Japanese patients with R/R B-cell NHL. The trial is currently recruiting.

EPCORE NHL-4 is a Phase Ib/II open-label trial to evaluate the safety and preliminary efficacy of epcoritamab as monotherapy or combined with standard of care therapies in Chinese patients with B-cell NHL. The trial is currently recruiting.

EPCORE NHL-5 is a Phase Ib/II open-label trial to evaluate the safety and tolerability of epcoritamab in combination with anti-neoplastic agents in patients with NHL. The trial is currently recruiting.

EPCORE NHL-6 is a Phase II open-label trial to evaluate the safety of epcoritamab monotherapy in subjects with R/R DLBCL and FL grade 1-3a when administered in the outpatient setting. The trial is currently recruiting.

EPCORE DLBCL-1 was the first Phase III trial 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 R/R DLBCL who have failed or are ineligible for ASCT. The trial is currently recruiting.

A new Phase III trial, EPCORE DLBCL-2, will be a randomized, open-label trial to evaluate the safety and efficacy of epcoritamab in combination with rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (“**R-CHOP**”) compared to R-CHOP in patients with newly diagnosed DLBCL. The trial is currently recruiting.

A new Phase II trial, EPCORE DLBCL-3, will be an open-label, multicenter, global trial evaluating the efficacy and safety of epcoritamab monotherapy and epcoritamab plus lenalidomide as first-line therapy for elderly patients with DLBCL who are deemed anthracycline ineligible. The trial is anticipated to start in February 2023.

EPCORE FL-1 is a Phase III, open-label trial to evaluate the safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (“**R2**”) compared to R2 in patients with R/R FL. The trial is currently recruiting.

EPCORE CLL-1, is a Phase I/II open-label, multi-center safety and efficacy trial of epcoritamab in R/R CLL and Richter’s Syndrome. The trial includes two parts, a dose escalation Phase (Phase Ib) and an expansion Phase (Phase II). Preliminary results in Richter’s Syndrome were presented at The American Society of Hematology (“**ASH**”) Annual Meeting in December 2022. The trial is currently recruiting.

EPCORE Peds-1 is a single arm, open-label Phase Ib trial of epcoritamab in pediatric patients with R/R aggressive mature B-cell neoplasms. The trial is currently recruiting.

An expanded access program for eligible patients is also available. This program is designed to provide access to epcoritamab prior to approval by the local regulatory agency. Availability will depend on territory eligibility. A medical doctor must decide whether the potential benefit outweighs the risk of receiving an investigational therapy based on the individual patient's medical history and program eligibility criteria.

### ***DuoBody-PD-L1x4-1BB (GEN1046/BNT311)***

DuoBody-PD-L1x4-1BB is a proprietary bispecific antibody designed to target PD-L1 and 4-1BB. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the tumor necrosis factor (“TNF”) receptor super-family and is expressed predominantly on activated T-cells. In pre-clinical 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. Pre-clinical trials 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 trial 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 anticipated enrollment for this trial is 752 patients and the trial is currently recruiting. A Phase II trial of DuoBody-PD-L1x4-1BB was initiated in November 2021. The multicenter, randomized, open-label trial is evaluating DuoBody-PD-L1x4-1BB as monotherapy and in combination with pembrolizumab as treatment for patients with R/R metastatic NSCLC after treatment with standard of care therapy with an immune checkpoint inhibitor. The trial is currently recruiting.

### ***DuoBody-CD40x4-1BB (GEN1042/BNT312)***

DuoBody-CD40x4-1BB is a proprietary bispecific antibody designed to conditionally activate both CD40-expressing antigen-presenting cells and 4-1BB-expressing T-cells using an inert DuoBody format. In pre-clinical settings, as presented at the 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 trial 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 trial was updated to include multiple expansion cohorts in combination and in additional indications. These include: in combination with pembrolizumab in first-line NSCLC, in first-line head and neck squamous cell carcinoma (“HNSCC”), in first-line melanoma, in combination with pembrolizumab and chemotherapy in first-line HNSCC, and in first-line pancreatic ductal adenocarcinoma. Safety and preliminary anti-tumor activity data in HNSCC patients treated with chemotherapy, pembrolizumab and DuoBody-CD40x4-1BB was presented at the European Society for Medical Oncology Immuno-Oncology Annual Congress in December 2022. The trial is currently recruiting. A Phase I/II randomized, open-label trial to evaluate the safety and clinical activity of DuoBody-CD40x4-1BB in combination with radiotherapy with or without pembrolizumab was announced in August 2022 and is not yet recruiting.

### **HexaBody-CD27 (GEN1053/BNT313)**

HexaBody-CD27 is a novel CD27 antibody with an IgG Fc domain engineered to induce CD27 agonist activity independently of FcγR-bearing cells. As presented at the Society for Immunotherapy of Cancer 37<sup>th</sup> Annual Meeting in November 2022, in pre-clinical trials *in vitro* and *in vivo*, HexaBody-CD27 increased T-cell activation, proliferation, cytokine secretion, and cytotoxic activity.

We are developing HexaBody-CD27 for the treatment of solid cancers in collaboration with BioNTech, using Genmab's proprietary HexaBody technology platform. In May 2022, the IND application and first CTA were submitted for HexaBody-CD27. The first patient was dosed in the first-in-human Phase I/II trial of HexaBody-CD27 for the treatment of patients with malignant solid tumors in November 2022. The trial is currently recruiting.

### **GEN1056 (BNT322)**

GEN1056 is an antibody product being co-developed by Genmab and BioNTech for the treatment of solid tumors and for use in combination with other products. The first CTA was submitted for GEN1056 in July 2022. A first-in-human Phase I trial of GEN1056 in patients with advanced solid tumors was initiated in November 2022.

### **DuoHexaBody-CD37 (GEN3009)**

DuoHexaBody-CD37 is a bispecific IgG1, created with our proprietary 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 complement-dependent cytotoxicity ("CDC") activity. CDC is an efficient effector mechanism employed by multiple existing antibody therapeutics. In pre-clinical 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 pre-clinical 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 trial investigating DuoHexaBody-CD37 in combination with epcoritamab. The trial is currently recruiting. In June 2022 AbbVie decided to discontinue co-development of DuoHexaBody-CD37. Upon expiry of the 180-day notice period on December 24, 2022, Genmab became solely responsible for the further development of DuoHexaBody-CD37, with low-single digit royalty payments payable by Genmab to AbbVie, up to an agreed maximum total royalty amount, based on future sales of the product, if any.

### **HexaBody-CD38 (GEN3014)**

HexaBody-CD38 is a novel human CD38 monoclonal antibody product incorporating our HexaBody technology. In pre-clinical 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 R/R 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. Preliminary dose-escalation results from the trial were presented at the ASH Annual Meeting in December 2022. Dose-escalation results show HexaBody-CD38 had a tolerable safety profile and clinical activity in patients with R/R MM, including patients with prior exposure to an anti-CD38 antibody. The pharmacokinetic profile was characterized by target-mediated drug disposition at lower doses and signs of saturation at doses >8 mg/kg. Biomarker analyses confirm biological activity in patients with R/R MM at all evaluated doses. The trial is currently recruiting. As of December 2022, this study includes an arm comparing HexaBody-CD38 to daratumumab in anti-CD38 monoclonal antibody-naïve R/R MM patients.

#### ***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 pre-clinical presentation of DuoBody-CD3xB7H4 was made at the SITC Annual Meeting in November 2021. In pre-clinical trials, 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 trial is currently recruiting.

#### ***Partnered Candidates***

Our collaboration partners currently have multiple product candidates in clinical development through collaboration agreements with us. These include three bispecific antibodies being developed by Janssen using our proprietary DuoBody technology, which are being tested to treat NSCLC, other solid tumors and certain MM indications. Additional products are being developed in collaboration with Bristol-Myers Squibb (“BMS”), ADC Therapeutics, Lundbeck, Provention Bio, Global Blood Therapeutics (now owned by Pfizer) and Novo Nordisk.

#### **Our Technology Platforms**

##### ***DuoBody Platform***

The DuoBody platform is our innovative proprietary platform for the discovery 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). 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 therapeutics for diseases such as 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 allows 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 that is 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 collaboration partners interested in developing antibody therapeutics using our DuoBody technology. We have a number of commercial collaboration partners for the DuoBody technology, including Janssen, BioNTech, AbbVie and Novo Nordisk. See “Item 4.B—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 collaboration, including amivantamab, which has been approved in the U.S., Europe and certain other markets,

teclistamab, which has been approved in the U.S. and Europe, and talquetamab, for which Janssen submitted a BLA to the FDA in December 2022 and an MAA to the EMA in January 2023.

### ***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.

Our current HexaBody-based products in clinical development are HexaBody-CD38, for which we entered into an exclusive license and option agreement with Janssen, and HexaBody-CD27, which we are co-developing with BioNTech. The IND for HexaBody-CD38 was submitted to the FDA in October 2020 and the first patient was dosed with HexaBody-CD38 in March 2021. The IND for HexaBody-CD27 was submitted in May 2022 and the first patient was dosed with HexaBody-CD27 in November 2022.

### ***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 collaboration partners or CMOs to supply drug product for our IND-enabling trials, clinical trials and process validation batches and related activities for BLA and other regulatory submissions, and we expect to rely on such collaboration 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 approved products in development with collaboration partners, DARZALEX, RYBREVANT and TECVAYLI, which are handled by Janssen; Kesimpta, handled by Novartis; and TEPEZZA, handled by Horizon, under the applicable agreements. Our partners Seagen and

AbbVie are responsible for the manufacturing processes for tisotumab vedotin and epcoritamab, respectively, under the applicable agreements.

Currently, the majority of the drug products required for our clinical trials and pre-clinical trials 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 pre-clinical trials. We also believe that, while limited, there are alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of commercial products and drug products for our planned clinical trials and pre-clinical trials. However, should our CMOs not be able to provide sufficient quantities of commercial products or drug product for our planned commercialization, clinical trials or pre-clinical trials, 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 approved products in development with collaboration partners are DARZALEX, RYBREVANT and TECVAYLI 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, TECVAYLI, Kesimpta and TEPEZZA, but we are not involved with commercialization activities or strategy.

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 patients and shareholders. Genmab became a commercial-stage company to support the launch of Tivdak for the treatment of cervical cancer. In October 2020, Genmab and Seagen entered into a joint commercialization agreement. Pursuant to this agreement, Genmab is co-promoting 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, which requires our own commercial infrastructure in these territories. We will receive tiered royalties between 22% and 26% on remaining global net sales. For 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. In June 2022 AbbVie decided to discontinue co-development of DuoHexaBody-CD37. Upon expiry of the 180-day notice period on December 24, 2022, Genmab became solely responsible for the further development of DuoHexaBody-CD37 with low-single digit royalty payments payable by Genmab to AbbVie, up to an agreed maximum total royalty amount, based on future sales of the product, if any.

Moving forward, we may choose to commercialize new products independently, or we may rely on our collaboration 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 collaboration 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, pre-clinical trials, 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 of their products. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development collaboration 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<sup>®</sup>, proteasome inhibitors ("PIs") such as Janssen and Takeda Pharmaceutical Company Limited ("Takeda")'s Velcade<sup>®</sup>, Amgen Inc. ("Amgen")'s Kyprolis<sup>®</sup>, and Takeda's Ninlaro<sup>®</sup>, histone deacetylase inhibitors such as Novartis' Farydak<sup>®</sup> and mAbs such as BMS' Emticiti<sup>®</sup>. 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 European Commission 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. CAR-Ts have also been approved for use in MM including BMS's and 2seventybio's ABECMA<sup>®</sup> and Janssen's CARVYKTI<sup>™</sup>. 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 has 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 European Commission approved SC ofatumumab for the treatment of RMS in adults. Competition in the multiple sclerosis market is intense. There are numerous FDA-approved drugs for the treatment of the various forms of MS, including Biogen Inc. ("Biogen")'s Tecfidera<sup>®</sup>, Novartis' GILENYA<sup>®</sup>, Sanofi's AUBAGIO<sup>®</sup>, BMS's ZEPOSIA<sup>®</sup>, Novartis's MAYZENT<sup>®</sup> and several monoclonal antibodies such as Genentech Inc.'s OCREVUS<sup>®</sup> (a CD20 antibody), Sanofi's LEMTRADA<sup>®</sup> and Biogen's TYSABRI<sup>®</sup>; glatiramer acetate-based therapies such as Teva Pharmaceutical Industries Limited's COPAXONE<sup>®</sup> and Sandoz's Glatopa<sup>®</sup>; and interferon-beta-based therapies such as Biogen's AVONEX<sup>®</sup> and PLEGRIDY<sup>®</sup>, Bayer AG's BETASERON<sup>®</sup>/Betaferon<sup>®</sup>, Novartis' EXTAVIA<sup>®</sup>, and Merck KGaA ("Merck")'s Rebif<sup>®</sup>. A number of companies are also working to develop additional potential treatments for multiple sclerosis that may in the future further intensify the competition in the multiple sclerosis market, such as TG Therapeutics' BRIUMVI<sup>™</sup>, approved in December 2022.

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 $\geq$ 1), as determined by an FDA-approved test. Keytruda was subsequently approved in this indication in Europe in April 2022.

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: Regeneron Pharmaceuticals's odronextamab, which was granted fast track designation by the FDA in R/R LBCL and DLBCL and from Roche: mosunetuzumab, which has BTD and which received conditional marketing authorization as Lunsumio<sup>®</sup> in Europe in third line plus FL in June 2022 and accelerated approval in the U.S. in December 2022, and glofitamab, which Roche filed for approval in both the U.S. and in Europe in 2022. 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. Some of these include ADC Therapeutics' ZYNLONTA<sup>®</sup>, approved by the FDA in April 2021 for R/R LBCL and approved in Europe in December 2022, MorphoSys AG's Monjuvi<sup>®</sup>, approved by the FDA in combination with lenalidomide in July 2020 in R/R DLBCL and two CAR-T therapies, Novartis's KYMRIAH<sup>®</sup> approved in the U.S. and EU in R/R FL in May 2022, BMS's Breyanzi<sup>®</sup>, approved in the U.S. in June 2022 for R/R LBCL and Gilead Sciences, Inc. ("Gilead")'s YESCARTA<sup>®</sup> approved in the U.S. in second line LBCL in April 2022 and second line DLBCL in Europe in October 2022. In addition, in June 2019 Roche received accelerated approval in the U.S. for POLIVY<sup>®</sup>, 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. The data was submitted to the FDA in 2022 with a target action date of April 2, 2023.

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 N.V. and Incyte Corporation's MCLA-145, Elpiscience and Inhibrx Inc.'s INBRX-105, Numab Therapeutics AG and Cstone Pharmaceuticals' NM21-1480, Pieris Pharmaceuticals, Inc.'s PRS-344, F-Star Therapeutics Inc.'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 collaboration partners may develop compounds utilizing our technology that may compete with product candidates that we are developing.

In addition, in the United States, the 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. 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 of a BLA for an innovator's biological product to support the biosimilar product's

approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. We are aware of many pharmaceutical and biotechnology 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, such as 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, 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, 2022, 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 Genmab-owned 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 a binding arbitration of two matters arising under its license agreement with Janssen relating to daratumumab. Under the license agreement, Genmab is, among other things, entitled to royalties from Janssen on net sales of daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the U.S. and as DARZALEX SC in Europe for SC administration). In April 2022, the arbitral tribunal issued an award in the binding arbitration of the two matters. Genmab did not seek a review of the award, and the award is now final. The first matter concerned the question as to whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement. As to that matter, the tribunal determined by majority opinion that Janssen's obligation to pay royalties to Genmab on sales of licensed product, in each applicable country, extends through the expiration or invalidation of the last-to-expire relevant Genmab-owned patent covering the product or use thereof, but not the relevant Janssen-owned patent. The relevant Genmab-owned issued U.S., European and Japanese patents will expire in the late 2020s and early 2030s. The second matter concerned the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for the Halozyme enzyme technology used in the SC formulation of daratumumab (marketed as DARZALEX *FASPRO* in the U.S.). The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SC daratumumab sales. As to that matter, the tribunal ruled by majority opinion that Janssen is permitted to continue reducing its royalty payments to Genmab as an offset against a share of Janssen's royalty payments made to Halozyme. On June 9, 2022, Genmab announced the commencement of a second arbitration under the daratumumab license agreement with Janssen. This second arbitration follows from the award in the prior arbitration, where the tribunal ruled in favor of Janssen on the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for its technology used in the daratumumab SC product. The tribunal based its ruling on

the finding that DARZALEX *FASPRO* constitutes a new licensed product under the license agreement. In this second arbitration, Genmab is consequently seeking an award of \$405 million plus interest in accrued milestone payments for DARZALEX *FASPRO* and a declaration that it is entitled to a new 13-year royalty term from the date of DARZALEX *FASPRO*'s first commercial sale.

*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 an 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 ofatumumab, marketed as 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 European Commission 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 TED, 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 sales of TEPEZZA. In December 2022, Horizon announced that it would be acquired by Amgen.

*Janssen DuoBody Collaboration (Amivantamab and Teclistamab)*

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. 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. Genmab will be entitled to a mid-single digit royalty on net sales

of any commercialized products with the exception of amivantamab. Genmab will receive milestones and royalties between 8% and 10% on net sales of amivantamab. 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. Of these, amivantamab and teclistamab are the first products created using the DuoBody technology platform to receive regulatory approval.

In May 2021, Janssen received approval from the FDA for amivantamab, marketed as RYBREVENT, 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. Amivantamab has also been approved in the EU and other markets.

In August 2022, Janssen received conditional marketing authorization from the European Commission for subcutaneously administered teclistamab, marketed as TECVAYLI, as monotherapy for the treatment of adult patients with relapsed and refractory MM. Patients must have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In October 2022, Janssen received FDA approval of teclistamab for the treatment of adult patients with R/R MM, who previously received four or more prior lines of therapy, including a proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody.

### ***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, epcoritamab (DuoBody-CD3xCD20), DuoHexaBody-CD37 and DuoBody-CD3x5T4. In addition, under the agreement, we agreed with AbbVie to enter into a discovery research collaboration for future differentiated antibody therapeutics for cancer.

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 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 (DKK 4,911 million) upfront payment in June 2020 and we were initially 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 were 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, DuoBody-CD3x5T4, was subsequently stopped and another, DuoHexaBody-CD37, now being solely developed by us.

As a result of one program being stopped and another now being solely developed by us, we are instead contractually entitled to receive an aggregate of up to \$2.55 billion in additional development, regulatory and sales milestone payments for all programs and up to \$550 million in payments related to clinical development and commercial success for the one remaining bispecific antibody program, epcoritamab, included in the original agreement. In addition, and also included in these potential milestones, if all four next-generation antibody product candidates developed as a

result of the discovery research collaboration are successful, we are eligible to receive up to \$2.0 billion in option exercise and success-based milestones. 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. We and AbbVie split 50:50 the development costs related to epcoritamab, while we will be responsible for 100% of the costs for DuoHexaBody-CD37 and the discovery research programs up to opt-in.

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. In June 2022 AbbVie decided to discontinue co-development of DuoHexaBody-CD37. Upon expiry of the 180-day notice period on December 24, 2022, Genmab became solely responsible for the further development of DuoHexaBody-CD37, with low-single digit royalty payments payable by Genmab to AbbVie, up to an agreed maximum total royalty amount, based on future sales of the product, if any.

#### *Seagen Tisotumab Vedotin Collaboration*

In October 2011, we entered into a license and collaboration agreement with Seagen that granted us rights 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 is co-promoting tisotumab vedotin, marketed as Tivdak, 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. In September 2022 Seagen and Zai Lab announced an exclusive collaboration and license agreement for the development and commercialization of Tivdak in mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, Seagen received an upfront payment of \$30 million and will receive development, regulatory and commercial milestone payments, as well as tiered royalties on net sales of Tivdak in the Zai Lab territory. Based on our agreement with Seagen, all upfront, milestone payments and royalties have been and will continue to be shared 50:50 with Genmab.

#### *BioNTech 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 proprietary antibodies and 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 expenses 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.

In July 2022, we expanded this collaboration. Under the expansion, the companies will jointly develop and commercialize, subject to regulatory approval, monospecific antibodies leveraging Genmab's proprietary HexaBody technology platform.

Genmab and BioNTech have four product candidates currently in clinical development: DuoBody-PD-L1x4-1BB, DuoBody-CD40x4-1BB, HexaBody-CD27 and GEN1056.

### ***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 collaboration 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 trials, 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% to 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.

### *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, and CureVac AG (“**CureVac**”) 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 enter into certain agreements where Genmab is obligated to make upfront cash payments and milestone payments to third parties upon the achievement of certain development, regulatory and commercial events as well as obligated to pay royalties on net sales of commercialized products.

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 collaboration 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 of 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.

### **Intellectual Property**

#### *Patents*

As of December 31, 2022, we held more than 2,450 patents and patent applications, including more than 74 issued U.S. patents and more than 135 U.S. patent applications. All of our current issued patents and patent applications are projected to expire between 2023 and 2043.

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 ADCs, 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 collaboration 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 collaboration 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 collaboration 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, we have patent term extensions (“**PTE**”) and supplementary protection certificates (“**SPC**”) covering the composition of matter for daratumumab which provide protection beyond 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 June 2031. 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 “Genmab’s Proprietary Products” 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, PTE and SPC 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 collaboration 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 collaboration partners. Our or our collaboration 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 collaboration partners. Our collaboration partners’ patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our collaboration 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 collaboration 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 collaboration partners. Our and our collaboration partners' challenges to patents of other organizations may not be successful, which may affect our and our collaboration partners' ability to commercialize daratumumab, ofatumumab, tisotumab vedotin, amivantamab, teclistamab 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 collaboration partners' ability to make, use or sell daratumumab, ofatumumab, tisotumab vedotin, amivantamab, teclistamab, teprotumumab or any other products or product candidates.

### ***Trademarks***

As of January 3, 2023, we and/or our subsidiaries own approximately 311 trademark registrations and applications, hereof 14 U.S. trademark registrations, including: Genmab<sup>®</sup>; the Y-shaped Genmab logo<sup>®</sup>; Genmab in combination with the Y-shaped Genmab logo<sup>®</sup>; KYSO<sup>™</sup>; HuMax<sup>®</sup>; DuoBody<sup>®</sup>; DuoBody in combination with the DuoBody logo<sup>®</sup>; HexaBody<sup>®</sup>; HexaBody in combination with the HexaBody logo<sup>®</sup>; DuoHexaBody<sup>®</sup> and HexElect<sup>®</sup>. Tivdak<sup>®</sup> is a trademark of Seagen Inc. EPCORE<sup>™</sup> is a trademark of AbbVie Biotechnology Ltd. Arzerra<sup>®</sup> is a trademark of Novartis Pharma AG. Kesimpta<sup>®</sup> is a trademark of Novartis Pharma AG or its affiliates. DARZALEX<sup>®</sup>, DARZALEX FASPRO<sup>®</sup> RYBREVANT<sup>®</sup> and TECVAYLI<sup>®</sup> are trademarks of Johnson & Johnson. TEPEZZA<sup>®</sup> 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 collaboration 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 collaboration partners may not sufficiently protect our confidential information, or third parties may independently develop equivalent information.

### ***Government Regulation***

The FDA, the EMA, the Pharmaceuticals and Medical Devices Agency (“PMDA”) 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 collaboration partners and third-party contractors, are required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct trials 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, European Union and the United Kingdom (following Brexit). While the regulatory process in many countries is similar to the United States, European Union or the United Kingdom, 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 pre-clinical laboratory tests and animal trials 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 collaboration 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 trials. The IND also includes results of animal and *in vitro* trials 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 trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, 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 trial 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 trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or data monitoring committee, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for patients or on other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial 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 trials 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 trials. Some of the Phase II trials 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 trials may be made a condition to approval of the BLA.

Concurrent with clinical trials, companies may complete additional animal trials 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 include 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 trials 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 trials 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 pre-clinical and clinical trials, 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 trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including trials 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 cGCPs. 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 collaboration 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 the 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 trials 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 trials.

### ***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 trials or completion of ongoing trials, including the start of a confirmatory Phase III trial, 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. 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 a

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 collaboration 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 collaboration 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 collaboration 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 CMOs 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 the 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 trials or clinical trials 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 trials;
- 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.

### ***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”). 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 trial, if the trial meets both the requirements of the IDE regulations and the IND regulations.

In the EU, *in vitro* devices are subject to the In Vitro Device Regulation (“IVDR”), which is directly applicable in all EEA member states. The IVDR, among other things, subjects the marketing and sale of applicable medical devices to stricter requirements, including in the areas of clinical evaluation requirements, quality systems and post-market surveillance; introduces a new classification system for companion diagnostics; and sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU. While the IVDR became effective on May 26, 2022, many classes of devices do not need to be fully compliant with the regulation until the end of the applicable transitional period, which ranges from 2025 to 2028, depending on device class.

### ***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 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, introducing 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. 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.

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

### ***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 trials 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. 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 trials 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 structure as in the United States. It entails satisfactory completion of pre-clinical trials 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 entered 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, based largely on 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 marketing authorization has been granted. A company may submit an 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 European Commission which is responsible for granting a centralized marketing authorization in the form of a binding European Commission decision. If the application is approved, the European Commission 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. 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 Reference Member State. In both the mutual recognition and decentralized procedures, the Reference Member State 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 Reference Member State 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 European Commission 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 trials 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 pre-clinical 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 products.

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 trial 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 trials 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 ("GMP"). 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 U.K. following Brexit***

The U.K.'s 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 following the end of the post-Brexit transition period on December 31, 2020. The Medicines and Healthcare products Regulatory Agency ("MHRA") is now the U.K.'s standalone regulator for medicines, medical devices and blood components for transfusion.

On December 24, 2020, the EU and U.K. reached an agreement on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement ("**TC Agreement**"), which formally entered into force on May 1, 2021. The TC 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 TC Agreement includes terms which apply generally (and so apply to medicinal products), greater detail on sector-specific issues is provided in Annex 12 (*Medicinal Products*) to the TC Agreement.

Among the changes that occurred are that Great Britain (England, Scotland and Wales) will be treated as a third country to the EU, and so will be outside of the EU's regulatory frameworks. Northern Ireland will, pursuant to the Protocol on Ireland/Northern Ireland, remain aligned to specified EU single market and customs rules. As part of the TC Agreement, the EU and the U.K. will recognize GMP inspections carried out by the other party and accept official GMP documents issued by the other party. The TC 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 for medicinal products.

However, among the areas of absence of mutual recognition are batch testing and batch release. The U.K. had unilaterally agreed to accept EU batch testing and batch release for a period of at least two years until January 1, 2023, and on December 15, 2022, decided to make permanent the approach of maintaining a list of approved countries for import which require no import testing or U.K. Qualified Person certification. Conversely, 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 rereleased when entering the EU market for commercial use.

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 uncertain to what extent the U.K. will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation in the EU on January 31, 2022. The MHRA is in the process of analysing feedback to a consultation on proposals for legislative changes for clinical trials, which closed on March 14, 2022, and the extent to which there will be alignment should become clearer when the outcome of this is published.

In relation to authorization for medicinal products to be marketed and made available to patients, since January 1, 2021, an applicant for a marketing authorization under the centralized procedure (described further in *'Review and Approval of Medicinal Products in the European Union'* above) must be established in an EU Member State or EEA country. Accordingly, 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 medicinal products in the U.K. 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 granted by the European Commission. For a three-year period from January 1, 2021, MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization under the centralized procedure 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). The MHRA has also been publishing revised guidance, for example, in relation to products that are the subject of approvals or pending applications under the EU decentralized procedure or mutual recognition procedure.

### 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	August, 2023
Copenhagen, Denmark	Office space	14,924	September, 2023
Copenhagen, Denmark	Office space	20,626	September, 2023 <sup>(1)</sup>
Utrecht, Netherlands	Office, laboratory, and pre-clinical development space	90,061	May, 2032
Zeist, Netherlands	Office, laboratory, and pre-clinical development space	45,267	December, 2025
Utrecht, Netherlands	Office, laboratory, and pre-clinical development space	119,102	April, 2032
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 September 2023 to align with the estimated move-in date to Genmab's new corporate headquarters in Copenhagen, Denmark. See the following table for additional information.

Future expansion plans include the leased facilities specified in the following table, which are intended to augment Genmab's capacity at its laboratory and 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
Ballerup, Denmark	Office and laboratory space	21,387	January, 2023	3.5 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 ADCs. We currently have nine product candidates in clinical development. Our most advanced products are tisotumab vedotin and epcoritamab. Tisotumab vedotin, marketed as Tivdak, is being 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. Genmab is co-promoting tisotumab vedotin in the United States, and we will lead commercial operational activities and record sales in Japan, while Seagen will lead operational and commercial activities in the United States, Europe and China with a 50:50 cost and profit split in those markets. Epcoritamab is being developed in collaboration with AbbVie. In September 2022, we submitted a BLA for SC epcoritamab to the FDA, which was subsequently accepted with Priority Review in November 2022 with a target action date of May 21, 2023. In December 2022 we submitted a JNDA to the MHLW. AbbVie submitted an MAA to the EMA in October 2022, which was validated that same month.

To develop and deliver novel therapies to patients, we have formed strategic collaborations 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 five 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; teclistamab, marketed in the U.S. and Europe as TECVAYLI for the treatment of certain adult patients with R/R MM; 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 collaboration partners. We expect to continue to fund a significant portion of our development expenses for our

proprietary product candidates as well as our planned commercialization activities with funds received from royalties and milestone payments from our collaboration 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 net sales of daratumumab (marketed as DARZALEX for IV administration and as DARZALEX FASPRO in the U.S. and as DARZALEX SC in Europe for SC administration). In April 2022, the arbitral tribunal issued an award in the binding arbitration of the two matters. Genmab did not seek a review of the award, and the award is now final. The first matter concerned the question as to whether Janssen's obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement. As to that matter, the tribunal determined by majority opinion that Janssen's obligation to pay royalties to Genmab on sales of licensed product, in each applicable country, extends through the expiration or invalidation of the last-to-expire relevant Genmab-owned patent covering the product or use thereof, but not the relevant Janssen-owned patent. The relevant Genmab-owned issued U.S., European and Japanese patents will expire in the late 2020s and early 2030s. The second matter concerned the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for the Halozyme enzyme technology used in the SC formulation of daratumumab (marketed as DARZALEX FASPRO in the U.S.). The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SC daratumumab sales. As to that matter, the tribunal ruled by majority opinion that Janssen is permitted to continue reducing its royalty payments to Genmab as an offset against a share of Janssen's royalty payments made to Halozyme. On June 9, 2022, Genmab announced the commencement of a second arbitration under the daratumumab license agreement with Janssen. This second arbitration follows from the award in the prior arbitration, where the tribunal ruled in favor of Janssen on the question as to whether Genmab is required to share in Janssen's royalty payments to Halozyme for its technology used in the daratumumab SC product. The tribunal based its ruling on the finding that DARZALEX FASPRO constitutes a new licensed product under the license agreement. In this second arbitration, Genmab is consequently seeking an award of \$405 million plus interest in accrued milestone payments for DARZALEX FASPRO and a declaration that it is entitled to a new 13-year royalty term from the date of DARZALEX FASPRO's first commercial sale. See "*Item 8 – Financial Information—Legal Proceedings*".

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, collaboration revenue and license fees. 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 certain level of net sales. Reimbursement revenue is mainly comprised of the reimbursement of certain research and development expenses 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 collaboration partners.

In 2022, DKK 10,620 million, or 73% of our total revenues, related to our various collaborations with Janssen, as compared to DKK 6,847 million, or 81% of our total revenues, in 2021. The percentage of Janssen revenue over total revenues decreased in 2022 as compared to 2021, mainly driven by AbbVie milestones achieved in 2022. In 2022, DKK 10,056 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 6,507 million, or 95% in 2021.

Of the revenue for 2022, 80% was attributable to royalties, 12% to milestone revenue, 6% to reimbursement revenue, 2% to collaboration revenue, and less than 1% to license revenue. This is compared to 82% attributable to royalties, 11% to milestone revenue, 6% to reimbursement revenue, and less than 1% to collaboration revenue in 2021. There was no license revenue in 2021.

At this time, all of our revenue is recognized from our collaboration 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 potential new 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 we, as well as our collaboration partners, will report results or preliminary data for a number of clinical trials in 2023. However, there can be no assurance that any of the trials conducted by us or our other collaboration partners will be completed on the expected timelines 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 collaboration 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 trials performed by external suppliers and collaboration partners. Internal research and development expenses 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 depreciation and impairment of property and 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 trials 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 expenses 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 expenses.

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*

While global health authorities and global vaccination efforts alleviated some of the adverse impacts of the COVID-19 pandemic, the full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop. 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, 2022 Compared to the Year Ended December 31, 2021*

The information on pages 53-59 in our Annual Report 2022 under the heading “Financial Review” is incorporated herein by reference.

##### *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.

#### ***Significant Accounting Policies***

The information in Note 1.1 to our Audited Financial Statements included in our Annual Report 2022 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 2022 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 2022 is incorporated herein by reference.

## **B. Liquidity and Capital Resources**

The information on pages 57-58 in our Annual Report 2022 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 2022 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 5.3 to our Audited Financial Statements included in our Annual Report 2022 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 5.3 to our Audited Financial Statements included in our Annual Report 2022 is incorporated herein by reference. The contingent commitments entail uncertainties regarding 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 member of our Board of Directors (“**Board**”) members as of the date of this Annual Report on Form 20-F. Our Board consists of six 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 expire in 2023 and the terms of office of the Employee Elected Members expire in 2025. 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.

<b>Name of Board Member</b>	<b>Age</b>	<b>Position(s)</b>
Deirdre P. Connelly	62	Chair (independent, Shareholder Elected)
Pernille Erenbjerg	55	Deputy Chair (independent, Shareholder Elected)
Anders Gersel Pedersen	71	Board member (non-independent, Shareholder Elected)
Paolo Paoletti	72	Board member (independent, Shareholder Elected)
Rolf Hoffmann	63	Board member (independent, Shareholder Elected)
Elizabeth O'Farrell	58	Board member (independent, Shareholder Elected)
Takahiro Hamatani	48	Board member (non-independent, Employee Elected)
Martin Schultz	47	Board member (non-independent, Employee Elected)
Mijke Zachariasse	49	Board member (non-independent, Employee Elected)

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, where she is also Chair 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 Certified Public Accountant ("CPA") at Arthur Anderson LLP from 1987 to 2002. Ms. Erenbjerg holds a B.S. and an 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 2 GP 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. Prior to its acquisition by Takeda, Dr. Paoletti was the CEO of GammaDelta Therapeutics Limited and was a member of the Board of

GammaDelta Therapeutics Limited. He is currently a member of the Board of Akamis Bio Limited. He is a member of the Investment Committee for Apollo Therapeutics Limited and a scientific advisor for 3B Future Health Fund. 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. He is a Board member 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 MBA from the University of North Carolina at Chapel Hill.

**Elizabeth O'Farrell** was elected to the Board in 2022 and is a member of the Audit and Finance Committee and the Compensation Committee. Ms. O'Farrell has over 24 years of experience at Eli Lilly including serving as CFO of some of the company's largest businesses including as Head of Global Finance Operations. Most recently she served as Chief Procurement Officer and Global Head of Shared Services at Eli Lilly. She is Chair of the Board of PDL BioPharma. She is also a member of the Board of LENSAR, Geron Corporation, and Karius and she is the Chair of the Audit Committee for all three. Ms. O'Farrell holds a degree in accounting as well as an MBA in Management Information Systems from Indiana University, Bloomington and has also served in roles at Price Waterhouse and Whipple & Company Corporation.

**Takahiro Hamatani** was elected to the Board in 2022. Mr. Hamatani joined Genmab in 2020 and currently serves as Senior Director, Finance Japan. He has 24 years of working experience with multiple global pharmaceutical companies including Novartis, Gilead Sciences and Takeda. Mr. Hamatani holds a B.A. in Economics from The University of Tokyo and an MBA from Hitotsubashi ICS. He is also a U.S. CPA.

**Martin Schultz** was elected to the Board in 2022. Mr. Schultz joined Genmab in 2005 and currently serves as Senior Director, Clinical Operations. For the past several years he has functioned as Clinical Project Leader and has overseen clinical trial budgets across Genmab's clinical trials. He has also been a member of Genmab's employee representatives' group for over 10 years.

**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.

### ***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. Effective January 1, 2023, only Jan G. J. van de Winkel and Anthony Pagano are registered

with the Danish Business Authority as members of executive management, or registered managers, within the meaning of the Danish Companies Act (“DCA”).

<b>Name of Member of Senior Management</b>	<b>Age</b>	<b>Position(s)</b>
Jan G. J. van de Winkel	61	President and Chief Executive Officer
Anthony Pagano	45	Executive Vice President and Chief Financial Officer
Judith Klimovsky	66	Executive Vice President and Chief Development Officer
Anthony Mancini	52	Executive Vice President and Chief Operating Officer
Tahamtan Ahmadi	50	Executive Vice President and Chief Medical Officer, Head of Experimental Medicines
Birgitte Stephensen	62	Executive Vice President and Chief Legal Officer
Christopher Cozic	45	Executive Vice President and Chief People Officer
Martine J. van Vugt	52	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 Hookipa Pharma Inc. and a member of the Board of LEO Pharma A/S. 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 CPA and received a B.S. in Accounting from The College of New Jersey, as well as an MBA 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 BMS and Novartis. 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 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 BMS including the leadership of BMS’ U.S. Innovative Medicines Unit, a cross-functional team of over 1100 people, across multiple therapeutic areas including Immunology & Cardiovascular diseases. He holds a B.S. 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 Executive Vice President and Chief Legal Officer in 2022. 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 and was appointed Executive Vice President and Chief People Officer in 2022. 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 B.A. 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, Corporate and Business Development, as well as Alliance Management. 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 2022, the aggregate remuneration paid to the Board was DKK 12.6 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 2022, the aggregate remuneration to our executive management was DKK 114.4 million, all of which was fully accrued at December 31, 2022. 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 2022 for details on compensation of our executive management. In addition, the aggregate remuneration to our senior management was DKK 138.2 million, all of which was fully accrued at December 31, 2022, 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 2022 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 Remuneration Policy. RSUs have been granted to Dr. van de Winkel, Mr. Pagano, Dr. Klimovsky, Mr. Mancini and Dr. Ahmadi under our RSU program for the 2021 performance year on February 25, 2022. The above-named individuals qualify for all of our benefit programs, including retirement 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.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2022 for more details of our warrant program, our outstanding warrants and a summary of the holders of such warrants as of December 31, 2022.

*Warrant Compensation*

During 2022, no members of executive management were granted warrants by our Board.

**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, are 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.

See Note 4.6 to our Audited Financial Statements included in our Annual Report 2022 for more details of our RSU program, our outstanding RSUs and a summary of the holders of such RSUs as of December 31, 2022.

*Restricted Stock Unit Compensation*

During 2022, our Board granted the following RSUs to members of our Board and our executive management:

<b>Name of Board Member or Executive Management, Position</b>	<b>Award Date</b>	<b>Granted</b>	<b>Share Price at Date of Grant (DKK)</b>
Deirdre P. Connelly, Chair	November 21, 2022	378	3,172
Pernille Erenbjerg, Deputy Chair	November 21, 2022	283	3,172
Anders Gersel Pedersen, Board Member	November 21, 2022	189	3,172
Paolo Paoletti, Board Member	November 21, 2022	189	3,172
Rolf Hoffmann, Board Member	November 21, 2022	189	3,172
Elizabeth O'Farrell, Board Member*	March 29, 2022 November 21, 2022	996 189	2,408 3,172
Mijke Zachariasse, Employee Elected Member	November 21, 2022	189	3,172
Martin Schultz, Employee Elected Member	November 21, 2022	189	3,172
Takahiro Hamatani, Employee Elected Member	November 21, 2022	189	3,172
Jan van de Winkel, Chief Executive Officer	February 25, 2022	12,315	2,175
Anthony Pagano, Chief Financial Officer	February 25, 2022	6,382	2,175
Anthony Mancini, Chief Operating Officer	February 25, 2022	7,830	2,175
Judith Klimovsky, Chief Development Officer	February 25, 2022	8,072	2,175
Tahamtan Ahmadi, Chief Medical Officer	February 25, 2022	5,854	2,175

\* Elizabeth O'Farrell was newly elected to the Board of Directors at the Annual General Meeting in March 2022.

## **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 2022, 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, Takahiro Hamatani, Mijke Zachariasse, and Martin Schultz. In total, our Board currently consists of nine Board members (including six 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.

### ***Management Appointments***

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. Non-registered managers are appointed by the Chief Executive Officer in consultation with the Board of Directors.

### ***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, Elizabeth O'Farrell 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 Item 407(d)(5)(ii) of Regulation S-K of the SEC 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, preapproving, and overseeing all audit and 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 auditors' 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;

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- 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 the integrity of the Company's information technology systems, processes and data and periodically (but no less than annually), at its discretion, reviewing and assessing with Management (including the Head Internal Auditor and Chief Information Officer), the adequacy of security for the Company's information technology systems, processes and data and the Company's contingency plans in the event of a breakdown or security breach affecting the Company's information technology systems, and data or the information technology systems;
- overseeing environmental, social and governance ("ESG") external reporting and assurance matters;
- 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, Elizabeth O'Farrell 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, is subject to the approval of our shareholders at the Annual General Meeting. The Compensation Committee's primary responsibilities are as follows:

- reviewing the 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 the 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 advisors, upon consideration of (i) whether such counsel, consultant or advisor 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 advisor designed to prevent conflicts of interest, (iii) any business or personal relationship of the consultant, counsel or advisor 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 advisor;
- approving the fees of outside counsel, compensation consultants or other advisors, to be appropriately funded by the Company and directly overseeing the work of such counsel, consultants or advisors; 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 ESG 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 pre-clinical 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 pre-clinical 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, 2022, we had 1,660 employees; 385 in Denmark, 575 in the Netherlands, 642 in the U.S. and 58 in Japan. Of these employees, 1,193 were engaged in or supported research and development and 467 were in selling, administrative and business-related positions. Each of our employees has signed confidentiality and inventions assignment agreements or has 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 22, 2023 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

Name of Beneficial Owner	Share Beneficial Ownership			Fully Diluted Percentage of Beneficial Ownership
	Number of Shares Beneficially Owned	Number of Warrants Exercisable and RSUs to be Settled Within 60 days	Fully Diluted Number of Shares Beneficially Owned	
<b>5% Shareholders</b>				
BlackRock, Inc. <sup>(1)</sup>			4,472,155	6.80 %
Wellington Management Group LLP <sup>(2)</sup>			4,073,304	6.18 %
<b>Board Members and Senior Management</b>				
Deirdre P. Connelly	5,115	—	5,115	0.01 %
Pernille Erenbjerg	4,596	—	4,596	0.01 %
Anders Gersel Pedersen	9,125	—	9,125	0.01 %
Paolo Paoletti	855	—	855	0.00 %
Rolf Hoffmann	3,196	—	3,196	0.00 %
Elizabeth O’Farrell	—	—	—	0.00 %
Mijke Zachariasse	297	—	297	0.00 %
Martin Schultz	175	617	792	0.00 %
Takahiro Hamatani	—	—	—	0.00 %
Jan van de Winkel	619,934	50,822	670,756	1.02 %
Anthony Pagano	4,187	13,594	17,781	0.03 %
Anthony Mancini	—	14,508	14,508	0.02 %
Judith Klimovsky	7,732	38,994	46,726	0.07 %
Tahamtan Ahmadi	3,723	22,613	26,336	0.04 %
Birgitte Stephensen	*	*	*	*
Christopher Cozic	*	*	*	*
Martine van Vugt	*	*	*	*
<b>All board members and senior management as a group (17 persons)</b>	<b>668,250</b>	<b>150,051</b>	<b>818,301</b>	<b>1.24 %</b>

\* 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 1, 2023 with the SEC. BlackRock, Inc. does not have different voting rights from other shareholders.
- (2) This information is based solely on the Schedule 13G filed by Wellington Management Group LLP on February 6, 2023 with the SEC. Wellington Management Group LLP 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 22, 2023 through the exercise of any options, warrants or other rights. There are 150,051 shares for which our board members and senior management as a group have the right to subscribe within 60 days of February 22, 2023 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 65,961,573 shares outstanding as of February 22, 2023. Shares for which a person has the right to subscribe within 60 days of February 22, 2023 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 2022 and we estimated that approximately 42%, or 28 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, 2022, 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 remuneration 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 2022 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 a binding arbitration of two matters arising under its license agreement with Janssen relating to daratumumab. Under the license agreement, Genmab is, among other things, entitled to royalties from Janssen on net sales of daratumumab (marketed as DARZALEX for IV administration and as DARZALEX *FASPRO* in the U.S. and as DARZALEX SC in Europe for SC administration). In April 2022, the arbitral tribunal issued an award in the binding arbitration of the two matters. Genmab did not seek a review of the award, and the award is now final. The first matter concerned the question as to whether Janssen’s obligation to pay royalties on sales of licensed product extends, in each applicable country, until the expiration or invalidation of the last-to-expire relevant Genmab-owned patent or the last-to-expire relevant Janssen-owned patent covering the product, as further defined and described in the license agreement. As to that matter, the tribunal determined by majority opinion that Janssen’s obligation to pay royalties to Genmab on sales of licensed product, in each applicable country, extends through the expiration or invalidation of the last-to-expire relevant Genmab-owned patent covering the product or use thereof, but not the relevant Janssen-owned patent. The relevant Genmab-owned issued U.S., European and Japanese patents will expire in the late 2020s and early 2030s. The second matter concerned the question as to whether Genmab is required to share in Janssen’s royalty payments to Halozyme for the Halozyme enzyme technology used in the SC formulation of daratumumab (marketed as DARZALEX *FASPRO* in the U.S.). The royalties Janssen pays to Halozyme represent a mid-single digit percentage rate of SC daratumumab sales. As to that matter, the tribunal ruled by majority opinion that Janssen is permitted to continue reducing its royalty payments to Genmab as an offset against a share of Janssen’s royalty payments made to Halozyme. On June 9, 2022, Genmab announced the commencement of a second arbitration under the daratumumab license agreement with Janssen. This second arbitration follows from the award in the prior arbitration, where the tribunal ruled in favor of Janssen on the question as to whether Genmab is required to share in Janssen’s royalty payments to Halozyme for its technology used in the daratumumab SC product. The tribunal based its ruling on the finding that DARZALEX *FASPRO* constitutes a new licensed product under the license agreement. In this second arbitration, Genmab is consequently seeking an award of \$405 million plus interest in accrued milestone payments for

DARZALEX *FASPRO* and a declaration that it is entitled to a new 13-year royalty term from the date of DARZALEX *FASPRO*'s first commercial sale.

**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 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 NASDAQ in the United States 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.

Under the Danish FDI Rules, a screening mechanism applies to foreign direct investments in certain sensitive sectors, if the foreign investor obtains at least 10% ownership or voting rights, or equivalent control by other means. Among such sensitive sectors are companies and entities within critical infrastructure in Denmark that are necessary to maintain or restore the production, registration, distribution, and monitoring of prescription drugs. If a contemplated foreign direct investment in Genmab A/S is considered to fall within the scope of the mandatory screening mechanism, the foreign investor is required to apply for prior authorization with the Danish Business Authority. If a foreign investor fails to comply with the Danish FDI Rules, the Danish Business Authority may impose restrictions, *inter alia*, ordering to reverse the investment or to suspend the foreign investor’s voting rights.

## **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**

Other than the applicable international trade and financial sanctions as outlined below, (i) 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, and (ii) 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.

International trade and financial sanctions are continually evolving. If applicable, such international trade and financial sanctions may under certain circumstances prevent the possibility of export and import of capital, and affect the remittance of dividends, interest and other payments to non-resident holders of shares or ADSs. In addition, international trade and financial sanctions may restrict the right of non-resident or foreign owners to acquire, transfer, hold or vote the shares and ADSs. Failure to comply with international trade and financial sanctions can lead to criminal and civil liability.

## **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 depository) 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, 2022, or in the foreseeable future. However, 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, 2022, 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 administrative practice from the Danish tax authorities indicates 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 administrative practice, the Danish tax authorities are of the opinion that the depository bank may be the owner of the shares underlying the ADSs, and that the qualification of whether the ADS holder or the depository bank is the holder of the underlying shares for Danish tax purposes depends 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 a holder 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 summary in the section immediately below assumes that the ADS holder for Danish tax purposes is treated as the direct owner of the shares underlying the ADSs.

If, however, an ADS holder is found not to be the owner of the shares underlying the ADSs and accordingly not to be a shareholder for Danish tax purposes, then the ADSs will likely be taxed pursuant to the Danish tax rules on taxation of financial contracts. The taxation of financial contracts differs from the taxation of shares in several ways, and, among other differences, any Danish resident ADS holders will - if taxed under the rules on financial contracts - be subject to a mark-to-market taxation, i.e., annual taxation on any unrealized gains accrued during the year. A high-level summary of the tax treatment of financial contracts is laid out in a later section.

## **Taxation of ADS holders considered to be owners of the underlying shares**

### ***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 58,900 (for cohabiting spouses, a total of DKK 117,800) and at a rate of 42% on share income exceeding DKK 58,900 (for cohabiting spouses over DKK 117,800) (all 2023 amounts and thresholds). The threshold is subject to annual adjustments and includes 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.

If 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, if 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 the refund. The rate per month will be 0.2833% 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 0.2833% 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.

#### **Taxation of ADS holders not considered to be owners of the underlying shares**

Pursuant to Danish administrative practice, ADSs which do not constitute shares for tax purposes are instead likely taxed as financial contracts, but there is some uncertainty in this respect. A high-level summary of the tax treatment of financial contracts is laid out below.

### ***Danish tax resident ADS holder individuals and companies***

#### *Gains and losses*

Danish tax resident holders of financial contracts are generally taxed according to a mark-to-market principle in respect of gains and losses on the financial contracts. The mark-to-market principle entails that unrealized gains and losses on financial contracts are taxed annually regardless of whether the ADSs have been sold or not. The deductibility of losses may in certain cases be restricted.

#### *Dividends*

If the ADS holders are not considered the shareholders for Danish tax purposes, any dividends received by the ADS holders in respect of the ADSs will likely be taxable, and the ADS holders will likely not be able to obtain a refund of any tax withholding on the dividend.

### ***Non-Danish tax resident ADS holder individuals and companies***

#### *Gains and losses*

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

#### *Dividends*

If the ADS holders are not considered the shareholders for Danish tax purposes, the ADS holders will likely not be eligible for a refund of withholding tax on dividends. Communications from the Danish tax authorities indicate that the depository bank in such cases in certain circumstances may be entitled to apply for a refund of Danish withholding tax on dividends.

### **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 a 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 2022](#), which includes our Audited Financial Statements, can be downloaded from the “Investors” page at [www.genmab.com](http://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](http://www.sec.gov).

**I. Subsidiary Information**

Not applicable.

**J. Annual Report to Security Holders**

Our [Annual Report 2022 has been furnished to the SEC as Exhibit 99.1\(a\) to Form 6-K, dated February 22, 2023](#).

**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 2022.

**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 Exhibits 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 Exchange Act), as of the end of the period covered by this Annual Report on Form 20-F. Based on such evaluation, management, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2022.

**Report of Genmab Management on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). 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 due to error or fraud. 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, 2022, 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, 2022, Genmab’s internal control over financial reporting was effective based on the COSO criteria.

The effectiveness of the Company’s internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers, Statsautoriseret Revisionspartnerselskab, Denmark, an independent registered public accounting firm, as stated in their report which appears on page 125 of this Annual Report on Form 20-F.

#### **Changes in Internal Control over Financial Reporting**

There were no changes 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 have 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, Elizabeth O’Farrell, 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 due to her experience and background within accounting, Pernille Erenbjerg qualifies as an “audit committee financial expert,” as defined in Nasdaq Rule 5605(c)(2)(A) and Item 407(d)(5)(ii) of Regulation S-K of the Securities and Exchange Commission, 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](http://www.genmab.com)). The contents of this website are not incorporated by reference into this Annual Report on Form 20-F.

During 2022, the Company did not materially amend its Code of Conduct or 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 5.4 to our Audited Financial Statements included in our Annual Report 2022.

##### **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 2022, Genmab made the following purchases of its ordinary shares in connection with covering its obligations under its RSU and warrant programs, as described in “Item 6—Directors, Senior Management and Employees—B. Compensation—Restricted Stock Unit Program.”

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share in DKK</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
<b>Share Repurchase Programs</b>				
June 20, 2022 - June 30, 2022	124,000	2,176.29	124,000	-
July 1, 2022 - July 29, 2022	83,600	2,505.95	83,600	-
August 1, 2022 - August 31, 2022	162,400	2,636.26	162,400	-
<b>Total</b>	<b>370,000</b>	-	<b>370,000</b>	-

Share repurchases were conducted pursuant to a share buy-back program providing for the repurchase of up to 370,000 ordinary shares (the “Share Buy-Back Program”), which was announced on June 17, 2022 and expired on August 31, 2022. The Share Buy-Back Program was conducted pursuant to (i) authorization of our shareholders to repurchase up to 500,000 shares with a nominal value of DKK 500,000, given in March 2019, which expires in March 2024, and (ii) authorization of our shareholders to repurchase up to an additional 500,000 shares with a nominal value of DKK 500,000, given in April 2021, which expires in April 2026 (the “2021 Authorization”). No shares remain to be repurchased under the Share Buy-Back Program, but up to 460,000 shares are authorized for repurchase by the shareholders pursuant to the 2021 Authorization, 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 prior to 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 76-115 of our Annual Report 2022.

**ITEM 19 EXHIBITS**

**a. Annual Report**

The following pages from our [Annual Report 2022, furnished to the SEC as Exhibit 99.1\(a\) to Form 6-K, dated February 22, 2023](#), and from our [Annual Report 2021, furnished to the SEC as Exhibit 99.1\(a\) to Form 6-K, dated February 16, 2022](#), 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 2022**

Financial Review – pages 53-59

Consolidated Financial Statements for the Genmab Group – pages 76-115

Consolidated Statements of Comprehensive Income for the years ended December 31, 2022, 2021 and 2020 – page 77

Consolidated Balance Sheets as of December 31, 2022 and 2021 – page 78

Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020 – page 79

Consolidated Statements of Changes in Equity for the years ended December 31, 2022, 2021 and 2020 – page 80

Notes to the Consolidated Financial Statements – pages 81-115

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

Financial Review – pages 61-65

**b. Exhibits**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of filing</b>
1.1	<a href="#">English translation of Articles of Association of Genmab A/S, as currently in effect</a>	Incorporated by reference to the Registrant’s Report furnished to the SEC on Form 6-K on January 30, 2023

## [Table of Contents](#)

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of filing</b>
2.1	<a href="#">Amended and Restated Deposit Agreement</a>	Incorporated by reference to Exhibit (a)(3) to the Registrant's Form F-6 filed with the SEC on July 15, 2019
2.2	<a href="#">Form of American Depositary Receipt</a>	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	<a href="#">Description of Securities Registered under Section 12 of the Exchange Act</a>	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†	<a href="#">License Agreement, dated as of August 30, 2012, by and between Janssen Biotech, Inc. and Genmab A/S</a>	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†	<a href="#">Amendment Number 1 to the License Agreement, dated as of January 31, 2013, by and between Janssen Biotech, Inc. and Genmab A/S</a>	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†	<a href="#">Amendment Number 2 to the License Agreement, dated as of October 10, 2013, by and between Janssen Biotech, Inc. and Genmab A/S</a>	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†	<a href="#">License and Collaboration Agreement, dated as of October 7, 2011, by and between Seagen, Inc. and Genmab A/S</a>	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†	<a href="#">Joint Commercialization Agreement dated October 19, 2020 between Genmab A/S and Seagen Inc.</a>	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†	<a href="#">Co-development and Collaboration Agreement, dated as of December 19, 2006, by and between Glaxo Group Limited and Genmab A/S</a>	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†	<a href="#">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</a>	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†	<a href="#">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</a>	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†	<a href="#">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</a>	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†	<a href="#">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</a>	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†	<a href="#">Novation Agreement, dated as of November 3, 2014, by and among Glaxo Group Limited, Novartis Pharma AG and Genmab A/S</a>	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†	<a href="#">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</a>	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†	<a href="#">Amended and Restated Evaluation and Commercialization Agreement, dated as of July 12, 2012, by and among Bristol Myer Squibb Corporation, Medarex, Inc., GenPharm International, Inc. and Genmab A/S</a>	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†	<a href="#">Collaboration and License Agreement, dated as of June 10, 2020 by and between AbbVie Biotechnology Ltd. and Genmab A/S</a>	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

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<b>Exhibit No.</b>	<b>Description</b>	<b>Method of filing</b>
4.15†	<a href="#">Amendment Number 1 to the Collaboration and License Agreement, dated as of November 8, 2022 by and between AbbVie Biotechnology Ltd. and Genmab A/S</a>	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2022
8.1	<a href="#">List of Subsidiaries</a>	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	<a href="#">Certification of the Principal Executive Officer</a>	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2022
12.2	<a href="#">Certification of the Principal Financial Officer</a>	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2022
13.1	<a href="#">Certification of the Principal Executive Officer pursuant to 18 U.S.C. section 1350</a>	Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2022
13.2	<a href="#">Certification of the Principal Financial Officer pursuant to 18 U.S.C. section 1350</a>	Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2022
15.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>	Filed together with this Annual Report on Form 20-F for the year ended December 31, 2022
EX-101.INS	<a href="#">Inline XBRL Instance Document</a>	Incorporated by reference to Exhibit 101.INS to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023
EX-101.SCH	<a href="#">Inline XBRL Taxonomy Extension Schema Document</a>	Incorporated by reference to Exhibit 101.SCH to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023
EX-101.CAL	<a href="#">Inline XBRL Taxonomy Extension Calculation Linkbase Document</a>	Incorporated by reference to Exhibit 101.CAL to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023
EX-101.DEF	<a href="#">Inline XBRL Taxonomy Extension Definition Linkbase Document</a>	Incorporated by reference to Exhibit 101.DEF to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023
EX-101.LAB	<a href="#">Inline XBRL Taxonomy Extension Labels Linkbase Document</a>	Incorporated by reference to Exhibit 101.LAB to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023
EX-101.PRE	<a href="#">Inline XBRL Taxonomy Extension Presentation Linkbase Document</a>	Incorporated by reference to Exhibit 101.PRE to the Registrant's report furnished to the SEC on Form 6-K on February 22, 2023

† 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 22, 2023

## 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, 2022 and 2021, 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, 2022, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, 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 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 was 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 judgements. 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 FASPRO*

As described in note 5.6 to the consolidated financial statements, the Company in June 2022 commenced binding arbitration of matters arising under its license agreement with Janssen Biotech, Inc. (Janssen) relating to DARZALEX FASPRO. The arbitration is to settle whether Janssen is required to pay milestone payments for the DARZALEX FASPRO product, and whether the Company is entitled to a new 13-year royalty term from the date of DARZALEX FASPRO's first commercial sale. Based on discussions with 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 milestone payments subject to the arbitration. The milestone payments constitute approximately DKK 2.8 billion (USD 405 million).

The principal considerations for our determination that performing procedures relating to revenue recognition of DARZALEX FASPRO is a critical audit matter are the significant judgement made 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 22, 2023

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

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

## AMENDMENT NUMBER 1 TO THE COLLABORATION AND LICENSE AGREEMENT

This AMENDMENT NUMBER 1 TO THE COLLABORATION AND LICENSE AGREEMENT (this “**Amendment**”) made as of 8 November, 2022 (the “**Amendment No. 1 Effective Date**”) by and between Genmab A/S, CVR No. 2102 3884, a Danish corporation having its principal office at Kalvebod Brygge 43, 1560 Copenhagen V, Denmark (“**Genmab**”) and AbbVie Biotechnology Ltd., a corporation organized under the laws of Bermuda, having a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda (“**AbbVie**”), amends the Collaboration and License Agreement between Genmab and AbbVie dated as of June 10, 2020. Genmab and AbbVie are each referred to herein individually as “**Party**” and collectively “**Parties**”.

### RECITALS

**WHEREAS**, the Parties entered into that certain Collaboration and License Agreement, dated as of June 10, 2020 (the “**Agreement**”), under which the Parties have agreed to collaborate to develop and commercialize pharmaceutical products containing the compounds known as [ \* ], [ \* ], [ \* ] and any Option Compound;

**WHEREAS**, pursuant to a letter dated June [ \* ], 2022, AbbVie gave notice of its intention to terminate [ \* ] and [ \* ] as Licensed Products in the Territory under the Agreement, such termination to take effect on December 24, 2022;

**WHEREAS**, the Parties desire to amend the Agreement with respect to [ \* ] in order to (i) clarify and confirm updates to the Global Development Plan and the Global Development Budget in respect of [ \* ], (ii) remove the [ \* ] under Clause 8.4 effective January 1, 2023; and (iii) amend other provisions of the Agreement as set forth herein; and

**WHEREAS**, the Parties have the authority to amend the Agreement pursuant to Clause 18.13 of the Agreement and now desire to amend the Agreement as hereafter provided.

**NOW, THEREFORE**, in consideration of the mutual covenants set out below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

[ \* ] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

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## ARTICLE 1

### AMENDMENTS

- 1.1 Capitalized terms used and not otherwise defined in this Amendment shall have the meanings ascribed to them under the Agreement.
- 1.2 Clause 8.4 of the Agreement shall not apply with respect to any [\*] incurred on or after January 1, 2023. For clarity, where [\*] under Clauses 8.1(A) and 8.1(C)(a) [\*] and [\*] have been incurred before January 1, 2023, such [\*] shall continue to be treated in accordance with Clause 8.4.
- 1.3 Clause 6.2.1 of the Agreement shall be amended by adding the following subsection (F) to the end of Clause 6.2.1:

“(F) The Clinical Studies plan of the GDP for the [\*] Product has been updated as of the Amendment No. 1 Effective Date which updated Clinical Studies plan is attached as Exhibit 1 to this Amendment. The Clinical Studies plan of the GDP shall include the following lists of Clinical Studies: (1) Clinical Studies which have been already approved by the JSC, including with respect to [\*]; and (2) pending Clinical Studies which are [\*] subject to JSC approval, including with respect to [\*]. Clinical Studies to be added to or removed from any list on the Clinical Studies plan of the GDP, or to be moved from one list to another, shall require JSC approval.”
- 1.4 Clause 6.2.1(D) of the Agreement shall be amended by adding the following sentences to the end of Clause 6.2.1(D):

“The Global Development Budget will include budgets for approved Clinical Studies as set out in the Clinical Studies plan of the GDP and will provide estimates for pending Clinical Studies as set out in the Clinical Studies plan of the GDP. For any pending Clinical Studies which later become approved Clinical Studies, the agreed budgets for such Clinical Studies will then be included in the Global Development Budget. The Global Development Budget should include Manufacturing Costs and FTE Costs where applicable.”
- 1.5 As of the Amendment No. 1 Effective Date, the updated Clinical Studies plan of the Global Development Plan (GDP) for the [\*] Product included as Exhibit 1 to this Amendment shall constitute binding updates to the current applicable GDP between the Parties. As contemplated under the definition of “Global Development Plans” and Clause 6.2.1 of the Agreement, the current GDP including the updated Clinical Studies plan of the GDP in Exhibit 1 is to be further updated from time to time and at least annually, subject to review and approval by the JSC.
- 1.6 The Parties shall agree on a full updated Global Development Budget at the JSC meeting on December [\*, 2022. As provided under Clause 6.2.1(D), such updated Global Development Budget should cover the [\*] with the [\*] budget being updated annually. The Global Development Budget for [\*] for the approved Clinical Studies in Exhibit 1 is not expected to [\*] for the [\*. If the proposed Global Development Budget presented at the JSC meeting on December [\*, 2022 [\*] (i) [\*] in [\*] with respect to the approved Clinical Studies in Exhibit 1 in [\*] or (ii) the total maximum aggregate amount of [\*] with respect to the approved Clinical Studies in Exhibit 1 for the period [\*] with respect to approved Clinical

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

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Studies, then the JSC shall discuss and consider in good faith whether such [\*] amounts are required to conduct the approved Clinical Studies and can be approved. For the avoidance of doubt, when the JSC has approved the full Global Development Budget, the above amounts in this Section relating to the approved Clinical Studies in Exhibit 1 shall be replaced by the budget amounts set out in the approved Global Development Budget. If the JSC is unable to agree on the updated Global Development Budget at the JSC meeting on December [\*], 2022, then the matter shall be referred [\*]. As contemplated under the definition of “Global Development Budgets” and as provided under Clause 6.2.1(D) of the Agreement, the Global Development Budget is to be updated each time the GDP is updated, including annual updates, and if and when the JSC mutually agrees to move pending Clinical Studies to approved Clinical Studies (such as for example the [\*]), which updates are to be prepared by the JDC and JFS, and is subject to review and approval by the JSC.

- 1.7 Clause 6.2.1(E) of the Agreement shall be amended by adding the following sentence to the end of Clause 6.2.1(E):

“The JSC shall jointly agree on which pending Clinical Studies should be taken into consideration for the planning of manufacturing and supply.”

- 1.8 The Parties shall agree on a full updated Development Manufacturing and Supply Plan at the JSC meeting on December [\*], 2022. Such updated Development Manufacturing and Supply Plan shall include the Manufacturing activities described and referenced in [\*], and the associated [\*], as such activities are identified in the attached Exhibit 2 to this Amendment.

## ARTICLE 2

### MISCELLANEOUS

- 2.1 Capitalized terms used, but not defined herein, shall have the meanings ascribed to them in the Agreement.
- 2.2 Except as specifically provided herein, the terms and provisions of the Agreement shall remain in full force and effect except that each reference to the “Agreement” or words of like import in the Agreement shall mean and be a reference to the Agreement as amended hereby.
- 2.3 This Amendment may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement.
- 2.4 Subject to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction, this Agreement and any non-contractual obligations arising from or connected with it shall be governed by [\*] and this Agreement shall be construed in accordance with [\*].

[SIGNATURE PAGE FOLLOWS]

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

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IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their representatives thereunto duly authorized as of the Amendment No. 1 Effective Date.

**Genmab A/S**

By: /s/ Jan van de Winkel  
Name: Jan van de Winkel  
Title: President and CEO

**AbbVie Biotechnology Ltd.**

By: /s/ Stephen Muldoon  
Name: Stephen Muldoon  
Title: SVP Manufacturing and Engineering

[\*] = Certain information contained in this document, marked by brackets, has been omitted because it is both not material and is the type of information that we treat as private or confidential.

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**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 22, 2023

/s/ Jan G. van de Winkel

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## 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 22, 2023

/s/ Anthony Pagano

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**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, 2022 (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 22, 2023

/s/ Jan G. van de Winkel

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**PRINCIPAL FINANCIAL OFFICER CERTIFICATION  
PURSUANT TO 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, 2022 (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 22, 2023

/s/ Anthony Pagano

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-253519, 333-232693 and 333-262970) of Genmab A/S of our report dated February 22, 2023 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 22, 2023

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PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, CVR-nr. 33 77 12 31  
Strandvejen 44, DK-2900 Hellerup T: 3945 3945, [www.pwc.dk](http://www.pwc.dk)

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